Swami Rama Himalayan University
Office of the Registrar

SRHU/Reg/OO/2025-195

Date: 7th August, 2025

OFFICE ORDER

I am directed to inform that in accordance with the decision taken by the Academic Council in its 35th Meeting under Agenda Item 35/5, the approved recommendations made by the **Board of Studies** for **PG programme - M.Sc. (Clinical Research)** under **Himalayan Institute of Medical Sciences**, effective from academic session 2025-26, as enclosed herewith, are being sent for implementation.

By Order,

Registrar

Copy to: Hon'ble President
Hon'ble Vice-Chancellor
Pro Vice-Chancellor
Director General (Academic Development)
} for kind information please
Dean cum Principal, Himalayan Institute of Medical Sciences
Controller of Examinations

Encl.: As above.

SWAMI RAMA HIMALAYAN UNIVERSITY

HIMALAYAN INSTITUTE OF MEDICAL SCIENCES

Department of Clinical Research

Swami Rama Himalayan University

BOARD OF STUDIES

M.Sc. Clinical Research Program

2025

COUNTERSIGNED

REGISTRAR
SWAMI RAMA HIMALAYAN UNIVERSITY

Index

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REGISTRAR
SWAMI RAMA HIMALAYAN UNIVERSITY

Dr Suman Bala

Dr Ginpreet Kaur

Dr Dilip Chander Dhasmana

Dr Deep Shikha

Dr Nikku Yadav

Dr Ashwani Bhat

Dr Neha Sharma

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU

NOTIFICATION OF CONSTITUTING BOARD OF STUDIES (REGISTRAR LETTER)

Swami Rama Himalayan University
Office of the Registrar

SRHU/Reg/OO/2025-68 Date 16th April, 2025

OFFICE ORDER

In accordance with Statute 5.07 of the University, the Hon'ble Vice-Chancellor has constituted the **Board of Studies** for **Allied Health PG Programme - M.Sc. (Clinical Research)** under Himalayan Institute of Medical Sciences (HIMS), as follows

	Dr. Nikku Yadav, In-charge, Department of Clinical Research, HIMS	Chairperson
As per the provisions of Statute 5.07(b) of the University, 02 (Two) Professors nominated by the Hon'ble Vice- Chancellor	Dr. Deep Shikha, Professor, Department of Community Medicine, HIMS	Member
	Dr. D. C. Dhasmana, Professor, Department of Pharmacology, HIMS	Member
As per the provisions of Statute 5.07(c) of the University, 02 (Two) Associate Professors nominated by the Hon'ble Vice-Chancellor	Dr. Neha Sharma, Associate Professor, Department of Community Medicine, HIMS	Member
	Dr. Ashwani Bhat, Associate Professor, Department of Neurology, HIMS	Member
As per the provisions of Statute 5.07(d) of the University, 02 (Two) external subject experts nominated by the Hon'ble Vice-Chancellor	Dr. Suman Bala, Professor & Head, Department of Pharmacology, Shri Guru Ram Rai Institute of Medical & Health Sciences, Patel Nagar, Dehradun	Member
	Dr. Ginpreet Kaur, Professor, Department of Pharmacology, SPP School of Pharmacy & Technology Management, SVKM'S NMIMS University, Mumbai	Member

By Order,

16/04/2025
Registrar

Copy to Hon'ble President
Hon'ble Vice-Chancellor
Director General (Academic Development)
Pro Vice-Chancellor
Principal, HIMS
Vice-Principal (Allied Health PG Programmes)
All above concerned
} for kind information please

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Dr Suman Bala Dr Ginpreet Kaur Dr Dilip Chander Dhasmana Dr Deep Shikha

Dr Nikku Yadav Dr Ashwani Bhat Dr Neha Sharma

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Jolly Grant, Dehradun-248011

NOTICE OF MEETING WITH AGENDA (REGISTRAR LETTER)

Swami Rama Himalayan University
Office of the Registrar

SRHU/Reg/Int/2025-246 Date: 30th April, 2025

Meeting Notice

The meeting of the **Board of Studies** constituted for **Allied Health PG Programme - M.Sc. (Clinical Research)** under Himalayan Institute of Medical Sciences, will be held on **24th May 2025 (Saturday) at 10:00 AM.**

The **'Agenda'** of the meeting shall be as follows:

1. To recommend, upon reference to it by the faculty, the courses of study, curriculum, question paper pattern and methods of assessment in the subject or group of subjects within its purview.
2. To recommend programme objective, programme outcomes and course outcomes.
3. To recommend books, including text-books, supplementary reading, reference books, online references and other study material for such courses of study.
4. To advise the faculty or faculties concerned regarding improvements in the courses of study.
5. To recommend organization of orientation and refresher courses in the subject.

All concerned members of the said 'Board of Studies' are requested to make it convenient to attend the meeting.

30/04/25

Commander Challa Venkateswar (Retd.)
Registrar

Copy to: Hon'ble President
Hon'ble Vice-Chancellor
Director General (Academic Development)
Pro Vice-Chancellor
for kind information please
Principal, Himalayan Institute of Medical Sciences
Vice-Principal (Allied Health PG Programmes)
Chairperson & Members of the Board of Studies

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Dr Suman Bala Dr Ginpreet Kaur Dr Dilip Chander Dhasmana Dr Deep Shikha

Dr Nikku Yadav Dr Ashwani Bhat Dr Neha Sharma

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Swami Rama Himalayan University
Office of the Registrar

SRHU/Reg/Int/2025- 263 Date: 8th May, 2025

Meeting Notice

In reference to the earlier Meeting Notice bearing No. SRHU/Reg/Int/2025-246 dated 30th April 2025 regarding meeting of the **Board of Studies (BOS)** constituted for **Allied Health PG Programme - M.Sc. (Clinical Research)** under Himalayan Institute of Medical Sciences, the meeting of the BOS for the said programme has been re-scheduled on **10th May 2025 (Saturday) at 11:00 AM.**

The 'Agenda' of the meeting shall be as per Statute 5.09 of Swami Rama Himalayan University.

All concerned members of the said 'Board of Studies' are requested to make it convenient to attend the meeting.

08/05/2025

Commander Challa Venkateswar (Retd.)
Registrar

Copy to: Hon'ble President
Hon'ble Vice-Chancellor
Director General (Academic Development)
Pro Vice-Chancellor
for kind information please
Principal, Himalayan Institute of Medical Sciences
Vice-Principal (Allied Health PG Programmes)
Chairperson & Members of the Board of Studies

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Dr Suman Bala Dr Ginpreet Kaur Dr Dilip Chander Dhasmana Dr Deep Shikha

Dr Nikku Yadav Dr Ashwani Bhat Dr Neha Sharma

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Jolly Grant, Dehradun-248016

ATTENDANCE OF MEETING

S.No	Name	Signature
1	Dr Nikku Yadav , Associate Professor Incharge Department of clinical Research	
2	Dr D.C. Dhasmana, Professor Department of Pharmacology	
3	Dr Deep Shikha, Professor Department of Community Medicine	
4	Dr Ashwani Bhat, Associate Professor Department of Neurology	
5	Dr Neha Sharma, Associate Professor Department of Community Medicine	
6	Dr Suman Bala, Professor & HOD Department of Pharmacology SGRRIM & HS, Dehradun	
7	Dr Ginpreet Kaur, Professor Department of Pharmacology SPP School of Pharmacy & Technology Management SVKM'S NMIMS University, Mumbai	
8	Ms Ruchika Thapliyal Batch 2023 (Senior Student)	
9	Mr Ashutosh Dangwal Batch 2022 (Alumni)	

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Dr Suman Bala | Dr Ginpreet Kaur | Dr Dilip Chander Dhasmana | Dr Deep Shikha

Dr Nikku Yadav | Dr Ashwani Bhat | Dr Neha Sharma

MINUTES OF MEETING

In pursuance of notification No SRHU/Reg/OO/2025-68, dated 16 April 2025, the meeting of the board of studies for MSc Clinical Research was held in the Department of Clinical Research on 10 May 2025 at 11.00 AM in the presence of the following members:

S.No.	Name	Designation
1	Dr Nikku Yadav, Associate Professor & Incharge Department of Clinical Research	Chairperson
2	Dr Deep Shikha, Professor Department of Community Medicine	Member
3	Dr D.C. Dhasmana, Professor Department of Pharmacology	Member
4	Dr Neha Sharma, Associate Professor Department of Community Medicine	Member
5	Dr Ashwani Bhat, Associate Professor Department of Neurology	Member
6	Dr Suman Bala, Professor & HOD Department of Pharmacology Shri Guru Ram Rai Institute of Medical & Health Sciences, Patel Nagar, Dehradun	External Expert
7	Dr Ginpreet Kaur, Professor Department of Pharmacology SPP School of Pharmacy & Technology Management, SVKM'S NMIMS University, Mumbai	External Expert
8	Ms Ruchika Thapliyal Batch 2023 Senior Student	Member
9	Mr Ashutosh Dangwal Batch 2022 Alumni	Member

Dr Nikku Yadav, the chairperson of the meeting introduced the members of the BoS. Dr. Nikku Yadav gave a brief outline of the MSc Clinical Research Programme and highlighted the Program objectives, Course & Examination pattern semester wise.

All members appreciated the MSc Clinical Research Programme curriculum.

Agenda no 1: To recommend, upon reference to it by the faculty, the course of study, curriculum, question paper pattern and methods of assessment in the subjects or group of subjects within its purview.

All members appreciated in the new MSc Clinical Research Curriculum and the uniformity brought about by its implementation.

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Dr Nikku Yadav | Dr Ashwani Bhat | Dr Neha Sharma

Vice Principal (Allied Health PG Programmes)

The course of study, curriculum, question paper pattern and methods of assessment for ascertaining the teaching and training of MSc Clinical Research students based on competency-based curriculum as mandated by UGC and based on the key stakeholder feedback were discussed.

Recommendations and changes mode:

1. Following courses along with required competencies are to be added.
   - **i) Fundamental Course**
   - **ii) Core Course**
   - **iii) Elective Courses**
   - **Generic Elective Course**
   - **Discipline Specific Elective Course**
   - **Project work/Research Work**
   - **iv) Ability Enhancement Courses**
   - **Skill Enhancement Course**
   - **Ability Enhancement Compulsory Course**
   - **v) Audit Course**
   - **vi) Value added course**

2. Competency based course content for lectures/ practical/tutorials/seminars/assignments/ self-directed learning
3. Logbook
4. Assessment
5. Question paper
6. Teaching hours and assessment patterns arranged as per UGC guidelines.
7. Learning Assessment system as per University norms.
8. MSc Clinical Program outcomes as well as course outcomes are defined and matched with each other.

Summary of Changes discussed as it follows.

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Dr Nikku Yadav | Dr Ashwani Bhat | Dr Neha Sharma

Himalayan Institute of Medical Sciences
Dean -cum- Principal

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Summary of changes in the curriculum

Justification: Changes were made considering, past experience with student choice options, stakeholder's feedbacks, knowledge expansion and market relevance

S. No.	Regulation and Syllabus - prior to revision	Regulation and syllabus - post revision	Approximate % of revision
1	Biostatistics (3 Cr)	Biostatistics (4 Cr) Content deleted from UNIT I, II, III New content added in Unit I, II, III, IV Books revised	50
2	Genetics; Molecular Biology (2 Cr)	Genetics; Molecular Biology (3 Cr) New content added in Unit IV, books updated Deleted content from Unit III	20
3	Introduction to Clinical Research (3 Cr)	Introduction to Clinical research (4 Cr) New content added in Unit II and books revised Deleted content from Unit II	20
4	Bio analytical Techniques (3 Cr)	Bio analytical techniques (4 Cr) New content added in all units, books updated, and credit increased Deleted content from Unit I	25
5	Clinical Trials (3 Cr)	Clinical Trials (4 Cr) Credit increased and new content added in 2nd and 4th unit Books revised	25
6	Systems Pharmacology; Pre-Clinical Drug Development & Safety (3 Cr)	Systems Pharmacology; Pre-Clinical Drug Development & Safety (4 Cr) Content deleted from Unit I Learning outcomes revised, credit increased New content added in Unit II and III and books revised	35

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7	Immunology (3 Cr)	Immunology (3 Cr) New Content Added in all units and E resources updated. Some content Deleted from all units	60
8	Microbiology (3 Cr)	Microbiology (3 Cr) Content deleted from Unit V. Course description and learning objectives updated. Content added in all Units. Books and Laboratory experiments updated	60
9	IPR; Ethics (3 Cr)	IPR and Ethics (3 Cr) Deleted content from Unit II. Content Added in Unit IV, V Updated books added	30
10	Environmental & Regulatory Physiology (3 Cr)	Physiology (4 Cr) Entire syllabus revised, books revised, and credit increased	80
11	Basics of Pharmaceutics (3 Cr)	Basics of Pharmaceutics (4 Cr) New content added in Unit II, learning objectives and outcomes updated, credit increased and books revised	30
12	Biopharmaceuticals& Drug Development (3 Cr)	Biopharmaceuticals& Drug Development (4 Cr) Credit increased, Books revised, and new content added in unit I, II.	30
13	Quality Control and Quality Assurance in Research (3 Cr)	Quality Assurance & Quality Control in Clinical Research (4 Cr) Credit increased, books updated, and new content added in Unit II	25
14	Clinical Data Management (3 Cr)	Clinical Data Management (4 Cr) Content added in unit II & IV	25

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15	Pharmacovigilance (3 Cr)	Pharmacovigilance (4 Cr) Learning outcomes updated, books revised New content added in Unit IV and credit increased	30
16	Regulatory Affairs (3 Cr)	Regulatory Affairs (4 Cr) Books and Journals revised, and credits increased	20
17	Clinical Trial Management (3 Cr)	Clinical Trial Management (4 Cr) Content deleted from Unit I, IV New content added in Unit I, II, III. Books updated and credit increased	30
18	Analytical tools for pharmaceutical industry (3 Cr)	Analytical tools for pharmaceutical industry (4 Cr) Latest books added and credit increased	20
19	General Epidemiology (3 Cr)	Content revised in all units (4cr)	50
20	Introduction to Clinical & Pharmaco-Epidemiology (3 Cr)	Content revised in all units (4cr)	50
21	CDSs101 Population Studies (2Cr)	CD course to Core Course (4cr), Content added	20
22	**Elective Course:** **Elective I: end term written assessment** **Elective II: report submission with presentation** • Intensive study of a Disease: Etiology, Diagnostics & Therapeutics • Pharmacovigilance • Medical writing	**Changed Nomenclature elective to Discipline specific elective courses (DSE):** **Elective I: end term written assessment** **Elective II: Report Submission with presentation** • Intensive study of a Disease: Etiology, Diagnostics & Therapeutics • Pharmacovigilance • Medical writing • Regulatory Affair • Analytical tools for Pharmaceuticals • Clinical Data Integration & Analysis	

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	• Regulatory Affairs • Clinical Data Integration & Analysis • Clinical Trial Management • Big Data Management **Courses Deleted: (Minor importance)** • Med Lab Technology **Newly Added Courses: (in view of Market relevance)** • Medical Coding • QC & QA Clinical Trials • Analytical tools for pharmaceuticals industry • Introduction to Healthcare Management • Pharmaceutical Business Development • Health Analytics • QC & QA in Pharmaceutics Regulatory affairs: Manufacturing (Drugs and Medical devices)	• Clinical Trial Management • Big Data Management • Medical Coding • QC &QA Clinical Trials • Introduction to Healthcare Management • Pharmaceutical Business Development • Health Analytics • QC &QA in Pharmaceutics • Regulatory affairs: Manufacturing (Drugs and Medical devices) Elective II: Shifted to Skill Enhancement Course as Hands on activity in healthcare industry in above stated (Elective I) specialization	
23	**Cross Disciplinary Courses** • Original Thinking: Live • Understanding energy of positive words & thoughts (Name revised) **Newly Added Courses:**	**Nomenclature changed from Cross Disciplinary Courses to Generic Elective Courses** **Two new courses are added:** • Mental Health and well being • Innovation, Business Model and Entrepreneurship	

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	• Spoken English • Population Studies • Artificial Intelligence • Principles of Management • Gender Inequality and Gender Studies	**Spoken English shifted to Ability enhancement compulsory course**	
24	**Value Added Courses:** • Power of Positive: Mind & Logic • Fundamentals of Clinical Research	**Value added course:** Will provide in different areas skill, language, Human Value, Health, Occupational Health & Safety in Clinical Research etc.	
25	**Choice-based short sessions available to students in the University (*Offered by the department)** • Soft skills development • Language and communication skills development • Yoga and wellness • Analytical skill development* • Human value development* • Personality and professional development • Employability skills development*	**Capability enhancement (Offered by the department) on weekly basis** • Soft skills development • Language and communication skills development • Yoga and wellness • Analytical skill development • Human value development • Personality and professional development • Employability skills development	
26	**No audit course**	**Audit course** • ACYW101: Yoga and wellness	

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27	**Evaluation:** Cumulative Assessment: 60% Formative Continuous Assessment:40%	**Evaluation:** Cumulative Assessment: 60% Formative Continuous Assessment:40%	

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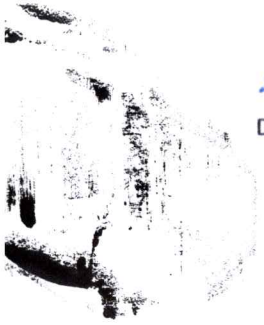

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Agenda No 2: To recommend programme objectives, programme outcomes and course outcomes.

The recommended programme objectives, programme outcomes (POs), and course outcomes (COs) were shared with the members. The members critically analyzed all the outcomes and thoroughly reviewed the PO-CO mapping. Constructive feedback was incorporated to ensure alignment with academic goals and industry relevance.

Agenda No 3: To recommend books including textbook, supplementary reading, reference books, online references and other study material for such courses of study.

The previously recommended list of textbooks, supplementary readings, reference books, and online resources was shared with the members. After due discussion, it was unanimously agreed that the existing list remains relevant and should be continued. Updates were made to the list based on suggestions from the members to ensure inclusion of the most current and comprehensive study materials.

The members emphasized the importance of integrating contemporary online teaching-learning tools and platforms into the academic process. It was recommended that faculty members actively share links to high-quality online resources with students as and when required.

Agenda No 4: To advise the faculty or faculties concerned regarding improvements in the courses of the study.

The members advised that all departmental faculty should be appropriately informed about the changes approved by the Board of Studies to ensure smooth and effective implementation of the revised curriculum. It was decided that this dissemination would be carried out through regular monthly departmental meetings. Furthermore, periodic feedback would be collected from faculty members to monitor the progress, address challenges, and ensure continuous improvement in the teaching-learning process.

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Agenda No 5: To recommended organization of the orientation and refresher courses in the program.

The inclusion of Value-Added Courses (VACs) and Capability Enhancement Schemes in the revised curriculum was appreciated by all members. The committee deliberated on various strategies for effective implementation of these components. It was recommended that orientation and refresher sessions be organized for faculty to familiarize them with the objectives, content, and delivery mechanisms of VACs and enhancement schemes. These sessions will support capacity building and ensure that the intended outcomes of the new curriculum are achieved effectively.

As per the agenda:

1. The course curriculum for MSc Clinical Research course was discussed and necessary changes as per the suggestions of the members were incorporated in the draft and approved by the Board.
2. The teaching learning methods and assessment methods were discussed in detail and necessary changes were incorporated in the draft and approved by the Board.

The meeting ended after necessary corrections were made and approved by all members of the Board unanimously.

The Chairman thanked all the members for attending the meeting.

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Dr Nikku Yadav | Dr Ashwani Bhat | Vice Principal (Allied Health PG Programmes) HIMS, SRHU Jolly Grant, Dehradun | Dr Neha Sharma

Schedule of Orientation Program (Tentative)
MSc (Clinical Research) Program
Date.....Month, Year

Day/Date	Program Schedule			Coordinators of the Event
	Reporting/Registration of Students **9.30 AM-10.30 AM**	Academic Unit Facilities Campus Tour, SRC **10.30 AM-1.30 PM**		**Dr Nikku Yadav** **Mr Abhinav Bahuguna** **Ms Akanksha Uniyal**
	Code of Conduct **9.30 AM-11.00 AM** **Prof Asha Chandola-Saklani**	Detail Account of Exam & Evaluation Pattern, Student Feed Back etc **11.00-12.00 PM** **Dr Nikku Yadav**	Effective Presentation Skills **12.00-1.00 PM** **Ms Manju Nautiyal**	**2.30-4.30 pm** **Introduction to Microsoft** **Mr Piyush Dhyani**
	Health & Hygiene **9.30-10.30 AM** **Dr Ruchi Juyal**	PDP **10.30-11.30 AM** **Dr Garima Kapoor**	Role of Biostatistics in Research **11.30-1.00 PM** **Mr Abhinav/ Ms Akanksha**	**2.30-4.30 pm** **Application of Microsoft** **Mr Piyush Dhyani**
	Professional Ethics **9.30 AM- 10.30 AM** **Prof D C Dhasmana**	Early Research Orientation **10.30-12.00 AM** **Prof Asha Chandola-Saklani**	Motivational Speech **Prof AK Srivastava** **12.00 -1.00 PM**	**2.30-4.30 pm** **Microsoft Word: Basics** **Dr Deep Shikha**
	Introduction to course curriculum **9.30 AM- 10.30 AM** **Dr Nikku Yadav**	Human Values - Concept and Importance **Prof Asha Chandola-Saklani**	Scientific Healthcare Quiz **10.00-11.30 AM** **MSc CR IInd Year Student**	**2.30-4.30 pm** **Microsoft Word: Advanced** **Dr Deep Shikha**
	Holistic Health Approach 9.30-11.00 **Dr Somlata Jha**	Gender Sensitization 11.00 -12.00 PM **Dr Geeta Bhandari**	Session on Fire Safety 12.00-1.00 PM **Mr Rawat**	**2.30-4.30 pm** **Microsoft PowerPoint: Basics** **Dr Nikku Yadav**

Dr Suman Bala Dr Ginpreet Kaur Dr Dilip Chander Dhasmana Dr Deep Shikha

Dr Nikku Yadav Dr Ashwani Bhat Dr Neha Sharma

Dean of Medical Sciences -cum- Principal

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	Communication Skills **9.30 AM-10.30 AM** **Dr Seema Madhok**	Emotional Intelligence **10.30-11.30 AM** **Dr Ekta Rao**	Team Building Activity (Treasure Hunt) **11.30-1.00 PM** **Dr Ekta Rao**	**2.30-4.30 pm** **Microsoft PowerPoint: Advanced** **Dr Nikku Yadav**
	Visit to Himalayan Centre for Incubation & Entrepreneurship **Dr Amjad Hussain** **9.30-1.00 PM**			**3.00-4.30 pm** **Microsoft Excel-Basics** **Mr Abhinav Bahuguna**
	Lecture on Substance Abuse **9.30 AM-10.30 AM** **Prof Jayanti Semwal**	YOUNITE **Dr. Ashish Gupta** **10.30-12.00 PM**	Visit to Hospital, Clinical Trial Centre & CRI **12.00-1.00 PM** **Mr Vikash CRC**	**2.30-4.30 pm** **Google mail service** **Mr Deep Lohani**
	Visit to Sun pharmaceutical industries ltd			**Dr Nikku Yadav** **Mr Abhinav Bahuguna** **Ms Akanksha Uniyal**
	Modus operandi for Placement **9.30 AM-10.30 AM** **Mr Ayush Sharma**	Library Data base **10.30-11.30 AM** **Prof Yoginder Singh**	Visit to Library, HCDRL & SSC **11.30-1.00 PM** **Dr Nikku Yadav**	**2.30-4.30 pm** **Google mail service: Google Drive, Google Forms etc** **Mr Deep Lohani**
	e-Content Platforms: Swayam, NPTEL, Other Moocs **9.30-10.30 AM** **Dr Vidisha Vallabh**	**Open Mic & Cultural Event with HSBS & Other AUs**		**Assessment & Feedback**

Dr Suman Bala

Dr Ginpreet Kaur

Dr Dilip Chander Dhasmana

Dr Deep Shikha

Dr Nikku Yadav

Dr Ashwani Bhat

Dean cum Principal

Dr Neha Sharma

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BOARD OF STUDIES IN M.Sc. CLINICAL RESEARCH
July 2025

Approved copy of BOS duly signed by the internal and external experts after incorporating the recommended suggestions

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THE MSC CLINICAL RESEARCH PROGRAM

Clinical Research comprises scientific investigations in healthcare sector viz., Clinical and Pharma. It cuts across all disciplines viz. Health science, Pharmacology, Epidemiology, Biology, Biochemistry, Omics, Statistics, Bio/Medico/Pharmaco-Informatics, Data Science & Analytics. Clinical Research helps translate basic concepts into knowledge, diagnoses, and therapies for human welfare. It determines the efficacy and safety of medications and treatment regimens intended for humans. Clinical trials may be used for prevention, treatment, analysis or for relieving symptoms of a disease. In recent times clinical researches have led to the development of new techniques for disease diagnosis, new drugs, new surgical methods, new therapeutic approaches including Gene therapy, and, new combinations & medical devices.

The Master of Science program in Clinical Research at SRHU has been designed considering the latest and diverse demands of healthcare industry. The program groom's science undergraduates for careers in Healthcare Industry, especially, Clinical Trials, Disease Epidemiology, Clinical Data Management, Health Analytics and Pharma sector.

Vision & Mission of HIMS:

Vision

To be the preferred institution for quality medical education and healthcare in the country.

Mission

To foster healthcare leaders for the service of humanity through high quality medical education, research compassionate patient Care, and innovation practice.

Program Outcomes (POs)

In order to fulfill the post graduate degree, the graduate must be able to function in the following roles appropriately and effectively.

PO1: **Basic researcher& critical thinker**, who thinks critically and develop power of reasoning in research.

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SWAMI RAMA HIMALAYAN UNIVERSITY

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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PO 2: **Data manager**, as an active member of the research team, they will be able to Analyze and Manage Clinical Data & Big Data in pharmaceutical industries /Healthcare settings.

PO 3: **Professional,** who adhere good practices in scientific investigations & clinical trials dealing with drugs, diseases and medical devices

PO 4**: Communicator**, work efficiently in teams to meet organizational and societal goals communicating effectively with stake holders with sensitivity and ethical awareness.

PO 5: **Lifelong learner** committed to continuous improvement of skills & knowledge in Quantitative tools & techniques in Health Care including Bio/ Pharmacy /Medico-Informatics, and basic Drug designing.

Program Specific Outcomes (PSOs):

PSO1: Clinical Trial Design & Execution

Graduates will be proficient in designing, conducting, and managing clinical trials (Phase I–IV), observational studies, and post-marketing surveillance to assess therapeutic interventions.

PSO2: Regulatory Affairs & Ethical Compliance

Graduates will demonstrate a deep understanding of national (CDSCO, ICMR) and international (ICH-GCP, USFDA, EMA, WHO) regulatory guidelines to ensure compliance and ethical integrity in research.

PSO3: Translational & Evidence-Based Research

Graduates will contribute to bridging laboratory discoveries with clinical applications through translational research, improving patient outcomes and public health policies.

Course Outcomes:
CMCR501: Biostatistics

CO1: Apply basic statistical concepts commonly used in Health and Medical Sciences
CO2: Use basic analytical techniques to generate results
CO3: Interpret results of commonly used statistical analyses in written summaries
CO4: Demonstrate statistical reasoning skills correctly and contextually

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CMCR502: General Biochemistry

CO1: Demonstrate knowledge and understanding of the principles that govern the structures of macromolecules, basic mechanisms of metabolic

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CO2: Use basic analytical techniques to generate result
CO3: Analyse, interpret, and report the results of their laboratory experiments

CMCR503: Molecular Biology; Genetics

CO1: Demonstrate knowledge and understanding of the principles that govern the structures of macromolecules, basic mechanisms of metabolic
CO2: Describe the recent development, scopes and applications of molecular biology and genetics and its role in human society.
CO3: Analyse, interpret, and report the results of their laboratory experiments
CO4: Discuss applications in genetic engineering, gene therapy, and personalized medicine; explore advancements in genomics, transcriptomics, and proteomics.

CMCR 504: Introduction to Clinical Research

CO1: Describe principles and processes in Clinical Research.
CO2: Explain the inter and cross-disciplinary nature of investigations in Clinical science, Epidemiology and Pharmacology.
CO3: Discuss the importance of Clinical Research in developing new techniques for disease diagnosis, new drugs, new surgical methods, new therapeutic approaches including Gene therapy, and new combinations & devices
CO4: Gain knowledge of various phases and kinds of clinical trials,
CO5: Understand the code of ethics and regulatory guidelines and modern biomedicine, i.e., frontline areas of medical biotechnology.
CO6: Prepare technical document (protocol, ICD, CRF, SOPs) and handling of clinical data
CO7: Understand the knowledge of Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices
CO8: Demonstrate the fundamental concepts of pharmacokinetics (absorption, distribution, metabolism, excretion) and pharmacodynamics (drug-receptor interactions, dose-response relationships).

CMCR505: Bio-medical, Bio-analytical Techniques & Instrumentation

CO1: Understand the knowledge of commonly used techniques e.g., histology, histochemistry, immunohistochemistry (IHC), fluorescent microscopy, cell culture, genetically modified (GM) cells, monoclonal antibodies (MAbs), polymerase chain reaction (PCR), ELISA, RIA, ECLIA
CO2: Knowledge of the types and principles of analytical techniques like centrifugation, spectroscopy, electrophoresis, and chromatographic systems
CO3: Demonstration of Immuno-diagnostic and PCR workstations.
CO4: Describe the applications of Biomedical and Bio-analytical techniques in industry & R&D area in healthcare.

CMCR506: General Epidemiology

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CO1: Describe the fundamentals of epidemiology.
CO2: Implement the principles of epidemiology to evaluate disease patterns, determinants, and prevalence in populations.
CO3: Compare and contrast the different epidemiological study designs and their respective strengths and weaknesses

CDLa101: Spoken English

CO1: Developing intellectual, personal, and professional abilities through effective communicative skills
CO2: Command of English and its linguistic Structures.
CO3: Critical frameworks to analyse the linguistic, cultural, and historical background of texts written in English

CMCR511: Clinical Trials

CO1: Discuss new drug discovery and development, history, scope of clinical research & areas, codes of ethics, clinical trial documentation & interpret results.
CO2: Demonstrate ability to choose pharmaceutical clinical trial research designs.
CO3: Differentiate phases of clinical trials from Phase I to Phase IV & types of clinical trials
CO4: Enumerate clinical studies (Clinical trials) effectively as per ICH GCP, USFADA/DCGI, National guidelines, and international guidelines.
CO5: Demonstrate ability to perform in various CR professional skills like; roles & responsibility of stake holders, time management skills,
CO6: Problem-solving skills, Presentation skills, Interpersonal skills &Communication skills
CO7: Describe the concept of audit and monitoring as per regulatory guidelines USFDA/WHO/DCGI etc.
CO8: Demonstrate the reporting of ADRs International & Indian context

CMCR512: Pharmacology

CO1: Explain the process of drug discovery and development
CO2: Understand the principles of basic and clinical pharmacology and their application to clinical development
CO3: Understand the principles of animal pharmacology studies and the alternatives to animal experiments
CO4: Explain the importance of bioinformatics, proteomics and pharmacogenomics in drug discovery and development
CO5: Describes the principles and methods of calculation of first in human dose

CMCR513: Basic & Applied Immunology

CO1: Explain mechanisms of infection and related immune reactions in body
CO2: Know the basis of producing vaccines, antibodies for use in healthcare

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CO3: Understand the use of immunological techniques such as ELISA, Western blot, flow cytometry, and immunohistochemistry.
CO4: Describe immune responses to organ transplants and graft rejection mechanisms.
CO5: Discuss the role of the immune system in cancer and tumor immunotherapy.

CMCR514: Basic and Applied Microbiology

CO1: Describe the microbial distribution & diversity, reproduction & growth, role in causing diseases, and potential biotechnological applications by imparting depth knowledge.
CO2: Demonstrate the ability to explore recent advances and techniques used to develop biotech-based applications in the food and beverage industries, biopharmaceutical industries, synthetic biology, and healthcare (e.g., antibiotics, vaccine development, probiotics, CRISPR-based applications).

CMCR515: IPR; Ethics

CO1: Highlight the role of patents in pharmaceutical research, their impact on drug pricing, and access to medicines.
CO2: Evaluate ethical concerns in patenting biotechnology and life-saving drugs, balancing public health and commercial interests.
CO3: Explain technology transfer, licensing, and intellectual property management in research and industry.
CO4: Understand autonomy, beneficence, non-malfeasance, and justice, along with frameworks like the Belmont report and declaration of Helsinki
CO5: Highlight the importance of voluntary participation and protecting vulnerable populations.
CO6: Identify unethical practices like data falsification and plagiarism and stresses transparency and reproducibility in research.

CMCR516: Clinical Data Management

CO1: Understanding of quality data management and metrics and best practices for quality data management.
CO2: Familiarity with CDM processes, Data collection modalities, electronic data capture, Storage, Retrieval and validation.
CO3: Application of data, data preparation and discrepancy management

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CMCR517: Environmental & Regulatory Physiology

CO1: Familiarize with various aspects of regulatory physiology & biological body systems.
CO2: Understand interaction of organisms with their immediate environment, life sustaining strategies, role of environmental cues & messenger in maintaining the information flow among organism & surroundings
CO3: Understand the types of chemical, hormonal messengers, their synthesis in body, diverse modes of actions, applications, and neuronal coordination

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CMCR518: Basics of Pharmaceutics

CO1: Demonstrate basic understanding of preparation, manufacturing, and packaging of pharmaceutical dosage forms.
CO2: Explain basic principles of formulation of pharmaceutical dosages with knowledge of their physicochemical properties
CO3: Explain basic steps of converting raw material into finished goods in manufacturing pharmaceutical dosage forms.
CO4: Describe the evaluation process to ensure quality of dosage forms.
CO5: Describe Current Good Manufacturing Practice (cGMP) and its compliance in Pharmaceutical Industry.

CMCR519: Population studies

CO1: Give knowledge of key population issues in India, other developing countries, less developed and developed countries
CO2: Demonstrate the relationships between population size and available resources; social, biological and economic influences on population growth rates, fertility decline and population ageing, and population distribution and migration.
CO3: Introduced to the main theories used to understand population and societal change.

CMCR601: Biopharmaceuticals & Drug Development

CO1: Describe Biopharmaceuticals and Drug development process.
CO2: Have a thorough knowledge and enforceability of development, research and production of pharmaceutical products (Demonstration)
CO3: Demonstrate the understanding of awareness of and national, international health problems related pharmaceutical biotechnology.

CMCR602: Quality control & Quality Assurance in Clinical Research
CO1: Discuss understanding of importance of Quality Assurance and Quality Control in Clinical investigations, translational as well as observational.
CO2: Demonstrate the understanding of cognizance with process of quality data generation, protocol compliance, documentation, monitoring in keeping with GCP guidelines.
CO3: Demonstrate the understanding of regulatory compliances (Audits/ inspections etc)

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CMCR603: Regulatory Affairs
CO1: Understand the role of a medical product's regulatory affairs specialist and the dynamic nature of the regulatory field.
CO2: Learn the laws and regulations that apply to the development, testing and production of medical products, including biologics, drugs, biotechnology-derived therapeutics, vaccines, and medical devices.

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CO3: Learn the laws and regulations that apply to the development, testing and production of medical products, including biologics, drugs, biotechnology-derived therapeutics, vaccines, and medical devices.

CMCR604: Introduction to Clinical & Pharmaco-Epidemiology

CO1: Define patterns, causes and effects of disorder/ disease in patient populations and association with exposures/ treatments and Health outcomes
CO2: Define patterns and impact of environmental deficiencies e.g., micronutrients on human populations.
CO3: Generate statistics of public health issues in local populations and appreciate the importance of Practices,
CO4: Guidelines and Policies in health systems
CO5: Describe disease screening and prevention
CO6: Gain expertise in systematic review methodology
CO7: Develop patient-centred registries and data marts within health information systems
CO8: Appreciate etymology of epidemics nationally and globally
CO9: Define Pharmacoepidemiology as the bridge science spanning both Pharmacology & Epidemiology

CMCR605: Research Methodology

CO1: Understanding of the importance of research in societal growth and development
CO2: Ability to identify original problems for research and develop research designs for problem solving
CO3: Familiarity with research methodologies i.e., surveys, sampling, experimental, in clinical investigations
CO4: Understanding of ethical and regulatory issues in scientific research
CO5: Adequate skill in statistical tools, techniques, and their application to arrive at relevant conclusions
CO6: Adequate skill in basic software used in data collection, compilation, storage, retrieval, and data analysis.

CMCR606: Pharmacovigilance

CO1: Explain classification of adverse events / adverse drug reactions.
CO2: Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval.
CO3: Describe the various pharmacovigilance methods and PMS methodologies
CO4: Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)
CO5: Understand ongoing benefit / risk assessment throughout the life cycle of a medicine.
CO6: Understand the basics of signal detection and management

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CMCR650: Research Project

CO1: Get hold of principles and hands on relevant techniques of biomedical research viz disease genesis, diagnostics & amp; management

CO2: Be able to prepare technical document (protocol, informed consent, clinical report form, clinical study report)

CO3: Be well with wet/dry lab methodologies and field activity

CO4: Get knowledge for data generation, integration & statistical analysis using SW.

CO5: Be able to design and interpret clinical case study, using medico informatics tools

CMCR651: Intensive study of a Disease: Etiology, Diagnostics & Therapeutics

CO1: Explain the fundamental causes and pathophysiology of specific diseases.

CO2: Identify genetic, environmental, infectious, and lifestyle-related factors contributing to disease development.

CO3: Analyze epidemiological data to determine disease prevalence, incidence, and risk factors.

CO4: Describe the cellular and molecular mechanisms leading to disease onset and progression.

CO5: Understand how biochemical and immunological processes contribute to disease pathology.

CO6: Differentiate between acute and chronic disease progression and their systemic effects.

CMCR652: Pharmacovigilance

CO1: Explain classification of adverse events / adverse drug reactions.

CO2: Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval

CO3: Describe the various pharmacovigilance methods and PMS methodologies

CO4: Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)

CO5: Understand ongoing benefit / risk assessment throughout the life cycle of a medicine.

CO6: Understand the basics of signal detection and management

CMCR653: Medical writing

CO1: Define medical writing and its role in healthcare, pharmaceuticals, and research.

CO2: Differentiate between various types of medical documents (regulatory, scientific, educational, promotional).

CO3: Write well-structured clinical study reports, research articles, and systematic reviews.

CO4: Prepare patient information leaflets, drug monographs, and medical communication materials.

CO5: Follow guidelines from regulatory agencies (FDA, EMA, ICH, GPP3) in medical writing.

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CO6: Adhere to ethical considerations, including plagiarism, data integrity, and authorship guidelines.

CMCR654: Regulatory Affairs, manufacturing [drugs and medical devices]

CO1: Understand regulatory frameworks
CO2: Apply good manufacturing practices (GMP)
CO3: Comprehend the drug development and approval process
CO4: Evaluate medical device regulations
CO5: Manage regulatory submissions & documentation
CO6: Ensure compliance & risk management
CO7: Understand ethical, Legal & Global Aspects of regulatory affairs

CMCR655: Analytical tools for pharmaceutics

CO1: Understand the role of analytical Tools in the Pharmaceutical Industry
CO2: Apply chromatographic and spectroscopic techniques
CO3: Perform drug assay and stability testing
CO4: Utilize advanced analytical techniques
CO5: Develop problem-solving skills for analytical challenges
CO6: Ensure regulatory compliance in Pharmaceutical Analysis

CMCR656: Clinical Data Integration and Analysis

CO1: Apprises students with the various methods & statistical procedures of mining, management, and analysis of clinical
studies-based data.
CO2: Become conversant in CDM processes, data management and validation plans
CO3: Use statistical tools and techniques in data management and analysis
CO4: Design surveys and develop independent projects
CO5: Application of data, data preparation and discrepancy management

CMCR657: Clinical Trial Management

CO1: Learn the process for managing biomedical product development for FDA approval
CO2: Gain an in-depth understanding of the clinical trials process through a modular, operations-focus approach
CO3: Acquire project management skills needed to successfully manage human clinical trials
CO4: Gain a global perspective on clinical trials management to better respond to the growing
industry across the globe
CO5: Demonstrate the ethical principles, regulations, and guidelines governing clinical trials, such as ICH-GCP, FDA, EMA, and CDSCO regulations.
CO6: Learn from instructors with industry expertise in clinical trials management

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CMCR658: Big Data Management

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health & PG Programmes)
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CO1: Define big data and its characteristics (Volume, Variety, Velocity, Veracity, and Value – 5Vs).
CO2: Explain the role of big data in various industries, including healthcare, finance, and e-commerce.
CO3: Demonstrate knowledge of big data storage solutions such as Hadoop Distributed File System (HDFS) and cloud-based storage.
CO4: Implement data processing frameworks like Apache Hadoop, Apache Spark, and NoSQL databases (MongoDB, Cassandra).
CO5: Understand data governance, security, and compliance regulations (GDPR, HIPAA).
CO6: Implement data quality management and metadata handling techniques.

CMCR659: Medical Coding
CO1: Understand the Basics of Medical Coding
CO2: Apply Medical Terminology and Anatomy in coding
CO3: Navigate ICD-10-CM, CPT, and HCPCS coding systems
CO4: Ensure accuracy and compliance in coding
CO5: Analyze and abstract medical records for coding
CO6: Understand medical billing and reimbursement processes
CO7: Use Medical Coding software and tools

CMCR660 Quality Assurance & Quality Control in Clinical Trials
CO1: Understand healthcare systems & policies
CO2: Develop leadership & management skills
CO3: Apply financial & economic principles in healthcare
CO4: Address public health & ethical considerations
CO5: Improve healthcare operations & Quality management
CO6: Enhance communication & teamwork in healthcare settings
CO7: Utilize Health information systems & technology

CMCR661: Introduction to Healthcare Management
CO1: Understand healthcare systems & policies
CO2: Develop leadership & management skills
CO3: Address public health & ethical considerations
CO4: Apply financial & economic principles in healthcare
CO5: Improve healthcare operations & Quality management
CO6: Enhance communication & teamwork in healthcare settings
CO7: Utilize health information systems & technology

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CMCR662 Pharmaceutical Business Development
CO1: Understand the history and development of the pharmaceutical industry.
CO2: Introduce the framework of the industry - research, development, manufacture, and distribution of pharmaceutical products on an international level.
CO3: Understand the role of business development within different types of pharmaceutical companies.

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CO4: Understand the different types of agreements used in the industry.
CO5: Understanding of the basic legal concepts with emphasis on application in a pharmaceutical and biotechnology business development and licensing context.
CO6: Understanding of the value and limitations of IPRs in encouraging innovation with emphasis on the use and application of IIPRs in a pharmaceutical and biotechnology business development and licensing context.

CMCR663: Health Analytics

CO1: Collect, clean, and manage healthcare datasets for analysis.
CO2: Apply statistical and machine learning methods to healthcare problems.
CO3: Use visualization techniques to communicate insights effectively.
CO4: Assess the impact of analytics on healthcare decision-making and Policy
CO5: Understand data security, privacy, and compliance in health analytics.

CMCR664: QA and QC in Pharmaceutics

CO1: Understand various aspects of quality control and quality assurance in pharmaceutical industries.
CO2: Familiarized with important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.
CO3: Understand the importance of documentation and responsibilities of QA & QC departments.
CO4: Understand the scope of quality certifications applicable to pharmaceutical industries.

CMCR700: Dissertation

CO1: Identify a research problem, formulate research questions, and define objectives.
CO2: Develop a research methodology, including experimental design and data collection strategies.
CO3: Conduct independent research while adhering to ethical and regulatory guidelines.
CO4: Analyze and interpret research findings using statistical tools and methodologies.
CO5: Write a well-structured dissertation with all key components.
CO6: Present research findings through oral presentations, posters, or seminars.
CO7: Apply research ethics, including plagiarism, data integrity, and responsible conduct.
CO8: Demonstrate problem-solving skills and critical thinking in addressing challenges.
CO9: Contribute to scientific knowledge through research publications and innovations.
CO10: Develop professional competencies such as time management and teamwork.

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GEST101: Introduction to Artificial Intelligence

CO1: Understand fundamental AI concepts, algorithms, and applications, including search strategies, machine learning, and knowledge representation.
CO2: Develop AI-based solutions using programming tools like Python and apply AI techniques in natural language processing, computer vision, and decision-making.

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Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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(Allied Health & PG Programmes)
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CO3: Critically evaluate the ethical and societal implications of AI and explore emerging trends shaping its future

GEMS101: Principles of Management

CO1: Understand the fundamental principles, functions, and roles of management in organizations.

CO2: Apply planning, organizing, leading, and controlling (POLC) concepts to real-world business scenarios.

CO3: Analyze different management theories and their relevance in modern business environments.

CO4: Develop decision-making, leadership, and strategic thinking skills for effective management.

CO5: Evaluate ethical, social, and global challenges in management and propose responsible solutions.

GEMS102 Innovation, Business Models and Entrepreneurship

CO1: Understand key concepts of innovation, business models, and entrepreneurship in various industries.

CO2: Analyze different types of innovation and their role in creating competitive advantages.

CO3: Develop and evaluate business models using frameworks such as the Business Model Canvas.

CO4: Identify opportunities, assess risks, and formulate strategies for launching and scaling a startup.

CO5: Apply entrepreneurial thinking to solve real-world business challenges and drive sustainable growth.

GESS101: Gender inequality and gender studies

CO1: Understand key concepts, theories, and frameworks related to gender inequality and gender studies.

CO2: Analyze historical and contemporary gender disparities across social, economic, political, and cultural domains.

CO3: Examine the role of institutions, policies, and media in shaping gender norms and identities.

CO4: Critically evaluate intersectionality and the impact of gender on diverse communities, including marginalized groups.

CO5: Develop informed perspectives on gender equity and propose strategies for social change and advocacy.

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GESS102: Mental Health & Well being

CO1: Understand the fundamental concepts of mental health, well-being, and psychological resilience.

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CO2: Identify common mental health disorders, their causes, symptoms, and available treatment approaches.

CO3: Analyze the impact of social, cultural, and environmental factors on mental health and well-being.

CO4: Apply stress management, mindfulness, and self-care techniques to promote personal and community well-being

CO5: Evaluate mental health policies, stigma reduction strategies, and the role of mental health advocacy in society.

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ORGANIZATION OF PROGRAM

	MSc Clinical Research
1. Major Requirement	A student must earn a minimum of 86 Credits. The broad distribution of courses is as follows: 1.1 Fundamental Courses (FC): 18 Credits 1.2 Core Courses (CC): 37 Credits 1.3. Generic Elective courses (GEC): 2 Credits 1.4 Discipline Specific Electives courses (DSE): 4 Credits 1.5 Research Project: 3 Credits 1.6 Dissertation/ Research Work: 16 Credits 1.6 Ability enhancement Compulsory Courses (AECC): 2 Credits 1.7 Skill Enhancement Courses (SEC): 4 Credits 1.8 Audit Courses (AC): Non-Credit Courses 1.9 Value Added Course (VAC): Non-Credit Courses
2. MOOC Course	One online course certificate per year viz., Swayam - NPTEL, Coursera etc.
3. Scientific Achievement	One poster/oral presentation certificate
3. Coding Structure	It has first 2 alphabets indicating school CM (parent department) and next 2 alphabets for course CR. Next three digits indicate the level of course starting from 501 to 714

1. **Fundamental Courses (FC):** These are basic courses which act as building blocks for the degree.
2. **Core Courses (CC):** These are courses which act as bridge between fundamental courses and electives and prepare the students to get aligned to a particular specialization. Some depth courses are Interdisciplinary, taught by different departments following the integration concept.
3. **Elective Courses (EC):** Student can choose two Electives out of the options provided. A certain number of Elective courses will be offered in the form of tracks to give further opportunities to the students to specialize or explore thematic interests. Electives provide an expanded scope & nurtures student's skill. Student is expected to opt minimum two Electives out of the options provided. Depending

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on the nature of course/ requirement it can also commence in 3rd Semester & evaluated in 4th Semester.

4. **Ability Enhancement Courses**

   Ability Enhancement Compulsory Course (AECC): Ability Enhancement Compulsory Courses (AECC) are mandatory courses designed to enhance knowledge and skills, typically focusing on foundational areas like Environmental Science and English/French Communication.

5. **Skill Enhancement Course (SEC):** A skill enhancement course is designed to improve existing skills or acquire new ones, focusing on both theoretical knowledge and practical application, to meet job market demands or excel in a specific field.

6. **Audit Course:** Audit course allows a student to take a class without the benefit of a grade or credit for a course. A student who audits a course does so for the purposes of self-enrichment and academic exploration viz., Yoga

7. **Value Added Courses:** Value-added courses are supplementary programs or courses designed to enhance skills, knowledge, and employability beyond the standard curriculum, offering practical skills and specialized knowledge.

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SCHEME:

MSc Clinical Research

Course distribution with Credits, contact teaching hours and Learning Assessment Components

1 Credit= 3 credit hr

Semester I

Course distribution with credits & contact teaching hrs
Credit requirement: 20 (18cr Fundamental courses+ 2cr Ability Enhancement Compulsory Course)
Contact teaching: Lectures (L), Hands-on activities (A), Tutorial (T)

Learning Assessment Components with Weight age distribution
Weight age distribution, Formative (Continuous) vs Cumulative evaluation: 40:60
Scale of assessment: 1-5

S No	Course Category	Course Code	Course Title	Credit	L T P hr/week			Formative (Continuous) Evaluation (Rubrics & Frequency) 40%				Cumulative Evaluation 60%
								Assignments (Originality, regularity) 10%	Hands-on Activities (wet/dry/field) 15%	Seminars (content originality, critical thought) 10%	Effort (portfolio /logbook) 5%	End Term 60%
1	FC	CMCR501	Biostatistics	4	2	1	2	5-8	5-8	3-5	Overall	Written
2	FC	CMCR502	General Biochemistry	3	2	0	2					
3	FC	CMCR503	Genetics; Molecular Biology	3	2	2	0	3-6	4-8	2-4		
4	FC	CMCR504	Introduction to Clinical Research	4	2	1	2	5-8	5-8	3-5		
5	FC	CMCR505	Bio medical, Bio analytical Techniques & Instrumentation	3	2	0	2	5-8	5-8	3-5		
6	FC	CMCR506	General Epidemiology	4	2	1	2					

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health & PG Programmes)
HIMS, SRHU
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7	AECC	CDLa101	Spoken English	2	0	0	4	3-6	4-8	2-4		

Semester II

Course distribution with credits
Credit requirement: 24 (22 cr core courses + 2cr Generic Elective Course)

Learning Assessment Components with Weightage distribution
Weightage distribution, Formative (Continuous) vs Cumulative evaluation :40:60
Scale of assessment: 1-5

S No	Course Category	Course Code	Course Title	Credit	L	T	P	Formative (Continuous) Evaluation (Rubrics & Frequency) 40%				Cumulative Evaluation 60%
					hr/week			Assignments (Originality, regularity) 10%	Hands-on Activities (wet/dry/field) 15%	Seminars (content, originality, critical thought) 10%	Effort (portfolio /logbook) 5%	End Term 60%
1	CC	CMCR511	Clinical Trials	4	2	1	2	5-8	5-8	3-5	Over all	Written
2	CC	CMCR 512	Pharmacology	4	2	1	2					
3	CC	CMCR 513	Immunology	3	2	0	2					
4	CC	CMCR 514	Basic Clinical Microbiology	3	2	0	2					
5	CC	CMCR515	IPR; Ethics	3	2	0	2					
6	CC	CMCR516	Clinical Data Management	4	2	1	2					
7	CC	CMCR517	Environmental & Regulatory Physiology	3	2	0	2					
8	CC	CMCR518	Basics of Pharmaceutics	4	2	1	2					
9	CC	CMCR519	Population Studies	3	2	0	2					
1	GE	GEST101	Introduction to Artificial Intelligence	2	0	0	4	2-3	4-5	1-2		
2	GE	GEMS101	Principle of Management	2	0	0	4					

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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3	GE	GESS101	Gender inequality and gender studies	2	0	0	4					
4	GE	GESS102	Mental Health & Well being	2	0	0	4					
5	GE	GEMS102	Innovation, Business Models and Entrepreneurship	2	0	0	4					

Semester III

Course distribution with credits
Credit requirement: 22 (15cr core courses + 3cr Research project+ 4cr Elective Level)

Learning Assessment Components with Weightage distribution
Weightage distribution, Formative (Continuous) vs Cumulative evaluation: 40:60
Scale of assessment: 1-5

S No	Course Category	Course Code	Course Title	Credit	L hr/week	A hr/week	P hr/week	Formative (Continuous) Evaluation (Rubrics & Frequency) 40%				Cumulative Evaluation 60%
								Assignments (Originality, regularity)10%	Hands-on Activities (wet/dry/field) 15%	Seminars (content, originality, critical thought) 10%	Effort (portfolio /logbook) 5%	End Term 60%
1	CC	CMCR601	Biopharmaceuticals & Drug development	4	2	1	2	5-8	5-8	3-5	Overall	Written
2	CC	CMCR602	Quality control and assurance in Clinical Research	4	2	1	2	5-8				
3	CC	CMCR603	Regulatory Affairs	4	2	1	2					
4	CC	CMCR604	Introduction to Clinical and Pharmaco Epidemiology	4	2	1	2					
5	CC	CMCR605	Research Methodology	4	2	1	2		5-8	3-5		
6	CC	CMCR606	Pharmacovigilance	4	2	1	2					
7	Project work (PW)	CMCR650	Research Project/ Clinical Case Study (Commenced in 2nd sem)	3	0	0	6	Precis of research papers 3 best 5%	Data generation, Data log, analysis, proficiency in	Critical thinking & Imagination as revealed	Efforts 5%	Submission of report/ Presentation with QA 60%

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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									skills being learnt assessed by periodic seminars 15%	in periodic writings seminars/ discussions 15%		
S.No	**Course Category**	**Course Code**	**Elective I (IIIrd)**									
1	DSE	CMCR651	Intensive study of a Disease: Etiology, Diagnostics & Therapeutics									**Elective I Written**
2	DSE	CMCR652	Pharmacovigilance	4	2	1	2	5-10	5-10	3-5		
3	DSE	CMCR653	Medical writing									
4	DSE	CMC 654	Regulatory Affair									
5	DSE	CMCR655	Analytical tools for Pharmaceuticals									
6	DSE	CMCR 656	Clinical Data Integration & Analysis									
7	DSE	CMCR 657	Clinical Trial Management									
8	DSE	CMCR 658	Big Data Management									
9	DSE	CMCR659	Medical Coding									
10	DSE	CMCR660	QC &QA Clinical Trials									
11	DSE	CMCR661	Introduction to Healthcare Management									
12	DSE	CMCR662	Pharmaceutical Business Development									
13	DSE	CMCR663	Health Analytics									
14	DSE	CMCR664	QC &QA in Pharmaceutics									

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
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15	DSE	CMCR665	Regulatory affairs: Manufacturing (Drugs and Medical devices)									
	Semester IV											
	Course distribution with credits **Total credits: 20 (16cr Dissertation+ 4cr Elective Level II)**					**Learning Assessment Components with Weightage distribution: 40:60** **Scale of assessment: 1-5**						
S No	**Course Category**	**Course code**	**Course Title**	**Credit**	**(Practical) Lab/Field Active Dry Activities hr/week**	**Formative (Continuous) Evaluation (Rubrics, Frequency) 40%**						**Cumulative Evaluation (End term) 60%**
1	Research Work (RW)	CMCR700	Dissertation (Elective-specific)	16	36	Precise of res-earch papers 5 best 5%	Data generation, Data log, analysis, proficiency in skills being learnt Assessed by periodic Seminars 15%	Critical thinking & Imagination as revealed In periodic writings seminars/ discussions 15%	Effort 5%	Submission of report/ Presentation with QA		
2	SEC	CMCR701	Hands on Intensive study of a Disease: Etiology, Diagnostics & Therapeutics	4	8							
3	SEC	CMCR702	Hands on Pharmacovigilance	4	8							
4	SEC	CMCR703	Hands on Medical writing	4	8							
5	SEC	CMCR704	Hands on Regulatory Affair	4	8							
6	SEC	CMCR705	Hands on Analytical tools for Pharmaceuticals	4	8							
7	SEC	CMCR706	Hands on Clinical Data Integration & Analysis	4	8							

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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(Allied Health PG Programmes)
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7	SEC	CMCR706	Hands on Clinical Data Integration & Analysis	4	8					
8	SEC	CMCR707	Hands on Clinical Trial Management	4	8					
9	SEC	CMCR708	Hands on Big Data Management	4	8					
10	SEC	CMCR709	Hands on Medical Coding	4	8					
11	SEC	CMCR710	Hands on QC &QA Clinical Trials	4	8					
12	SEC	CMCR711	Hands on Introduction to Healthcare Management	4	8					
13	SEC	CMCR712	Hands on Pharmaceutical Business Development	4	8					
14	SEC	CMCR712	Hands on Health Analytics	4	8					
15	SEC	CMCR713	Hands on QC &QA in Pharmaceutics	4	8					
16	SEC	CMCR714	Hands on Regulatory affairs: Manufacturing (Drugs and Medical devices)	4	8					

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Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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COMPETENCY-BASED CURRICULUM OVERVIEW:

Course Category	Number	COMPETENCY The student should be able to	Domain K/S/A/C	Level K/KH/SH/P	Suggested Teaching Learning Method	Assessment Method	Horizontal Integration
FC		**CMCR 501: Biostatistics**				**Number of Competencies (4)**	
	501.1	Apply basic statistical concepts commonly used in Health and Medical Sciences	K/S	KH/SH	Lecture, DOAP (Demonstrate-Observe-Assist-Perform), Small Group Discussion	Written, Viva voce	Biostatistics
	501.2	Use basic analytical techniques to generate results	K	KH	Lecture, DOAP, Practical Exercises	Written, Viva voce, Assignment	Biostatistics
	501.3	Interpret results of commonly used statistical analyses in written summaries	S	SH	DOAP, Guided Practice, Group Discussion	Written, Viva voce, Skill assessment	Biostatistics
	501.4	Demonstrate statistical reasoning skills correctly and contextually	S	SH	DOAP, Case-Based Learning, Hands-on Data Sessions	Written, Skill assessment, Viva voce	Biostatistics
		CMCR 502 General Biochemistry				**Number of Competencies (3)**	
	502.1	Demonstrate knowledge and understanding of the principles that govern the structures of macromolecules, basic mechanisms of metabolic control and their participation in molecular recognition	K	SH	Lecture, Interactive Discussion, Problem-Based Learning	Written, Viva voce	Biochemistry
	502.2	Use basic laboratory skills and apparatus to obtain reproducible data from biochemical experiments	K/S	KH	Lecture, Seminar, Group Discussion	Written, Viva voce	Biochemistry

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
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	502.3	Analyze, interpret, and report the results of their laboratory experiments	S	SH	DOAP, Laboratory Exercises, Report Writing	Practical Exam, Skill assessment, Viva voce	Biochemistry
FC		**CMCR 503: Molecular Biology; Genetics**				**Number of Competencies (4)**	
	503.1	Discuss the fundamental laws, discoveries, assumptions of genetics and the characteristic features of Nucleic acids & its analysis.	K	KH	Lecture, Interactive Discussion, PBL (Problem-Based Learning	Written, Viva voce	Clinical Research
	503.2	Describe the recent development, scopes and applications of molecular biology and genetics and its role in human society.	K	KH	Lecture, Seminar, Group Discussion	Written, Viva voce	Clinical Research
	503.3	Analyse, interpret, and report the results of their laboratory experiments	S	SH	DOAP, Hands-on Lab Sessions, Report Writing	Practical Exam, Skill Assessment, Viva voce	Clinical Research
	503.4	Discuss applications in genetic engineering, gene therapy, and personalized medicine, explore advancements in genomics, transcriptomics, and proteomics.	K	KH	Lecture, Case-Based Learning, Seminar	Written, Viva voce	Clinical Research
FC		**CMCR 504: Introduction to Clinical Research**				**Number of Competencies (8)**	
	504.1	Describe principles and processes in Clinical Research.	K	KH	Lecture, Case-Based Discussion	Written, Viva voce	Pharmacology
	504.2	Explain the inter and cross-disciplinary nature of investigations in Clinical science, Epidemiology and Pharmacology.	K	KH	Lecture, Interdisciplinary Seminars	Written, Viva voce	Pharmacology
	504.3	Discuss the importance of Clinical Research in developing new techniques for disease diagnosis, new drugs, new surgical methods, new therapeutic approaches including Gene therapy, and, new combinations & devices	K	KH	Seminar, Case-Based Learning	Written, Viva voce	Pharmacology

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Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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	504.4	Gain knowledge of various phases and kinds of clinical trials	S	SH	Lecture, DOAP, Group Activity	Written, Skill Assessment, Viva voce	Pharmacology
	504.5	Understand the code of ethics and regulatory guidelines and also modern biomedicine, i.e., frontline areas of medical biotechnology.	K	KH	Lecture, Discussion, Role-play	Written, Viva voce	Pharmacology
	504.6	Prepare technical document (protocol, ICD, CRF, SOPs) and handling of clinical data	S	SH	Workshop, DOAP, Assignments	Assignment, Skill Assessment, Viva voce	Pharmacology
	504.7	Understand the knowledge of Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices	K	KH	Lecture, DOAP, Group Exercise	Written, Viva voce,	Pharmacology
	504.8	Demonstrate the fundamental concepts of pharmacokinetics (absorption, distribution, metabolism, excretion) and pharmacodynamics (drug-receptor interactions, dose-response relationships).	S	SH	Lecture, Problem-Based Learning, Simulations,	Written, Viva voce	Pharmacology
FC		**CMCR 505 Bio-medical, Bio-analytical Techniques & Instrumentation**				**Number of Competencies (4)**	
	505.1	Understand the knowledge of commonly used techniques e.g., histology, histochemistry, immunohistochemistry (IHC), fluorescent microscopy, cell culture, genetically modified (GM) cells, monoclonal antibodies (MAbs), polymerase chain reaction (PCR), ELISA, RIA, ECLIA	K	KH	Lecture, DOAP, Visual Demonstration	Written, Viva voce	Bioscience
	505.2	Knowledge of the types and principles of analytical techniques like centrifugation, spectroscopy, electrophoresis and chromatographic systems	K	KH	Lecture, Demonstration, Group Discussion	Written, Viva voce	Bioscience

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
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	505.3	Demonstration of Immuno-diagnostic and PCR workstations.	S	SH	DOAP, Hands-on Lab Sessions	Practical Exam, Skill Assessment	Bioscience
	505.4	Describe the applications of Biomedical and Bio-analytical techniques in industry & R&D area in healthcare.	K	KH	Lecture, Case Study, Seminar	Written, Viva voce	Bioscience
FC		**CMCR 506 General Epidemiology**				**Number of Competencies (3)**	
	506.1	Describe the fundamentals of epidemiology.	K	KH	Lecture, Case-Based Learning	Written, Viva voce	Community Medicine
	506.2	Implement the principles of epidemiology to evaluate disease patterns, determinants, and prevalence in populations.	S	SH	DOAP, Field Visits, Group Activities	Skill Assessment, Viva voce, Written	Community Medicine
	506.3	Compare and contrast the different epidemiological study designs and their respective strengths and weaknesses	S	SH	Lecture, Small Group Discussion, Problem-Based Learning	Written, Viva voce	Community Medicine
	CDLa101: Spoken English					**Number of Competencies (3)**	
	101.1	Developing intellectual, personal and professional abilities through effective communicative skills	K	KH	Lecture, Seminar	Written, Viva voce	School of Management Studies
	101.2	Command of English and its linguistic Structures.	S	SH	Lecture, Small Group Discussion, Problem-Based Learning	Skill Assessment, Viva voce, Written	School of Management Studies
	101.3	Critical frameworks to Analyse the linguistic, cultural, and historical background of texts written in English	S	SH	Lecture, Small Group Discussion, Problem-Based Learning	Skill Assessment, Viva voce, Written	School of Management Studies
CC		**CMCR 511: Clinical Trials**				**Number of Competencies (7)**	
	511.1	Discuss new drug discovery and development, history, scope of clinical research & areas, codes of ethics, Clinical Trial Documentation & interpret results.	K	KH	Lecture, Seminar, Case-Based Learning	Written, Viva voce	Clinical Research

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	511.2	Demonstrate ability to choose pharmaceutical clinical trial research designs.	S	SH	DOAP, Workshops, Group Discussion	Skill Assessment, Viva voce	Clinical Research
	511.3	Differentiate phases of Clinical Trials from Phase I to Phase IV & types of clinical trials	K	KH	Lecture, Flowcharts, Simulations	Written, Viva voce	Clinical Research
	511.4	Enumerate clinical studies (Clinical trials) effectively as per ICH GCP, USFADA/DCGI, Schedule Y, National guidelines and international guidelines.	K	KH	Lecture, Regulatory Document Review	Written, Viva voce	Clinical Research
	511.5	Demonstrate ability to perform in various CR professional skills like; Roles & responsibility of stake holders, time management skills, Problem-solving skills, Presentation skills, Interpersonal skills & Communication skills	S	SH	DOAP, Workshops, Group Discussion, Role play	Skill Assessment, Viva voce	Clinical Research
	511.6	Describe the concept of audit and monitoring as per regulatory guidelines USFDA/WHO/DCGI etc.	S	SH	DOAP, Case Studies, Mock Audit Sessions	Viva voce, Skill Assessment	Clinical Research
	511.7	Demonstrate the reporting of ADRs International & Indian context	S	SH	DOAP, ADR Reporting Exercises	Skill Assessment, Practical, Viva voce	Clinical Research
CC		**CMCR 512: Pharmacology**					**Number of Competencies (4)**
	512.1	Explain the process of drug discovery and development	K	KH	Lecture, Case Studies, Guest Lectures	Written, Viva voce	Pharmacology
	512.2	Understand the principles of basic and clinical pharmacology and their application to clinical development	K	KH	Lecture, Practical Sessions, Group Discussions	Written, Viva voce	Pharmacology
	512.3	Understand the principles of animal pharmacology studies and the alternatives to animal experiments	K	KH	Lecture, Case Studies, Ethical Discussions	Written, Viva voce	Pharmacology

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Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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(Allied Health PG Programmes)
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	512.4	Explain the importance of bioinformatics, proteomics and pharmacogenomics in drug discovery and development	K	KH	Lecture, Seminar, Research Review	Written, Viva voce	Pharmacology
CC		**CMCR 513: Immunology**					**Number of Competencies (5)**
	513.1	Explain mechanisms of infection and related immune reactions in body	K	KH	Lecture, Case Studies, Discussion	Written, Viva voce	Himalayan Centre for Entrepreneurship & Innovation
	513.2	Know the basis of producing vaccines, antibodies for use in healthcare	K	KH	Lecture, Laboratory Demonstration	Written, Viva voce	Himalayan Centre for Entrepreneurship & Innovation
	513.3	Understand the use of immunological techniques such as ELISA, Western blot, flow cytometry, and immunohistochemistry.	K	KH	Lecture, DOAP, Hands-on Lab Sessions	Practical Exam, Skill Assessment	Himalayan Centre for Entrepreneurship & Innovation
	513.4	Describe immune responses to organ transplants and graft rejection mechanisms.	K	KH	Lecture, Case Discussions	Written, Viva voce	Himalayan Centre for Entrepreneurship & Innovation
	513.5	Discuss the role of the immune system in cancer and tumor immunotherapy.	K	KH	Lecture, Case Studies, Research Seminars	Written, Viva voce	Himalayan Centre for Entrepreneurship & Innovation
CC		**CMCR 514 Basic and Applied Microbiology**					**Number of Competencies (2)**
	514.1	Describe microbial distribution & diversity, reproduction & growth, role in causing diseases and potential industrial, biopharmaceutical and clinical applications by imparting depth knowledge.	K	KH	Lecture, Case Study, Research Seminars	Written, Viva voce	Microbiology
	514.2	Demonstrate the ability to explore recent advances and techniques used to develop biotech-based applications in the food and beverage industries, biopharmaceutical industries, synthetic biology, and healthcare (e.g.,	S	SH	Lecture, Laboratory Demonstration, Seminar	Written, Viva voce	Microbiology

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Dehradun

Vice Principal
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HIMS, SRHU
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		antibiotics, vaccine development, probiotics, CRISPR-based applications).					
CC		**CMCR 515 IPR; Ethics**				**Number of Competencies (6)**	
	515.1	Highlight the role of patents in pharmaceutical research, their impact on drug pricing, and access to medicines.	K	KH	Lecture, Case Studies, Guest Lectures	Written, Viva voce	IPR Cell
	515.2	Evaluate ethical concerns in patenting biotechnology and life-saving drugs, balancing public health and commercial interests.	K	KH	Lecture, Debate, Group Discussion	Written, Viva voce	IPR Cell
	515.3	Explain technology transfer, licensing, and intellectual property management in research and industry.	K/S	KH/SH	DOAP, Case Studies, Workshops	Practical Exam, Viva voce	IPR Cell
	515.4	Understand autonomy, beneficence, non-maleficence, and justice, along with frameworks like the Belmont Report and Declaration of Helsinki	K	KH	Lecture, Seminar, Case Studies	Written, Viva voce	Clinical Research
	515.5	Highlight the importance of voluntary participation and protecting vulnerable populations.	K	KH	Lecture, Discussion, Research Case Reviews	Written, Viva voce	Clinical Research
	515.6	Identify unethical practices like data falsification and plagiarism and stresses transparency and reproducibility in research.	S	SH	Case Studies, Group Discussion	Practical Assessment, Viva voce	Clinical Research
CC		**CMCR 516 Clinical data management**				**Number of Competencies (3)**	
	516.1	Understanding of quality data management and metrics and best practices for quality data management.	K	KH	Lecture, Case Studies, Workshops	Written, Viva voce	Biostatistics
	516.2	Familiarity with CDM processes, Data collection modalities, electronic data capture, Storage, Retrieval, and validation.	S	SH	DOAP, Practical Sessions	Practical Exam, Viva voce	Biostatistics

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	516.3	Application of data, data preparation and discrepancy management	S	SH	Lecture, Hands-on Practice, Group Discussions	Practical Assessment, Viva voce	Biostatistics
CC		**CMCR 517: Regulatory Physiology**			**Number of Competencies (3)**		
	517.1	Familiarize with various aspects of regulatory physiology & biological body systems.	K	KH	Lecture, Case Studies, Group Discussions	Written, Viva voce	Physiology
	517.2	Understand interaction of organisms with their immediate environment, life sustaining strategies, role of environmental cues & messenger in maintaining the information flow among organism & surroundings	K	KH	Lecture, Research Seminars, Interactive Discussions	Written, Viva voce	Physiology
	517.3	Understand the types of chemical, hormonal messengers, their synthesis in body, diverse modes of actions, applications and neuronal coordination	K/S	SH/SH	DOAP, Laboratory Sessions, Case Studies	Practical Exam, Viva voce	Physiology
CC		**CMCR 518 : Basics of Pharmaceutics**				**Number of Competencies (5)**	
	518.1	Demonstrate basic understanding of preparation, manufacturing, and packaging of pharmaceutical dosage forms.	S	SH	DOAP, Laboratory Sessions, Demonstrations	Practical Exam, Viva voce	School of Pharmaceutical Sciences
	518.2	Explain basic principles of formulation of pharmaceutical dosages with knowledge of their physicochemical properties	K	KH	Lecture, Case Studies, Group Discussions	Written, Viva voce	School of Pharmaceutical Sciences
	518.3	Explain basic steps of converting raw material into finished goods in manufacturing pharmaceutical dosage forms.	K	KH	Lecture, Workshops, Laboratory Demonstrations	Written, Viva voce	School of Pharmaceutical Sciences
	518.4	Describe the evaluation process to ensure quality of dosage forms.	K	KH	Lecture, Lab Work, Case Study	Written, Viva voce	School of Pharmaceutical Sciences

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	518.5	Describe Current Good Manufacturing Practice (cGMP) and its compliance in Pharmaceutical Industry.	K	KH	Lecture, Workshops, Industry Seminars	Written, Viva voce	School of Pharmaceutical Sciences
	CMCR519: Population studies					**Number of Competencies (3)**	
	519.1	Give knowledge of key population issues in India, other developing countries, less developed and developed countries	K	KH	Lecture, Case Studies, Group Discussions	Written, Viva voce	Biostatistics
	519.2	Demonstrate the relationships between population size and available resources; social, biological, and economic influences on population growth rates, fertility decline and population ageing, and population distribution and migration.	S	SH	DOAP, Laboratory Sessions, Demonstrations	Practical Exam, Viva voce	Biostatistics
	519.3	Introduced to the main theories used to understand population and societal change.	K	KH	Lecture, Case Studies, Group Discussions	Written, Viva voce	Biostatistics
CC	**CMCR 601: Biopharmaceuticals & Drug Development**					**Number of Competencies (3)**	
	601.1	Describe Biopharmaceuticals and Drug development process.	K	KH	Lecture, Case Studies, Industry Seminars	Written, Viva voce	Clinical Research
	601.2	Have a thorough knowledge and enforceability of development, research, and production of pharmaceutical products (Demonstration)	K	KH	DOAP, Laboratory Demonstration, Workshops	Practical Exam, Viva voce	Clinical Research
	601.3	Demonstrate the understanding of awareness of and national, international health problems related pharmaceutical biotechnology.	S	SH	Lecture, Research Papers, Group Discussions	Written, Viva voce	Clinical Research
CC		**CMCR 602: Quality control & Quality Assurance in Clinical Research**				**Number of Competencies (3)**	
	602.1	Discuss understanding of importance of Quality Assurance and Quality Control in clinical investigations, translational as well as observational.	K	KH	Lecture, Case Studies, Industry Seminars	Written, Viva voce	Clinical Research

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
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	602.2	Demonstrate the understanding of Cognizance with process of quality data generation, protocol compliance, documentation, monitoring in keeping with GCP guidelines.	S	SH	DOAP, Workshops, GCP Guidelines Review	Practical Exam, Viva voce	Clinical Research
	602.3	Demonstrate the understanding of Regulatory compliances (audits/ inspections etc)	K	SH	Lecture, Regulatory Training, Case Studies	Written, Viva voce	Clinical Research
CC		**CMCR 603: Regulatory Affairs**				**Number of Competencies (3)**	
	603.1	Understand the role of a medical product's regulatory affairs specialist and the dynamic nature of the regulatory field.	K	KH	Lecture, Case Studies, Expert Talks	Written, Viva voce	Clinical Research
	603.2	Learn the laws and regulations that apply to the development, testing and production of medical products, including biologics, drugs, biotechnology-derived therapeutics, vaccines and medical devices.	S	SH	DOAP, Workshops, GCP Guidelines Review	Written, Viva voce	Clinical Research
	603.3	Learn the laws and regulations that apply to the development, testing and production of medical products, including biologics, drugs, biotechnology-derived therapeutics, vaccines and medical devices.	S	SH	DOAP, Workshops, GCP Guidelines Review	S	Clinical Research
CC		**CMCR 604: Introduction to Clinical & Pharmaco-Epidemiology**				**Number of Competencies (9)**	
	604.1	Define patterns, causes and effects of disorder/ disease in patient populations and association with exposures/ treatments and Health outcomes	K	KH	Lecture, Case Studies, Group Discussions	Written, Viva voce	Community Medicine
	604.2	Define patterns and impact of environmental deficiencies e.g., micronutrients on human populations.	K	KH	Lecture, Workshops, Field Observations	Written, Viva voce	Community Medicine

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health/PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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	604.3	Generate statistics of public health issues in local populations and appreciate the importance of Practices,	S	SH	Data Collection, Statistical Analysis, Case Studies	Written, Viva voce, Assignment	Community Medicine
	604.4	Guidelines and Policies in health systems	K	KH	Lecture, Case Studies, Demonstration	Written, Viva voce	Community Medicine
	604.5	Describe disease screening and prevention	K	KH	Literature Review, Meta-Analysis, Group Work	Practical Exam, Report Submission	Community Medicine
	604.6	Gain expertise in systematic review methodology	S	SH	Workshop, Data Analysis, Software Training	Practical Exam, Project	Community Medicine
	604.7	Develop patient-centered registries and data marts within health information systems	S	SH	Lecture, Case Studies,	Written, Viva voce	Community Medicine
	604.8	Appreciate etymology of epidemics nationally and globally	K	KH	Lecture, Case Studies, Group Discussions	Written, Viva voce	Community Medicine
	604.9	Define Pharmacoepidemiology as the bridge science spanning both Pharmacology & Epidemiology	K	KH	Lecture, Workshops, Field Observations	Written, Viva voce	Community Medicine
CC		**CMCR 605: Research Methodology**					**Number of Competencies (6)**
	605.1	Understanding of the importance of research in societal growth and development	K	KH	Lecture, Case Studies, Discussions	Written, Viva voce	Community Medicine
	605.2	Ability to identify original problems for research and develop research designs for problem solving	S	SH	Workshops, Brainstorming Sessions, Problem-Solving Exercises	Written, Viva voce, Project	Community Medicine
	605.3	Familiarity with research methodologies i.e., surveys, sampling, experimental, in clinical investigations	S	SH	Practical Demonstration, Case Studies, Field Work	Practical Exam, Report	Community Medicine

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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	605.4	Understanding of ethical and regulatory issues in scientific research	K	KH	Lecture, Ethical Case Studies, Role Plays	Written, Viva voce	Community Medicine
	605.5	Adequate skill in statistical tools, techniques, and their application to arrive at relevant conclusions	S	SH	Data Analysis Workshops, Statistical Software Training	Practical Exam, Report	Community Medicine
	605.6	Adequate skill in basic software used in data collection, compilation, storage, retrieval, and data analysis.	S	SH	Software Training, Hands-on Exercises	Practical Exam, Assignment	Community Medicine
DSE		**CMCR606: Pharmacovigilance**				**Number of Competencies (6)**	
	606.1	Classify of adverse events / adverse drug reactions.	K/S	KH/SH	Lecture, Case Studies, Group Discussions	Written, Viva voce, Case Analysis	Pharmacology
	606.2	Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval.	K	KH	Lecture, Safety Report Workshops	Written, Viva voce	Pharmacology
	606.3	Describe the various pharmacovigilance methods and PMS methodologies	K	KH	Lecture, Case Studies, Research Papers	Written, Viva voce	Pharmacology
	606.4	Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)	K	KH	Workshop, Safety Report Writing Exercises	Written, Practical Exam	Pharmacology
	606.5	Understand ongoing benefit / risk assessment throughout the life cycle of a medicine.	K	KH	Lecture, Case Studies, Research Articles	Written, Viva voce	Pharmacology
	606.6	Understand the basics of signal detection and management	K	KH	Lecture, Group Discussions, Workshops	Written, Viva voce	Pharmacology
DSE	**CMCR651: Intensive study of a Disease: Etiology, Diagnostics and Therapeutics**					**Number of Competencies (6)**	

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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	651.1	Explain the fundamental causes and pathophysiology of specific diseases.	K/S	KH/SH	Lecture, Case Studies, Research Articles	Written, Viva voce	Pathology/ Microbiology
	651.2	Identify genetic, environmental, infectious, and lifestyle-related factors contributing to disease development.	K/S	KH/SH	Lecture, Discussions, Group Projects	Written, Viva voce	Pathology/ Microbiology
	651.3	Analyze epidemiological data to determine disease prevalence, incidence, and risk factors.	K/S	KH/SH	Data Analysis Workshops, Case Studies	Written, Practical Exam	Pathology/ Microbiology
	651.4	Describe the cellular and molecular mechanisms leading to disease onset and progression.	K	KH	Lecture, Interactive Learning	Written, Viva voce, Lab Reports	Pathology/ Microbiology
	651.5	Understand how biochemical and immunological processes contribute to disease pathology.	K/S	KH/SH	Lecture, Case Studies, Laboratory Exercises	Written, Viva voce	Pathology/ Microbiology
	651.6	Differentiate between acute and chronic disease progression and their systemic effects.	K/S	KH/SH	Lecture, Case Studies, Group Discussions	Written, Viva voce	Pathology/ Microbiology
DSE	**CMCR 652: Pharmacovigilance Elective**						**Number of Competencies (6)**
	652.1	Explain classification of adverse events / adverse drug reactions.	K/S	KH/SH	Lecture, Case Studies, Group Discussions	Written, Viva voce	Pharmacology
	652.2	Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval	K	KH	Lecture, Safety Report Workshops	Written, Viva voce	Pharmacology
	652.3	Describe the various pharmacovigilance methods and PMS methodologies	K	KH	Lecture, Case Studies, Research Papers	Written, Viva voce	Pharmacology
	652.4	Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)	K	KH	Workshop, Safety Report Writing Exercises	Written, Practical Exam	Pharmacology

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University

Vice Principal
(Allied Health & PG Programmes)
HIMS, SRHU
Jolly Grant Dehradun-248016

Himalayan Institute of Medical Sciences
Dean -cum- Principal

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	652.5	Understand ongoing benefit / risk assessment throughout the life-cycle of a medicine.	K	KH	Lecture, Case Studies, Research Articles	Written, Viva voce	Pharmacology
	652.6	Understand the basics of signal detection and management	K/S	KH/SH	Lecture, Group Discussions, Workshops	Written, Viva voce	Pharmacology
DSE	**CMCR653: Medical Writing**					**Number of Competencies (6)**	
	653.1	Define medical writing and its role in healthcare, pharmaceuticals, and research	K	KH	Lecture, Case Studies, Discussions	Written, Viva voce	Clinical Research
	653.2	Differentiate between various types of medical documents (regulatory, scientific, educational, promotional).	K	KH	Lecture, Document Analysis	Written, Viva voce	Clinical Research
	653.3	Write well-structured clinical study reports, research articles, and systematic reviews.	S	SH	Workshop, Writing Exercises, Peer Review	Written Assignment, Practical Exam	Clinical Research
	653.4	Prepare patient information leaflets, drug monographs, and medical communication materials.	K/S	KH/SH	Practical Exercises, Workshops, Group Discussions	Written Assignment, Peer Review	Pharmacology
	653.5	Follow guidelines from regulatory agencies (FDA, EMA, ICH, GPP3) in medical writing	K/S	KH/SH	Lecture, Case Studies, Document Review	Written, Viva voce	Clinical Research
	654.6	Adhere to ethical considerations, including plagiarism, data integrity, and authorship guidelines.	K/S	KH/SH	Lecture, Ethical Case Studies, Discussions	Written, Viva voce	Pharmacology
DSE	**CMCR654: Regulatory Affairs (Manufacturing Drugs and Medical Devices)**					**Number of Competencies (7)**	
	654.1	Understand the role of a medical understand regulatory frameworks	K	KH	Lecture, Case Studies, Discussions	Written, Viva voce	Pharmacology

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Dehradun-248016

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	654.2	Apply Good Manufacturing Practices (GMP)	S	SH	Lecture, Practical Exercises	Written, Practical Exam	Pharmacology
	654.3	Comprehend the drug development and approval process	K	KH	Lecture, Case Studies, Workshops	Written, Viva voce	Pharmacology
	654.4	Evaluate medical device regulations	S	SH	Lecture, Hands on Document Review, Case Studies	Written, Viva voce	Pharmacology
	654.5	Manage regulatory submissions & documentation	K	KH	Practical Exercises, Document Preparation	Written Assignment, Practical Exam	Pharmacology
	654.6	Ensure compliance & risk management	K	KH	Lecture, Risk Management Workshops	Written, Case Study Analysis	Pharmacology
	654.7	Understand ethical, legal & global aspects of regulatory affairs	K	KH	Lecture, Case Studies, Discussions	Written, Viva voce	Pharmacology
DSE	**CMCR655: Analytical tool for Pharmaceuticals**						**Number of Competencies (6)**
	655.1	Understand the role of analytical Tools in the Pharmaceutical Industry	K	KH	Lecture, Case Studies, Demonstration	Written, Viva voce	School of Pharmaceutical Sciences
	655.2	Apply chromatographic and spectroscopic techniques	K/S	KH/SH	Practical Lab, Demonstration	Practical Exam, Written Report	School of Pharmaceutical Sciences
	655.3	Perform drug assay and stability testing	K	KH	Practical Lab, Case Studies	Practical Exam, Written Report	School of Pharmaceutical Sciences
	655.4	Utilize advanced analytical techniques	K	KH	Practical Lab, Workshops	Practical Exam, Report Writing	School of Pharmaceutical Sciences

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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	655.5	Develop problem-solving skills for analytical challenges	K	KH	Workshops, Case-Based Learning	Case Study Analysis, Written Report	School of Pharmaceutical Sciences
	655.6	Ensure regulatory compliance in Pharmaceutical analysis	K/S	KH/SH	Practical Lab, Demonstration	Practical Exam, Written Report	School of Pharmaceutical Sciences
DSE	**CMCR656: Clinical Data Integration and Analysis**					**Number of Competencies (5)**	
	656.1	Apprises students with the various methods & statistical procedures of mining, management, and analysis of clinical studies-based data.	K	KH	Lecture, Case Studies, Practical Lab	Written, Viva voce	Community Medicine/ Biostatistics/ Clinical Research
	656.2	Become conversant in CDM processes, data management and validation plans	S	SH	Lecture, Workshops, Practical Application	Written Test, Case Study	Community Medicine/ Biostatistics/ Clinical Research
	656.3	Use statistical tools and techniques in data management and analysis	S	SH	Practical Lab, Hands-on Exercises	Practical Exam, Report Writing	Community Medicine/ Biostatistics/ Clinical Research
	656.4	Design surveys and develop independent projects	S	SH	Project-Based Learning, Case Studies	Project Report, Presentation	Community Medicine/ Biostatistics/ Clinical Research
	656.5	Application of data, data preparation and discrepancy management	S	SH	Practical Lab, Case Studies	Practical Exam, Written Report	Community Medicine/ Biostatistics/ Clinical Research
DSE	**CMCR657: Clinical Trial Management**					**Number of Competencies (6)**	
	657.1	Learn the process for managing biomedical product development for FDA approval	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Clinical Research/ Clinical Trial Centre
	657.2	Gain an in-depth understanding of the clinical trials process through a modular, operations-focus approach	K	KH	Lecture, Module-Based Learning,	Written Exam, Viva Voce	Clinical Research/ Clinical Trial Centre

Dr. Vikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU

Himalayan Institute of Medical Sciences
Dean
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					Interactive Discussions		
	657.3	Acquire project management skills needed to successfully manage human clinical trials	S	SH	Workshops, Hands-on Training, Simulations	Practical Exam, Project Report	Clinical Research/ Clinical Trial Centre
	657.4	Gain a global perspective on clinical trials management to better respond to the growing industry across the globe	K	KH	Global Case Studies, Webinars, Group Discussions	Written Test, Global Case Analysis	Clinical Research/ Clinical Trial Centre
	657.5	Demonstrate the ethical principles, regulations, and guidelines governing clinical trials, such as ICH-GCP, FDA, EMA, and CDSCO regulations.	S	SH	Lecture, Case Studies, Group Discussions	Written Test, Skill Assessment	Clinical Research/ Clinical Trial Centre
	657.6	Learn from instructors with industry expertise in clinical trials management	S	SH	Guest Lectures, Industry Expert Sessions	Skill Assessment, Group Discussions	Clinical Research/ Clinical Trial Centre
	CMCR658: Big Data Management					**Number of Competencies (6)**	
	658.1	Define big data and its characteristics (Volume, Variety, Velocity, Veracity, and Value – 5Vs).	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	School of Science & Technology / Department of Clinical Research
	658.2	Explain the role of big data in various industries, including healthcare, finance, and e-commerce.	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	School of Science & Technology / Department of Clinical Research
	658.3	Demonstrate knowledge of big data storage solutions such as Hadoop Distributed File System (HDFS) and cloud-based storage.	S	SH	Lecture, Case Studies, Group Discussions	Written Test, Skill Assessment	School of Science & Technology / Department of Clinical Research
	658.4	Implement data processing frameworks like Apache Hadoop, Apache Spark, and NoSQL databases (MongoDB, Cassandra)	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	School of Science & Technology / Department of Clinical Research

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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	658.5	Understand data governance, security, and compliance regulations (GDPR, HIPAA)	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	School of Science & Technology / Department of Clinical Research
	658.6	Implement data quality management and metadata handling techniques.	S	SH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	School of Science & Technology / Department of Clinical Research
	CMCR659: Medical Coding					**Number of Competencies (6)**	
	659.1	Understand the Basics of Medical Coding	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Skill Assessment	Clinical Research
	659.2	Apply Medical Terminology and Anatomy in Coding	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
	659.3	Navigate ICD-10-CM, CPT, and HCPCS Coding Systems	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
	659.4	Ensure Accuracy and Compliance in Coding	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
	659.5	Analyze and abstract medical records for coding	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
	659.6	Understand medical billing and reimbursement processes	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Clinical Research
	659.7	Use medical coding software and tools	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
	CMCR660 Quality Assurance & Quality Control in Clinical Trials					**Number of Competencies (7)**	
	660.1	Understand healthcare systems & policies	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Clinical Research

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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	660.2	Develop leadership & management skills	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Clinical Research
	660.3	Apply financial & economic principles in healthcare	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
	660.4	Address public health & ethical considerations	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Clinical Research
	660.5	Improve healthcare operations & quality management	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Clinical Research
	660.6	Enhance communication & teamwork in healthcare settings	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
	660.7	Utilize health information systems & technology	S	SH	Lecture, Lab activity, Group Discussions	Written Test, Skill Assessment	Clinical Research
DSE	**CMCR661: Introduction to Healthcare Management**					**Number of Competencies (7)**	
	661.1	Understand healthcare systems & policies	K	KH	Lecture, Case Studies, Group Discussions	Written Test, Case Analysis	Hospital Administration/ School of Management Studies
	661.2	Develop leadership & management skills	K	KH	Workshops, Role-Playing, Mentorship	Practical Exam, Leadership Simulation	Hospital Administration/ School of Management Studies
	661.3	Address public health & ethical considerations	S	SH	Ethical Case Studies, Group Discussions, Role-Play	Skill Assessment, Case Analysis	Hospital Administration/ School of Management Studies

Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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	661.4	Apply Financial & Economic Principles in Healthcare	S	SH	Lectures, Case Studies, Problem Solving	Written Test, Case Study Analysis	Hospital Administration/ School of Management Studies
	661.5	Improve Healthcare Operations & Quality Management	S	SH	Workshops, Process Improvement Exercises	Practical Exam, Process Improvement Report	Hospital Administration/ School of Management Studies
	661.6	Enhance Communication & Teamwork Healthcare Settings	S	SH	Group Activities, Team Projects, Role Play	Peer Evaluation, Practical Assessment	Hospital Administration/ School of Management Studies
	661.7	Utilize Health Information Systems &Technology	S	SH	Hands-on Training, Software Demonstrations	Practical Exam, Project Report	Hospital Administration/ School of Management Studies
DSE	**CMCR662: Pharmaceutical Business Development**					**Number of Competencies (6)**	
	662.1	Understand the history and development of the pharmaceutical industry	K	KH	Lecture, Historical Case Studies	Written Test, Historical Analysis	School of Pharmaceutical Sciences / School of Management Studies
	662.2	Introduce the framework of the industry - research, development, Manufacture and distribution of pharmaceutical products on an international level.	K	KH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	School of Pharmaceutical Sciences / School of Management Studies

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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	662.3	Understand the role of Business Development within different types of pharmaceutical companies.	K	KH	Group Discussions, Guest Lectures, Case Studies	Case Study, Written Test	School of Pharmaceutical Sciences / School of Management Studies
	662.4	Understand different types of agreements used in the industry	K	KH	Lectures, Case Studies, Legal Analysis	Written Test, Agreement Analysis	School of Pharmaceutical Sciences/ School of Management Studies
	662.5	Understanding of the basic legal concepts with emphasis on application in a pharmaceutical and biotechnology business development and licensing context.	S	SH	Lectures, Legal Case Studies, Discussions	Case Study, Legal Analysis	School of Pharmaceutical Sciences / School of Management Studies
	662.6	Understanding of the value and limitations of IPRs in encouraging innovation with emphasis on the use and application of IIPRs in a pharmaceutical and biotechnology business development and licensing context.	S	SH	Lectures, Case Studies, Research Projects	Written Test, Case Study	School of Pharmaceutical Sciences / School of Management Studies
DSE	**CMCR663: Health Analytics**					**Number of Competencies (5)**	
	663.1	Collect, clean, and manage healthcare datasets for analysis	S	SH	Lectures, Hands-on Datasets, Case Studies	Practical Assessment, Data Cleaning Exercises	Clinical Research/ Biostatistics/ Pharmacology

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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	663.2	Apply statistical and machine learning methods to healthcare problems	S	SH	Lectures, Workshops, Real-World Problem Solving	Project, Written Test	Clinical Research/ Biostatistics/ Pharmacology
	663.3	Use visualization techniques to communicate insights effectively	S	SH	Workshops, Visualization Tools, Case Studies	Practical Assessment, Report Submission	Clinical Research/ Biostatistics/ Pharmacology
	663.4	Assess the impact of analytics on healthcare decision-making & policy	S	SH	Lectures, Case Studies, Discussions	Case Study Analysis, Written Test	Clinical Research/ Biostatistics/ Pharmacology
	663.5	Understand data security, privacy, and compliance in health analytics	K	KH	Lectures, Case Studies on Security & Privacy	Quiz, Case Study Evaluation	Clinical Research/ Biostatistics/ Pharmacology
	CMCR664: QA and QC in Pharmaceutics					**Number of Competencies (4)**	
	664.1	Understand various aspects of quality control and quality assurance in pharmaceutical industries	K	KH	Lectures, Case Studies, Industry Examples	Written Test, Group Discussions	School of Pharmaceutical Sciences
	664.2	Familiarized with important aspects like cGMP, QC tests,	K	KH	Lectures, Workshops, Regulatory Guidelines Review	Case Study Analysis, Quiz	School of Pharmaceutical Sciences

Dr. Nikku Yadav
Incharge Dept. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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		documentation, quality certifications, GLP, and regulatory affairs					
	664.3	Understand the importance of documentation and responsibilities of QA & QC departments	K	KH	Workshops, Role-playing, Documentation Simulations	Written Report, Role-play Assessment	School of Pharmaceutical Sciences
	664.4	Understand the scope of quality certifications applicable to pharmaceutical industries	K	KH	Lectures, Case Studies on Certification Processes	Multiple Choice Test, Presentation on Certifications	School of Pharmaceutical Sciences
RP	**CMCR650: Research Project**						**Number of Competencies (5)**
	650.1	Get hold of principles and hands on relevant techniques of biomedical research viz disease genesis, diagnostics & amp; management	S	SH	Lab Sessions, Fieldwork, Disease Case Studies	Lab Reports, Practical Exam	All department as per student Choice
	650.2	Be able to prepare technical Document (protocol, informed consent, clinical report form, clinical study report)	S	SH	Workshops, Document Preparation Exercises	Document Submission, Peer Review	All department as per student Choice
	650.3	Be well with wet/dry lab methodologies and field activity	S	SH	Hands-on Lab Practice, Field Research	Lab Practicals, Fieldwork Reports	All department as per student Choice

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun.

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	650.4	Get knowledge for data generation, integration & statistical analysis using SW.	S	SH	Data Analysis Workshops, Software Training (e.g., SPSS)	Data Analysis Assignment, Software-Based Test	All department as per student Choice
	650.5	Be able to design and interpret clinical case study, using medico informatics tools	S	SH	Case Study Design, Informatics Software Training	Case Study Presentation, Interpretation Exam	All department as per student Choice
	CMCR700: Dissertation						**Number of Competencies (10)**
RW	700.1	Identify a research problem, formulate research questions, and define objectives.	S	SH	Brainstorming Sessions, Literature Review	Research Proposal, Objective Validation	All department as per student Choice
	700.2	Develop a research methodology, including experimental design and data collection strategies.	S	SH	Research Design Workshops, Case Studies	Research Methodology Submission	All department as per student Choice
	700.3	Conduct independent research while adhering to ethical and regulatory guidelines.	S	SH	Independent Research Projects, Ethics Workshops	Research Compliance Check, Peer Review	All department as per student Choice
	700.4	Analyze and interpret research findings using statistical tools and methodologies.	S	SH	Data Analysis Exercises, Software Tutorials	Data Analysis Report, Statistical Test	All department as per student Choice
	700.5	Write a well-structured dissertation with all key components.	S	SH	Dissertation Writing Workshops	Dissertation Submission, Peer Review	All department as per student Choice
	700.6	Present research findings through oral presentations, posters, or seminars.	S	SH	Presentation Workshops, Seminar Practice	Oral Presentation, Poster Evaluation	All department as per student Choice

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
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	700.7	Apply research ethics, including plagiarism, data integrity, and responsible conduct.	S	SH	Ethics and Integrity Sessions, Case Discussions	Ethics Test, Research Evaluation	All department as per student Choice
	700.8	Demonstrate problem-solving skills and critical thinking in addressing challenges.	S	SH	Problem-Solving Exercises, Critical Thinking Workshops	Problem-Solving Case Studies, Project Reflection	All department as per student Choice
	700.9	Contribute to scientific knowledge through research publications and innovations.	S	SH	Research Publication Support, Innovation Workshops	Publication Submission, Innovation Demonstration	All department as per student Choice
	700.10	Develop professional competencies such as time management and teamwork.	S	SH	Time Management Workshops, Team Projects	Peer Evaluation, Self-Reflection	All department as per student Choice
GE	**GEST101: Introduction to Artificial Intelligence**						
	101.1	Understand fundamental AI concepts, algorithms, and applications, including search strategies, machine learning, and knowledge representation.	K	KH	Lectures, Case Studies on Certification Processes	Multiple Choice Test, Presentation on Certifications	School of Science & Technology
	101.2	Develop AI-based solutions using programming tools like Python and apply AI techniques in natural language processing, computer vision, and decision-making	S	SH	Hands-on Training, Software Demonstrations	Practical Exam, Project Report	School of Science & Technology
	101.3	Critically evaluate the ethical and societal implications of AI and explore emerging trends shaping its future	K/S	KH/SH	Hands-on Training, Software Demonstrations	Practical Exam, Project Report	School of Science & Technology
GE	**GEMS101: Principles of Management**					**Number of Competencies (5)**	
	101.1	Understand the fundamental principles, functions, and roles of management in organizations.	K	KH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	School of Management Studies

Dr. Ajay Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
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	101.2	Apply planning, organizing, leading, and controlling (POLC) concepts to real-world business scenarios.	K	KH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	School of Management Studies
	101.3	Analyze different management theories and their relevance in modern business environments.	S	SH	Hands-on Training, Software Demonstrations	Practical Exam, Project Report	School of Management Studies
	101.4	Develop decision-making, leadership, and strategic thinking skills for effective management.	S	SH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	School of Management Studies
	101.5	Evaluate ethical, social, and global challenges in management and propose responsible solutions.	K	KH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	School of Management Studies
	GESS101: Gender inequality and gender studies					**Number of Competencies (5)**	
	101.1	Understand key concepts, theories, and frameworks related to gender inequality and gender studies.	K	KH	Lectures, Reports, Case Studies	Written Test, Report Analysis	Humanities
	101.2	Analyze historical and contemporary gender disparities across social, economic, political, and cultural domains.	S	SH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	Humanities
	101.3	Examine the role of institutions, policies, and media in shaping gender norms and identities.	S	SH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	Humanities
	101.4	Critically evaluate intersectionality and the impact of gender on diverse communities, including marginalized groups.	K	KH	Lectures, Reports, Case Studies	Written Test, Report Analysis	Humanities
	101.5	Develop informed perspectives on gender equity and propose strategies for social change and advocacy.	S	SH	Lectures, Industry Reports, Case Studies	Written Test, Report Analysis	Humanities
	GESS102 Mental Health & Wellbeing					**Number of Competencies (5)**	
	102.1	Understand the fundamental concepts of mental health, well-being, and psychological resilience.	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Community Medicine

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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(Allied Health PG Programmes)
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	102.1	Identify common mental health disorders, their causes, symptoms, and available treatment approaches.	S	SH	Lectures, Hands on activity, Case Studies	Written Test, Report Analysis	Community Medicine
	102.3	Analyze the impact of social, cultural, and environmental factors on mental health and well-being.	S	SH	Lectures, Hands on Activity, Reports, Case Studies	Written Test, Report Analysis	Community Medicine
	102.4	Apply stress management, mindfulness, and self-care techniques to promote personal and community well-being	S	SH	Lectures, Hands on Activity, Reports, Case Studies	Written Test, Report Analysis	Community Medicine
	102.5	Evaluate mental health policies, stigma reduction strategies, and the role of mental health advocacy in society.	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Community Medicine
	GEMS102 Innovation, Business Models and Entrepreneurship					**Number of Competencies (5)**	
	102.1	Understand key concepts of innovation, business models, and entrepreneurship in various industries.	K	KH	Lecture, Case Studies, Expert Sessions	Written Test, Case Study Presentation	Himalayan Centre for Entrepreneurship & Innovation
	102.2	Analyze different types of innovation and their role in creating competitive advantages.	S	SH	Lectures, Hands on Activity, Reports, Case Studies	Written Test, Report Analysis	Himalayan Centre for Entrepreneurship & Innovation
	102.3	Develop and evaluate business models using frameworks such as the Business Model Canvas.	S	SH	Lectures, Hands on Activity, Reports, Case Studies	Written Test, Report Analysis	Himalayan Centre for Entrepreneurship & Innovation
	102.4	Identify opportunities, assess risks, and formulate strategies for launching and scaling a startup	K/S	SH/SH	Lectures, Hands on Activity, Reports, Case Studies	Written Test, Report Analysis	Himalayan Centre for Entrepreneurship & Innovation
	102.5	Apply entrepreneurial thinking to solve real-world business challenges and drive sustainable growth	S	SH	Lectures, Hands on Activity, Reports, Case Studies	Written Test, Report Analysis	Himalayan Centre for Entrepreneurship & Innovation

Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
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COURSE CONTENT- FIRST SEMESTER

CMCR501 Biostatistics (4 Cr)

Course Description:

Biostatistics involves the concepts and the application of statistics to analyze biological problems of various domains. the course is designed aiming to understand the basic concepts of experimental design, quantitative analysis of data and statistical inferences. the course strengthens the foundation of students to evaluate data critically to support research objectives or hypothesis. course introduces the various applications of biostatistical methods in the various domain viz., public health, clinical research, genetics, ecology, healthcare, evolution etc.

Course Outcomes:

At the end of the course the learner must demonstrate ability to:

CO1: Apply basic statistical concepts commonly used in Health and Medical Sciences

CO2: Use basic analytical techniques to generate results

CO3: Interpret results of commonly used statistical analyses in written summaries

CO4: Demonstrate statistical reasoning skills correctly and contextually

Course Contents and Structure

UNIT I

Basics of Mathematics and Statistics: Relation of life science with mathematics, set theory, linear function concept, coordinate system, differentiation & integration concept, logarithms, plotting of graphs, matrices.

Introduction to Probability: Random Experiments, Sample Space, Definition and axioms of probability, Addition rule, Conditional Probability, multiplication rule, Bayes theorem and its applications. Random variables, probability mass and density function, Probability Distributions- Binomial, Poisson & Normal distributions.

UNIT II

Introduction to Biostatistics. Role of statistical methods in biomedical research, Variable and Attribut Collection of Data: Primary & Secondary, Data Types: Qualitative and Quantitative, Scales measurement: Nominal, ordinal, Interval, Ratio.

Descriptive Statistics: Measures of Central Tendency- Mean, Median, and Mode. Measures of dispersion- Range, Mean deviation, Standard deviation. Measures of skewness & kurtosis, Graphical Representation

of data- pie chart, bar chart, histogram, whisker-box plot, etc.

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UNIT III

Inferential Statistics: Testing of hypothesis, Null hypothesis, Alternative hypothesis, Type 1 and Type 2 error, Level of significance, Power of test, One tail and two tail tests.

Statistical tests of significance: Testing of normality, parametric and non-parametric tests, chi square test and its application in research, comparison of means of two samples, comparison of means of three or more samples (t test, F test, ANOVA, etc.), Z scores, etc.

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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Correlation and Regression: Concept of bivariate analysis in biomedical research, Scatter plot, Karl Pearson's correlation coefficient, Spearman's rank correlation coefficient, Simple linear regression, Properties of regression coefficients, multiple linear regression, Logistic regression.

UNIT IV

Applied Statistics

Time series analysis; its component- trend, seasonality, cyclic variation, etc.

Statistical Quality control- process and product control, control charts for variables and attributes, single and double sampling plan.

Introduction to hardware, systems, and another related configuration

Introduction to Softwares: Introduction to Computers, data storage device, memory concepts. software and types of software. Elementary idea of disk operating system (DOS), WINDOWS (95, 98). computer applications in biology and information communications (databases, e-mail, and local networks), applications of common packages, google forms, Microsoft Office, PAST.

UNIT V

Introduction to Statistical software's, Microsoft Excel, Word, PowerPoint, Paid and open-source software's, Advantages and disadvantages of software's, SPSS, R, Python, PAST, Epi-Info, N-master software, GraphPad, MedCalc.

Details of laboratory experiments/activities (Tentative)

Following's lab practical/activities are planned (Min. 06)

1. Methods for sampling and data generation
2. Methods for data coding and tabulation
3. Methods for data presentation: Tabular
4. Methods for data presentation: Graphical
5. Hands on exposure [s/w]: MS excel
6. Hands on exposure [s/w]: SPSS
7. Hands on exposure [s/w]: PAST
8. Hands on exposure [s/w]: GraphPad
9. Hands on exposure[s/w] : MedCalc

Teaching Methodology: Direct classroom teaching, discussion, case study, quiz, homework, assignment, project work, video, animation etc.

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Primary (Textbooks)

1. Biostatistics: A Foundation for Analysis in the Health Sciences, (201)11th edition. Wayne W. Daniel, Chad L. Cross Jocelyn e. Krebs, Anchorage Elliott S, Stephen t. Kilpatrick
2. Principles of Biostatistics, Marcello Pagano, Kimberlee Gauvreau, 3rd Edition (2022)
3. Biostatistics for the Biological and Health Sciences, Marc M. Triola, Mario F. Triola, 2nd Edition (2018)

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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(Allied Health PG Programmes)
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Reference Book

1. Fundamentals of Biostatistics, Bernard Rosner, 8th Edition (2015)
2. Essentials of Biostatistics in Public Health, Lisa M. Sullivan, 3rd Edition (2017)

Online: MOOC Course

- http://ocw.mit.edu/courses/biology/7-03-genetics-fall-2004/
- http://ocw.mit.edu/courses/biology/
- http://geneed.nlm.nih.gov
- http://www.yourgenome.org
- http://www.wellcome.ac.uk/en/genome/genesandbody/hg07f006.html

Reference Material (Journals, Hand-outs), Journals

- Current Biology
- Genome Research

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & Critical Thinker	Data Manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Apply basic statistical concepts commonly used in Health and Medical Sciences	3	3	1	1	3	1	2	2
CO2	Use basic analytical techniques to generate results	3	3	2	1	3	3	2	3
CO3	Interpret results of commonly used statistical analyses in written summaries	3	3	3	2	3	3	3	3
CO4	Demonstrate statistical reasoning skills correctly and contextually	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
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CMCR 502 General Biochemistry (3 Cr)

Course Description:

This course imparts sound knowledge on basic principles of biochemistry, emphasizing broad understanding of chemical events in living systems in terms of metabolism and structure-function relationships of biologically important molecules causes disorders.

Course Outcome:

At the end of the course the learner must be able to:

- Understanding of enzymes and their classification
- Demonstrate knowledge and understanding of the principles that govern the structures of macromolecules, basic mechanisms of metabolism
- Use basic analytical techniques to generate results, interpret and report.

Course Contents and Structure

UNIT I

Enzymes: Classification, Zymogens and their activation, enzyme substrate complex: concept of E-S complex, binding sites, active site, specificity, Lock and Key Hypothesis, Induced –Fit Hypothesis.

UNIT II

Carbohydrate: Classification, structure and functions, carbohydrate metabolism: Glycolysis citric acid cycle and its regulation, electron transport chain and oxidative phosphorylation, clinical significance of pentose phosphate pathway, disorders of carbohydrate metabolism

UNIT III

Protein: Classification and structural organization of protein. Functions of plasma protein. Transamination Urea cycle (conversion of ammonia into urea, linkage between urea cycle and citric acid cycle) and its regulation, metabolism and disorders of amino acid metabolism (Glycine, Tyrosine, Tryptophan and Methionine)

UNIT IV

Fatty Acids: Classification of Lipids, fatty acid metabolism- β-oxidation and fatty acid biosynthesis and regulation. Disorders of fatty acid metabolism, cholesterol biosynthesis and regulation, Lipoprotein its functions.

UNIT V

Nucleic Acid: Structure and functions of nucleic acid, Formation of deoxy ribonucleotides. Salvage pathway for purine & pyrimidine in nucleotides, degradation of purines and pyrimidines into uric acid Integration of metabolism. TCA cycle + all cycle merging to it

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
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Details of laboratory experiments (Tentative)

1. Measurement of urea in urine, creatinine , blood glucose.
2. Determination of NH3 in biological sample
3. Electrophoresis separation of blood proteins
4. Determination of HbA1c in clinical lab and interpretation
5. Demonte ration of ELISA and colorimetry
6. Calculation of body Basal metabolic Rate using given Harris-Benedict equation
7. Calculation of respiratory quotient of food types

LEARNING RESOURCE MATERIAL

Textbooks:

1. Lehninger Principles of Biochemistry (2021) 8th Edition: David L. Nelson & Michael M. Cox.

2. Biomolecules (2003): S.R. Mishra

Reference Books

1. Enzymes: a Practical Introduction to Structure, Mechanism and Data Analysis (2002) 2nd Edition: Robert A. Copeland

2. Clinical Biochemistry (2016) 2nd Esdition: Maheshwai Nanda

2. Reference Material (Journals, Hand-outs), Journals:

1. Biomolecules
2. Chem Bio Chem

Laboratory equipment

Colorimeter, pH meter, electronic weighing balance, electrophoresis apparatus, UV/Visible spectrophotometer, LC-MS

Dr. Nikku Yadav
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Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understanding of enzymes and their classification	3	2	2	1	3	2	2	3
CO2	Demonstrate knowledge and understanding of the principles that govern the structures of macromolecules, basic mechanisms of metabolism	3	3	2	1	3	3	2	3
CO3	Use basic analytical techniques to generate results interpret and report.	3	3	3	2	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
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CMCR503 Molecular Biology; Genetics (3 Cr)

Course Description:

This course would provide an understanding of the basics of Mendelian inheritance, Mendel's experiments on inheritance and outcomes, cytogenetics & introduction to molecular biology. Course would enable students to understand molecular basis of the inheritance of traits (central dogma) and different molecular biology techniques.

Course outcome:

At the end of the course the learner mustable to

- Describe the recent development, scopes and applications of molecular biology and genetics and its role in human society.
- Analyse, interpret, and report the results of their laboratory experiments
- Discuss applications in genetic engineering, gene therapy, and personalized medicine; explore advancements in genomics, transcriptomics, and proteomics.

Course Content & Structure

UNIT I

Introduction, definitions, history, scopes, Genetics & Biology, Human Genetics, Mendelian Genetics: Mendel's laws of inheritance, experiments, Traits, Genes, Allele, genotypes. Nature of genetic material: Chromosome, Karyotype, features, Nucleic acids, Basic DNA structure, bases, base-pairing. Chromosome theory of Inheritance: The chromosome theory of heredity, Sex chromosomes.

UNIT II

Population Genetics: Darwin's revolution, Variation, and its modulation. The source of variation, Distribution of Mendelian traits in human populations. Punnet square, Pedigree analysis, Techniques of genetic analysis: Phenotypic traits analysis, Karyotyping, DNA fingerprinting. Introduction to Human Genome Project, Genetic diseases in humans

UNIT III

Patterns of inheritance: Introduction to Inheritance patterns: Autosomal, X-linked & mtDNA linked inheritance, Fine Structure of Genes: The concept of promoter, Coding sequence, Terminator.

UNIT IV

Introduction to Molecular biology: Introduction, building blocks of life, History & discoveries, experiments, Structure, and properties of nucleic acids Models of DNA structure, Types & features; RNA structure, types, features; Methods of DNA isolation. Applications of molecular genetics- Disease diagnosis and Disease inheritability, Vaccine development and Gene therapy and other molecular genetics based therapeutic approaches.

UNIT V

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal (Allied Health PG Programmes) HIMS, SRHU Jolly Grant, Dehradun-248016

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Central Dogma, Molecular basis of inheritance: Models of DNA replication: The replication process; Initiation, Elongation & Termination of replication; Telomeres. Transcription and mRNA processing: Components of transcriptional machinery in prokaryotes and eukaryotes; Initiation, Elongation & Termination of transcription. Translation: The Genetic code. tRNA & enzymes, Ribosomes, Translation process, Initiation, Elongation & termination

Details of laboratory experiments (Tentative)

1. Isolation of genetic material
2. Demonstration of DNA amplification by PCR
3. DNA analysis by agarose gel electrophoresis
4. Meiotic chromosome preparation from animal tissue (Grasshopper testis)
5. Isolation of salivary gland from drosophila larvae
6. Distribution of human traits in a group or population to study the basis of human inheritance (Pedigree analysis)
7. Calculation of the probability of genotypes in monohybrid & dihybrid crosses using the Punnett Square method, manually as well as by e-resources
8. SNP database generation using human genome analysis based on bioinformatics genomics tools
9. Karyotyping using dry lab method

Primary(Textbooks)

- Brooker RJ. Genetics: Analysis and Principles. 7th ed. New York: McGraw-Hill; 2023.
- Krebs JE, Goldstein ES, Kilpatrick ST. Lewin's Genes XII. 12th ed. Burlington: Jones & Bartlett Learning; 2020.
- Cox MM, Doudna J, O'Donnell M. Molecular Biology: Principles and Practice. 3rd ed. New York: W.H. Freeman; 2015.

Reference Book

- Allison L. Fundamental Molecular Biology. 3rd ed. Hoboken: Wiley; 2021.
- Cooper GM, Hausman RE. The Cell: A Molecular Approach. 8th ed. Sunderland: Sinauer Associates; 2022.

- **Reference Material (Journals, Hand-outs), Journals**
- Nature Genetics
- Genetics
- American Journal of Human Genetics (AJHG)
- Genome Research, PLoS Genetic

Dr. Nikka Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
Dean -cum- Principal

Vice Principal (Allied Health PG Programmes)
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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Describe the recent development, scopes and applications of molecular biology and genetics and its role in human society.	3	2	2	1	3	2	2	3
CO2	Analyse, interpret, and report the results of their laboratory experiments	3	2	2	2	3	2	3	3
CO3	Discuss applications in genetic engineering, gene therapy, and personalized medicine; explore advancements in genomics, transcriptomics, and proteomics.	3	3	3	2	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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CMCR504 Introduction to Clinical Research (4 Cr)

Course Description:

This course provides insight on fundamentals of clinical research and its basic study designs in varied health and biomedical/biotechnical settings. The course acquaints students with the process of new drug discovery, pharmacology, medical devices, diagnostics, pharmacovigilance, medical writing, regulatory affairs, clinical trial and healthcare management.

Course Outcome: After successful completion of this course, students should be able to

- Describe principles and processes in Clinical Research.
- Explain the inter and cross-disciplinary nature of investigations in Clinical science, Epidemiology and Pharmacology.
- Discuss the importance of Clinical Research in developing new techniques for disease diagnosis, new drugs, new surgical methods, new therapeutic approaches including Gene therapy, and, new combinations & devices
- Gain knowledge of various phases and kinds of clinical trials,
- Understand the code of ethics and regulatory guidelines and also modern biomedicine, i.e., frontline areas of medical biotechnology.
- Prepare technical document (protocol, ICD, CRF, SOPs) and handling of clinical data
- Understand the knowledge of Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices
- Demonstrate the fundamental concepts of pharmacokinetics (absorption, distribution, metabolism, excretion) and pharmacodynamics (drug-receptor interactions, dose-response relationships).

Course Structure and Contents

Unit I

Ancient medicine to Modern Medicine System: Introduction to various system of medicine viz; Ayurveda, Unani, Homeopathic, Siddha, Acupuncture, Chinese system of medicine, Allopathy and their pros and cons, current scenario of clinical research in India, new career opportunities in clinical research & scope in India.

Unit II

Introduction to Pharmacology: Drugs & classification system, receptors, mechanism of action, drug-receptor interaction, dosage forms, route of drug administration.

Pharmacokinetics: Membrane Transport, Absorption and Distribution of Drugs, Metabolism and Excretion of Drugs, Kinetics of Elimination

Unit III

Pillars of Clinical Research: Role of clinical research in drug discovery & development, historical case studies, clinical trials: types, phases, design of clinical research studies, clinical trial design, clinical data management, Pharmacovigilance, medical writing and coding etc.

Unit IV

Ethical Guideline in Clinical Research: Nuremberg code, Declaration of Helsinki, Belmont report, Guidelines for Good Clinical Practice ICH, ICMR, Institutional Review Board /Independent Ethics Committee, Key players of clinical research viz., Regulators, Sponsor, Investigator, CRO, SMO etc

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Himalayan Institute of Medical Sciences
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Unit V

Clinical Trial Process: Clinical trial protocol and amendment(s), project management, informed consent, case report form, investigator's brochure (IB), selection of an investigator and site, monitoring visits, project auditing, inspection, fraud and misconduct of clinical research.

Details of laboratory experiments

1. Real life case studies on different diseases, allotted to physician/ hospitals.
2. Placebo effect of drug substance on blood pressure
3. To calculate BMI and interpret as per WHO classification
4. Measurement of pulse rate and blood pressure at pre and post exercise condition using electronic sphygmomanometer
5. Estimation of glucose & protein in urine sample
6. To understand importance of measuring blood glucose levels and learn the basics of enzymatic estimation of glucose
7. To calculate human pharmaceutical dose from given animal dose using software
   To what blood group do we belong
9. To isolate serum sample from whole blood for antigen and antibody detection.
10. Qualitative estimation of antigen-antibody interaction by dot ELISA
11. Estimation of liver enzymes AST (SGOT) and ALT (SGPT) in blood samples
12. Study of drug efficacy and genetic polymorphisms by Insilco data mining Demonstration of various blood withdrawal techniques

Equipment's:

Autoanalyzer, U V Spectrophotometer, Computers, sphygmomanometer, Internet, Software, Physiological examination tools

LEARNING RESOURCE MATERIAL

Prescribed Texts:

- Fundamental of Clinical Trials- Lawrence M. Friedman
- Clinical Trials: A Practical Guide to Design, Analysis, and Reporting
- Introduction to Clinical Pharmacology- Edmunds
- Essentials of Medical Pharmacology 9th edition (2024)- KD Tripathi

Reference Books:

- Drug Safety: From Molecule To Man- Park
- Drugs: From Discovery To Approval - NG

Internet Reference:

- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

Reference Material (Journals, Handout)

- Contemporary Clinical Trials
- Clinical Trials: Journal of the Society for Clinical Trials
- Clinical Endocrinology
- Journal of Ayurveda and Integrative Medicine

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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SWAMI RAMA HIMALAYAN UNIVERSITY

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Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Describe principles and processes in Clinical Research.	3	2	3	2	3	3	3	3
CO2	Explain the inter and cross-disciplinary nature of investigations in Clinical science, Epidemiology and Pharmacology.	3	2	3	2	3	3	3	3
CO3	Discuss the importance of Clinical Research in developing new techniques for disease diagnosis, new drugs, new surgical methods, new therapeutic approaches including Gene therapy, and, new combinations & devices	3	2	3	2	3	3	3	3
CO4	Gain knowledge of various phases and kinds of clinical trials,	3	3	3	2	3	3	3	3
CO5	Understand the code of ethics and regulatory guidelines and modern biomedicine, i.e., frontline areas of medical biotechnology.	3	2	3	3	3	3	3	3
CO6	Prepare technical document (protocol, ICD, CRF, SOPs) and handling of clinical data	3	3	3	2	3	3	3	3

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Doiwala, Grant, Dehradun-248016

Dr. Neeraj Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
Dean
-cum-
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CO7	Understand the knowledge of Good Clinical Practices, Good Laboratory Practices, Good Manufacturing Practices	3	3	3	2	3	3	3	3
CO8	Demonstrate the fundamental concepts of pharmacokinetics (absorption, distribution, metabolism, excretion) and pharmacodynamics (drug-receptor interactions, dose-response relationships).	3	3	3	2	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
...d Health PG Programmes)
HIMS, SRHU
...ll, Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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CMCR505 Bio analytical Techniques (3 Cr)

Course Description:

This course is intended to provide students with an overview of the general principles under lying various types of instruments & analytical techniques along with their application in biotechnology& allied sciences. The broad topics include introduction to the principle sand applications of classical & contemporary analytical techniques like centrifugation, microscopy, spectroscopy, electrophoresis and chromatography used extensively in industry &R&D area are dealt theoretically, and experiments are designed to give opportunity to students to experience application of theory to practical knowledge.

Course Outcomes

At the end of the course the learner must demonstrate

- Understand the knowledge of commonly used techniques e.g., histology, histochemistry, immunohistochemistry (IHC), fluorescent microscopy, cell culture, genetically modified (GM) cells, monoclonal antibodies (MAbs), polymerase chain reaction (PCR), ELISA, RIA, ECLIA
- Knowledge of the types and principles of analytical techniques like centrifugation, spectroscopy, electrophoresis, and chromatographic systems
- Demonstration of Immuno-diagnostic and PCR workstations.
- Describe the applications of Biomedical and Bio-analytical techniques in industry & R&D area in healthcare.

Course Contents and Structure

UNIT I

Microscopy (Principles and applications): Principle and application of: Light, phase contrast microscopy, and confocal microscopy, Scanning and transmission electron microscopy; Biosensors: Introduction and principles, Cell based biosensors, Enzyme immunosensors, DNA biosensor.

UNIT II

Centrifugation: Basic principle and applications of centrifugation; Centrifugal force; Sedimentation rate; Sedimentation coefficient; Common centrifuges used in laboratory, Types of rotors, Types of centrifugations (Principle and applications): Preparative (Differential and density gradient centrifugation) and analytical centrifugation. Ultracentrifugation

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UNIT III

Chromatography: General principle and applications of chromatography; Types of chromatography (Principles and applications): Adsorption chromatography, Ion exchange chromatography, Affinity chromatography, Size exclusion chromatography, thin layer chromatography, Gas chromatography,

Dr. Nikku Yadav
Incharge Dept. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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High pressure liquid chromatography (HPLC), Fast protein liquid chromatography, Supercritical fluid chromatography.

UNIT IV

Electrophoretic Techniques: General principle and applications of electrophoresis; Types of electrophoresis (Principles and applications): Paper electrophoresis, moving boundary electrophoresis, Isotachophoresis, Agarose gel electrophoresis, Polyacrylamide gel electrophoresis (SDS-PAGE, Native-PAGE, Denaturing-PAGE and Reducing-PAGE), Isoelectric focusing (IEF), 2-D PAGE, Pulse field gel electrophoresis (PFGE), Disc gel electrophoresis

UNIT V

Spectroscopy and Radiotracer Techniques: Spectroscopic methods (principle and applications): UV, Visible, IR, NMR, Fluorescence, ESR, Atomic absorption, CD, ORD and Raman Spectroscopy; ELISA: Types and application; Radiotracer techniques: Applications of radioisotopes in biology, Properties and units of radioactivity, Radioactive isotopes and half-life, Safety rules in handling of radioisotopes, Measurement of radioactivity, Autoradiography: Principle and its applications. Radioactive waste management.

Textbooks:

1. Techniques in Microscopy and Cell Biology (2016) Kindle edition :Sharma VK Tata McGraw Hill
2. Molecular biology of the cell (2018) 6th Edition: Alberts et al

Reference Book

1.Biochemical Technique: Theory & Practical (2015) 5th Edition: J.F. Robyt& B.J. White
2. Manual of Industrial Microbic. & Biotech (2017) 2nd Edition: Arnold L. Domain & Julian E. Davies

E-Resources

1. Journal of analytical & bioanalytical techniques
2. Science

Hands on Activities (Tentative)

1.Verification of Beer's law
2 Determination of absorption maxima
3 Electrophoresis of proteins-native and under denaturing conditions.
4 Amino acid and carbohydrate separations by paper & thin layer chromatography
5 Gas chromatography
6 Ion exchange and gel filtration chromatography
7 Separation of blood cells by density gradient centrifugation

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Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the knowledge of commonly used techniques (e.g., histology, IHC, microscopy, cell culture, GM cells, MAbs, PCR, ELISA, RIA, ECLIA).	3	2	3	1	3	3	2	3
CO2	Knowledge of the types and principles of analytical techniques like centrifugation, spectroscopy, electrophoresis, and chromatographic systems.	3	3	3	1	3	3	2	3
CO3	Demonstration of Immuno-diagnostic and PCR workstations.	3	3	3	2	3	3	3	3
CO4	Describe the applications of Biomedical and Bio-analytical techniques in industry & R&D areas in healthcare.	3	3	3	2	3	3	3	3

Vice Principal
Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
Dean
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CMCR 506 General Epidemiology (3 Cr)

Course Description

This course will help the student appreciate the fundamentals and techniques of epidemiology. The students shall learn about different health determinants, natural history of a disease, its prevention, and intervention. This course will also cover the basics of designing epidemiological studies and associated study defects. They will learn how to critically evaluate real-world public health scenarios through case studies to develop their critical appraisal skills. This course analyses important concepts for the description and interpretation of phenomena of morbidity as well as the application of epidemiology in medicine and research.

Course Outcomes

At the end of the course the student is expected to:

- Describe the fundamentals of epidemiology.
- Implement the principles of epidemiology to evaluate disease patterns, determinants, and prevalence in populations.
- Compare and contrast the different epidemiological study designs and their respective strengths and weaknesses.

Course Content and Structure

UNIT 1: Introduction to Epidemiology health, wellbeing, and disease, Definition, scope, aims and components of epidemiology, prevalence and incidence of diseases, determinants of health. Epidemiology vs clinical medicine,

UNIT 2: Fundamentals of Epidemiology: Cause and effect, causal inference, causation, association and correlation, Level of evidence in epidemiological studies, design considerations, timeline in epidemiological studies, historical epidemiological studies including John Snow and Cholera.

UNIT 3: Observational Studies: Study designs, strengths, limitations and biases in case reports, case series, ecological studies, cross sectional studies, case control studies and cohort studies, data collection and measurement tools in studies.

UNIT 4: Experimental studies: Study designs, strengths, limitations and biases in Clinical Trials, Community Trials, Other forms of experimental research, data collection and measurement tools in studies.

UNIT 5: Applied Epidemiology and Case Studies: disease frequency measures: Incidence, prevalence, and mortality rates, measures of association: Risk ratios, odds ratios, Case studies of major epidemiological investigations

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LEARNING RESOURCE MATERIAL

Text books

- Park, K. (2025) Parks Textbook of Preventive and Social Medicine. 28th Edition, M/S Banarsidas Bhanot Publishers, Jabalpur.
- Rajvir Bhalwar (2023). Textbook of Community Medicine. Wolters kluwer India Pvt Ltd.

Dr. Vikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean -cum- Principal

Reference Books

- Rashmi Kundapur, Maroof Amir Khan, Kakkar, R., Sheth, A. and Nidhi Mangrola (2024). Textbook of Community Medicine. Jaypee Brothers Medical Publishers Pvt Limited.
- Bonita, R., Beaglehole, R. and Kjellström, T. (2006). Basic Epidemiology. 2nd ed. Geneva World Health Organization.
- Gordis, L. (2014). Epidemiology. 5th ed. Philadelphia, PA: Elsevier/Saunders.

E Resources

- CDC PUBLIC HEALTH 101 SERIES. https://www.cdc.gov/training-publichealth101/php/training/introduction-to-epidemiology.html
- BMJ resources https://www.bmj.com/about-bmj/resources-readers/publications/epidemiology-uninitiated/1-what-epidemiology#chapters

Journals, Handout

Nature, Science, journal of public health, Journal of Epidemiology, American Journal of Epidemiology

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Describe the fundamentals of epidemiology.	3	3	3	1	2	3	2	3
CO2	Implement the principles of epidemiology to evaluate disease patterns, determinants, and prevalence in populations.	3	3	3	1	2	3	3	3
CO3	Compare and contrast the different epidemiological study designs and their respective strengths and weaknesses.	3	3	3	1	2	3	2	3

Vice Principal
(Allied Health PG Programmes)
HIHER, SRHU
Jolly Grant, Dehradun-248016

Dr. Vikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

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CDLa101 Spoken English (3Cr)

Course Description

This course aims to enhance students' ability to communicate effectively in English, focusing on developing fluency, pronunciation, and vocabulary. Through interactive and practical activities, students will gain confidence in everyday conversations, academic discussions, and professional communication.

Course Objectives

- Developing intellectual, personal, and professional abilities through effective communicative skills
- Command of English and its linguistic Structures.
- Critical frameworks to analyse the linguistic, cultural, and historical background of texts written in English

Introduction to Communication: - **Types of communication –** Written and oral, verbal and non-verbal (spoken and written) – internal and external, formal & informal, barriers and strategies - intrapersonal, interpersonal and group communication.

Pronunciation and Accent Neutralization: Common pronunciation challenges, Introduction to Phonetics, Phonetic Transcription, Stress, intonation, and rhythm in English.

Building Fluency: - Vocabulary Development- Synonyms, Antonyms, One-word substitutions, Homophones, word formation with prefixes and suffixes. Remedial Grammar, Sentence formation and error correction.

Listening and Responding: -Active listening techniques, listening exercises: TED Talks, interviews, and conversations, Responding appropriately to questions and comments.

Advanced Speaking Skills: Expressing agreement, disagreement, and elaboration, Group Discussions, Debates, Public Speaking, Presentation Skills, Speaking in seminars and academic settings.

LEARNING MATERIAL:

Primary Textbooks

- English for Everyone: Level 1, 2, 3 & 4 (Course Book & Practice Book), DK (Dorling Kindersley), Updated Edition (2022)
- Perfect Spoken English: Tips & Techniques, Lena Goldfinch, 1st Edition (2023)
- The Quick and Easy Way to Effective Speaking, Dale Carnegie, Updated Edition (2022)

Reference books:

- Advanced English Conversation Dialogues, Jackie Bolen, 1st Edition (2021)
- English Conversation Practice, Grant Taylor, 1st Edition (2022)
- Speak English Like a Pro: Learn to Speak English Fluently, Sherry Collin, 1st Edition (2023)

Reference Material (Journals, Hand-outs)-

Journals-

- Healthcare analytics
- Health care analysis
- International Journal of Big Data and Analytics in Healthcare (IJBDAH)
- International Journal of Applied Health Care Analytics
- Journal of Healthcare Informatics Research

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SWAMI RAMA HIMALAYAN UNIVERSITY

Himalayan Institute of Medical Sciences
Dean -cum- Principal

Dr. Vinod Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health & PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Developing intellectual, personal, and professional abilities through effective communicative skills	3	2	2	3	2	2	2	2
CO2	Command of English and its linguistic Structures	3	2	2	3	2	1	1	1
CO3	Improve pronunciation and clarity in speech.	3	1	2	3	2	1	1	1

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
Allied Health PG Programmes
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Course Content- Second Semester

CMCR511 Clinical Trials (4 Cr)

Course Description:

The course describes the process of drug discovery, which involves the identification of candidates, synthesis, characterization, screening, and assays for therapeutic efficacy. The course with the introduction and progress through drug discovery acquaints students to the process of clinical trials which forms next step after drug discovery. Makes student aware of the regulatory affairs and regulatory bodies associated with the whole process of introducing the drug in the market.

Course Outcome:

- At the end of the course the learner must:
- Discuss new drug discovery and development, history, scope of clinical research & areas, codes of ethics, Clinical Trial Documentation & interpret results.
- Demonstrate ability to choose pharmaceutical clinical trial research designs.
- Differtiate phases of Clinical Trials from Phase I to Phase IV & types of clinical trials
- Enumerate clinical studies (Clinical trials) effectively as per ICH GCP, USFADA/DCGI, National guidelines and international guidelines.
- Demonstrate ability to perform in various CR professional skills like; Roles & responsibility of stake holders, time management skills, Problem-solving skills, Presentation skills, Interpersonal skills & Communication skills
- Describe the concept of audit and monitoring as per regulatory guidelines USFDA/WHO/DCGI etc
- Demonstrate the reporting of ADRs International & Indian context

COURSE STRUCTURE AND CONTENTS

Unit 1: Introduction to Clinical Research & Health Care Industry, Drug Discovery & Development; Historical Case Studies,, Clinical Trial Design, Codes of Ethics, Role Of Statistics, Area of Clinical Research: Clinical Trials, Clinical Data Management, Bioequivalence & Bioavailability, Quality Assurance, Medical Writing, Pharmacovigilance

Unit 2: Clinical Trial: Design, analysis & management, clinical trial documents, study design-randomized controlled studies, historical controls, crossover designs, nested designs, factorial designs, group allocation design, hybrid designs, designs with repeated measures, randomization & blinding, clinical data analysis & interpretation; multicentred trial and publication, academic trails

Unit 3: Roles & Responsibilities Of Clinical Trial Personnel: investigator, sponsors, regulatory authority, Clinical Research Coordinator (CRC), Clinical Research Associate (CRA), principal investigator, co-pi, sub-pi, medical officer/writer, technicians, research pharmacist, statistician, regulatory manager, monitor/auditor, data manager, scientific writer/publisher

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Unit 4: Fundamentals of Monitoring & Auditing, Inspections: CRO Sponsor End & Hospitals USFDA, Regulatory Authority in India (DCGI & CDSCO), Schedule Y, ICH guidelines, Old CT Rule and New CT Rule 2019. Regulations Governing Clinical Trials • Clinical Research regulations in India – CDSCO guidelines, ICMR guidelines • Clinical trial application requirements in India- IND, ANDA, AADA and

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
Dean cum Principal

NDA. • USFDA regulations to conduct drug studies • Clinical Research regulations in UK – Medicines and Healthcare Products Regulatory Agency (MHRA) • Clinical Research regulations in Europe (EMEA), SUGAM and NAITIK portal, Difference between E6(R2) and E6(R3) guidelines.

Unit 5: Clinical safety & Pharmacovigilance: Objectives & importance, AE, ADR, SAE, UADR, Post Marketing Surveillance; ADR Recording & Reporting National & International, Pharmacovigilance: international procedures; pharmacovigilance in the Indian context. PSUR, SUSAR& ICH guidelines. Case studies of drugs withdrawn due to Pharmacovigilance, identification of necessary skills & attributes of the clinical research professional

Details of laboratory experiments

- Real life case studies on different diseases, allotted to physician/ hospitals.
- Intensive writing work-

  SOP designing, Protocol writing, Clinical Study report including synopsis, CRF Designing, ICD designing, SMPc , Package Insert, ADR/ AE reporting, Narrative writing, Medical coding

LEARNING RESOURCE MATERIAL

Prescribed Texts:

- Fundamental of Clinical Trials (2019) 5th Edition- Lawrence M. Friedman
- **"A Concise Guide to Clinical Trials"** by Allan Hackshaw (First Edition, 2024).
- **"Clinical Trials"** edited by Timothy M. Pawlik and Julie A. Sosa (First Edition, 2020).

Reference Books:

- Drug Safety From Molecule To Man (2017) 8th Edition - Park
- "Fundamentals of Clinical Trials" by John I. Gallin, Frederick P. Ognibene, and Laura Lee Johnson (Fifth Edition, 2020).
- Clinical Trials A Practical Guide to Design, Analysis, and Reporting (2018) Kindle edition: Duolao Wang,

Internet Reference:

- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

Reference Material (Journals, Handout)

- Contemporary Clinical Trials
- Clinical Trials: Journal of the Society for Clinical Trials
- Journal of Ayurveda and Integrative Medicine

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Discuss new drug discovery and development, history, scope of clinical research & areas, codes of ethics, Clinical Trial Documentation & interpret results.	3	2	3	2	3	3	3	3
CO2	Demonstrate ability to choose pharmaceutical clinical trial research designs.	3	3	3	2	3	3	3	3
CO3	Differentiate phases of Clinical Trials from Phase I to Phase IV & types of clinical trials	3	3	3	2	3	3	3	3
CO4	Enumerate clinical studies (Clinical trials) effectively as per ICH GCP, USFADA/DCGI, National guidelines and international guidelines.	3	3	3	2	3	3	3	3
CO5	Demonstrate ability to perform in various CR professional skills like; Roles & responsibility of stake holders, time management skills,	2	3	3	3	3	3	3	2

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Ajikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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	Problem-solving skills, Presentation skills, Interpersonal skills & Communication skills								
CO6	Describe the concept of audit and monitoring as per regulatory guidelines USFDA/WHO/DCGI etc.	3	2	3	3	3	2	2	2
CO7	Demonstrate the reporting of ADRs International & Indian context	3	3	3	2	3	3	3	3

Vice Principal
Health Pr Programmes;
HIMS, SRHU
Jolli, Ekant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
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CMCR512 Systems Pharmacology; Pre-Clinical Drug Development & Safety (4 Cr)

Course Description:

This course provides a basic knowledge of pre-clinical pharmacologic and toxicological drug responses with respect to dose regimen and route of administration enable to initiate and continue research in human beings. It apprises about how pre-clinical studies are performed to predict the safety and efficacy data from the animal models which support the conduct of research in human beings.

Course Outcomes:

At the end of the course the learner must demonstrate

- Explain the process of drug discovery and development
- Understand the principles of basic and clinical pharmacology and their application to clinical development
- Understand the principles of animal pharmacology studies and the alternatives to animal experiments
- Explain the importance of bioinformatics, proteomics and pharmacogenomics in drug discovery and development
- Describes the principles and methods of calculation of first in human dose

Course Content and Structure

Unit I

Drug Discovery: Historical aspects, pre-clinical to clinical development-general introduction of clinical trials– recent advances, combinatorial chemistry, and high throughput screening.

Unit II

Systems Pharmacology: Fundamentals of pharmacokinetics and pharmacodynamics Classification of Drugs acting on various systems- Autonomic Nervous System, Cardiovascular System, Central Nervous System, Respiratory System, Endocrine system, Gastrointestinal System

Unit III

Animal Pharmacology: Animals used in research; Alternatives to animal experiments: *In vivo* method, *In vitro* methods, invitro methods in clinical safety assessment, comparison of *in vitro* and *in vivo* methods, *ex-vivo* studies, advantages-application of *in silico* in clinical research.

Unit IV

Toxicology: Acute, sub-acuteandchronictoxicity,mutagenicity,teratogenicity,oncogenicity and effects on fertility, special toxic city studies– purpose; general principles- carcinogenicity-teratogenicity-effectsonfertilityandreproduction

Unit V

Bioinformatics& Calculation of First Human Dose: Overview of bioinformatics in drug discovery and development, Proteomics, application of proteomics in clinical trials, application of

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Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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pharmacogenomics and pharmacogenetics in therapeutics, NOAEL-High risk medicinal products-MABEL assessment of preclinical data for safety and efficacy

Details of laboratory experiments (Tentative)

1. Pharmacokinetic and pharmacodynamic evaluation (Dry lab)
2. Preparation of Pharmaceutical solutions, Emulsions, Suspensions (Dry lab)
3. Bioassays and screening methods of important diseases (CAL/dry lab)

LEARNINGRESOURCEMATERIAL Primary (Textbooks):

Prescribed Texts:

• "Katzung's Basic & Clinical Pharmacology" by Bertram G. Katzung, Anthony J. Trevor, and Susan B. Masters (16th Edition, published in 2020).
• "Pharmacology: A Patient-Centered Nursing Process Approach" by Joyce LeFever Kee, Evelyn R. Hayes, and Linda E. McCuistion (11th Edition, published in 2021).
• "Pharmacology: An Introduction" by Henry Hitner and Barbara Nagle (7th Edition, published in 2020).

Reference Books:

• Drug Safety From Molecule To Man (2017) 8th Edition - Park
• "Goodman & Gilman's: The Pharmacological Basis of Therapeutics" by Laurence L. Brunton, Randa Hilal-Dandan, and Bjorn C. Knollmann (13th Edition, published in 2017).

Internet Reference:

• www.trialscentral.org/
• www.fda.gov/oc/gcp/
• www.who.int
• www.sciencedirect.com

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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Health PG Programmes
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Dehradun-248016

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Explain the process of drug discovery and development	3	2	3	2	3	3	3	3
CO2	Understand the principles of basic and clinical pharmacology and their application to clinical development	3	3	3	2	3	3	3	3
CO3	Understand the principles of animal pharmacology studies and the alternatives to animal experiments	3	2	3	1	3	3	2	3
CO4	Explain the importance of bioinformatics, proteomics and pharmacogenomics in drug discovery and development	3	2	3	2	3	3	3	3
CO5	Describes the principles and methods of calculation of first in human dose	3	3	3	2	3	3	3	3

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences Dean -cum- Principal

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CMCR513 Basic & Applied Immunology (4 Cr)

Course Description:

It is a trans-departmental, multidisciplinary, translational program. Its objective is to educate in order to elucidate and the immunological mechanisms that regulate homeostasis in health and underlie the physiopathology of diseases.

Course outcomes:

- Explain mechanisms of infection and related immune reactions in body
- Know the basis of producing vaccines, antibodies for use in healthcare
- Understand the use of immunological techniques such as ELISA, Western blot, flow cytometry, and immunohistochemistry.
- Describe immune responses to organ transplants and graft rejection mechanisms.
- Discuss the role of the immune system in cancer and tumor immunotherapy.

Course Structure and Contents

UNIT I

Introduction to immune system – innate and acquired immunity, memory response. Structure and functions of primary and secondary lymphoid organs, Cells, organs and microenvironment of the immune system.

Hematopoiesis and cells of immune system. Primary lymphoid organs, secondary lymphoid organs. Lymphoid cells (b-lymphocytes, t-lymphocytes and null cells), mononuclear cells (phagocytic cells and their killing mechanisms), granulocytic cells (neutrophils, eosinophils and basophils), mast cells and dendritic cell. Dysfunctional immune response. Understanding the mammalian immune system and its advancements.

UNIT II

Recognition and response in immune system. Nature of antigen and antibody, classification, fine structure and functions of immunoglobulins, antigenic determinants on immunoglobulins, isotypic, allotype and idiotypic variants, generation of diversity in immune system – clonal selection theory - concept of antigen specific receptor. Complement system. Cytokines, basics of cell signaling in immune system. The outcome of immune system response. The expression of immune receptor genes. B cell receptor expression, T cell receptor expression.

UNIT III

Immune effector mechanisms – kinetics of primary and secondary immune responses, cytokines and co-stimulatory molecules: role in immune responses, Major histocompatibility complex (MHC) and antigen presentation. The structure and function of MHC class I and MHC Class II molecules. The endogenous and exogenous pathways of antigen processing and presentation. T- Cell development and activation. TH and Tc cell types and their roles in immune system.

cell mediated cytotoxicity, mechanism of T cell and NK cell mediated lysis, tissue transplantation and graft rejection, cancer and immune system, immune response to infectious agents.

UNIT IV

Measurement of antigen–antibody interactions – Agglutination, precipitation and opsonization, gel diffusion (Ouchterloney double immunodiffusion and Mancini's Radial immunodiffusion), immunoblotting, RIA, ELISA and ELISPOT, Immuno-fluorescence and Flow cytometry. Preparation of monoclonal antibody.

Cancer and immune system, Tumor antigens, immune response to cancer, Anticancer immunotherapies. Cell cycle analysis, cell death assays

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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(Allied Health PG Programmes)
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UNIT V

Allergy, inflammation, and hypersensitive reactions. Viral infections, Immunodeficiency diseases, primary and secondary immunodeficiencies, HIV and host defense evasion, bacterial infections, fungal infections. Vaccines and types, new technologies in vaccine development and trials, vaccination strategies.

Details of laboratory experiments (tentative depend on feasibility)

Following lab practical are planned

1. Detection of health condition of individual using Blood film preparation and identification of cells.
2. Purification of IgG from serum for application in prenatal therapy & molecular biology research.
3. Analysis of food adulteration using Double immuno-diffusion (Testing for egg protein in food products
3. Application of antibodies in research using immunoblotting technique
4. To isolate peripheral blood mononuclear cells (PBMC) from whole blood by Ficoll-Hypaque density gradient centrifugation.
5. Detection of cytokines using ELISPOT assay.
6. Qualitative and quantitative detection of the hormone by ELISA
7. Western blot to detect and quantify protein bands from crude tissue extracts.

Resource Material

Textbook

1. Basic Immunology: Functions and Disorders of the Immune System by Abul K. Abbas, Andrew H. Lichtman, and Shiv Pillai (7th Edition, published in 2020).
2. Immunobiology: The Immune System in Health and Disease by Charles A. Janeway Jr., Paul Travers, Mark Walport, and Mark J. Shlomchik (5th Edition, published in 2001).
3. The Immune System by Peter Parham (5th Edition, published in 2020)

Reference Book

1. Clinical Immunology: Principles and Practice Hardcover (2018) 5th Edition: Robert R. Rich, Thomas A Fleisher
2. Immunology: A Short Course" by Richard Coico and Geoffrey Sunshine (7th Edition, published in 2020)

Resource

http://ndl.iitkgp.ac.in/document/SGhmbVpJeXkyWlA4OFBMVHBtUjMxTlM1UFhJUEhiamZseEpoSHRlcVNIOD0

http://ndl.iitkgp.ac.in/document/UGZCc1hPR3k3b2tUWllxK0k1TTFLcEo1ejhKSXJhSktqeVFkYnloNElEOD0

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Explain mechanisms of infection and related immune reactions in body	3	2	3	2	3	2	2	3
CO2	Know the basis of producing vaccines, antibodies for use in healthcare	3	2	3	2	3	2	3	3
CO3	Understand the use of immunological techniques such as ELISA, Western blot, flow cytometry, and immune his to chemistry	3	3	3	2	3	3	2	3
CO4	Describe immune responses to organ transplants and graft rejection mechanisms.	3	2	3	2	3	2	3	3
CO5	Discuss the role of the immune system in cancer and tumor immunotherapy.	3	2	3	2	3	2	3	3

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HIMS[illegible]RHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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CMCR514 Basic & Applied Microbiology (3Cr)

Course Description:

The course is designed to impart knowledge about pathogenic & economically important microbes, their identification & quantification using microbial techniques. The student is also familiarized with the microbial culture, growth, and potential industrial, pharmaceutical, and clinical applications, including recent advancements in microbiome research and synthetic biology.

Course Outcomes:

At the end of the course, the learner must demonstrate:

- Describe the microbial distribution & diversity, reproduction & growth, role in causing diseases, and potential biotechnological applications by imparting depth knowledge.
- Demonstrate the ability to explore recent advances and techniques used to develop biotech-based applications in the food and beverage industries, biopharmaceutical industries, synthetic biology, and healthcare (e.g., antibiotics, vaccine development, probiotics, CRISPR-based applications).

Course Contents and Structure:

UNIT I

Landmark achievements in the 20th and 21st century, major contributions of scientists, identification, characterization, and classification of microorganisms. Distinguishing characteristics between prokaryotic and eukaryotic cells. Structure and function of cell walls of bacteria, cell membranes, flagella, pili, capsule, gas vesicles, carboxy some, magnetosomes, and phycobilisomes.

UNIT II

Methods of sterilization: Physical methods – Dry heat, moist heat, radiation methods, filtration methods, chemical methods, and their application. Microbial cultures: Concept of pure culture, methods of pure culture isolation, staining methods, Microbiological media – Natural and synthetic; autotrophic, heterotrophic, and phototrophic media: basal, defined, complex, enrichment, selective, differential, maintenance, and transport media.

UNIT III

Preservation and maintenance of microbial cultures: Repeated subculturing, preservation at low temperatures, sterile soil preservation, mineral oil preservation, deep freezing, and liquid nitrogen preservation, drying, glycerol cultures, freeze-drying (lyophilization). Advantages and disadvantages of each method. Newer methods, such as cryoprotectant-enhanced techniques and genomic preservation approaches, are introduced.

UNIT IV

Bacterial nutrition and cultural characteristics, synchronous, stock, batch, and continuous cultures. Growth measurement methods. Cultivation of aerobes and anaerobes, reproduction in bacteria and spore formation. Morphology, ultrastructure, and chemical composition of bacteria, actinomycetes,

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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and archaebacteria. Introduction to bacterial biofilms and quorum sensing in industrial and medical applications.

UNIT V

Ecological importance and significance of algae, Algal SCP, emphasis on Spirulina. Ecological importance and significance of fungi. Characteristics of lichens and mycorrhiza. Conservation of microbial diversity, marine environment, and bacterial diversity. Cultivation and enumeration of marine bacteria. Applications of microbial biotechnology in environmental bioremediation and bioenergy production.

Details of Laboratory Experiments

1. Preparation of different types of media.
2. Isolation and enumeration of bacterial and fungal populations in air.
3. Enumeration of bacterial populations in water.
4. Isolation and enumeration of bacterial and fungal populations in soil.
5. Demonstration of bacterial motility by hanging drop technique.
6. Staining techniques: i) Gram staining, ii) Endospore staining, iii) Capsule staining iv) Albert staining.
7. Basics of Antimicrobial susceptibility testing using disc diffusion methods.
8. Quantification of biofilm formation using crystal violet assay.

Learning Resource Material:

Primary (Textbooks, Software, CD-ROM, etc.)

1. Microbiology (2024) 6thEdition: Michael Pelczar
2. Microbiology (2023)12th Edition: Dorothy Wood, Joanne Willey, Kathleen Sandman
3. Brock Biology of Microorganisms, Global Edition, (2024) 16th Edition: Michael T. Madigan

Reference Books

1. A Clinician's Dictionary of Pathogenic Microorganisms (2004) 5th Edition: James H. Jorgensen; Michael A. Pfaller
2. Fundamental Principles of Bacteriology (2017) 8th Edition: Salle A.J.
3. *Topley &* Wilson's *Microbiology and Microbial Infections*. 10th ed., Hodder Arnold ; ASM Press, 2005.

3. Reference Material (Journals, Hand-outs), Journals

1. International Journal of Medical Microbiology
2. Journal of Applied Microbiology
3. Journal of Clinical Microbiology
4. Nature Microbiology

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4.Laboratory Equipment: Glass slides, cover slips, centrifuges, colorimeter, pH meter, electronic balance, hot air oven, magnetic stirrer, weighing machine, digital thermometer, microscope.

Reagents: Nutrient media, Gram stain, biofilm staining dyes.

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health Programmes)
HIMS, SRHU
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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Describe the microbial distribution & diversity, reproduction & growth, role in causing diseases, and potential biotechnological applications by imparting depth knowledge	3	2	3	2	3	3	2	3
CO2	Demonstrate the ability to explore recent advances and techniques used to develop biotech-based applications in the food and beverage industries, biopharmaceutical industries, synthetic biology, and healthcare (e.g., antibiotics, vaccine development, probiotics, CRISPR-based applications).	3	2	3	2	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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CMCR515 IPR, Ethics (3 Cr)

Course Description:

The course introduces students with basics of regulatory affairs and management practices with latest developments in the life science industry. The course basically deals with fundamental concepts required in understanding and their applicability to all aspects of management sciences and protection of intellectual property rights. It provides an examination of the regulatory considerations in the major regions of the world where marketing applications are pursued and compares the application requirements in all regions including India by gaining knowledge of Schedule Y.

Course outcome:

- Highlight the role of patents in pharmaceutical research, their impact on drug pricing, and access to medicines.
- Evaluate ethical concerns in patenting biotechnology and life-saving drugs, balancing public health and commercial interests.
- Explain technology transfer, licensing, and intellectual property management in research and industry.
- Understand autonomy, beneficence, non-malfeasance, and justice, along with frameworks like the Belmont Report and Declaration of Helsinki
- Highlight the importance of voluntary participation and protecting vulnerable populations.
- Identify unethical practices like data falsification and plagiarism and stresses transparency and reproducibility in research.

Course Content & Structure

Unit 1

Basics of IPR and types of IPR, patentable and non-patentable inventions, PCT and WIPO, procedure for patent filing, copyright registration and design registration, patent licensing and commercialization, compulsory licensing, Indian patents act 1970

Unit 2

Rights and duties of patentee, restoration of lapsed patents, surrender and revocation of patents, Infringement, remedies and penalties, copyright piracy, copyrights with special reference to software, passing off and penalties in trademark

Unit 3-

Importance of Ethics in Clinical Research: Evolution of Ethics Guidelines, Examples of unethical Behaviors in Clinical Research: Plutonium Trials, Tuskegee Syphilis Study, Willow brook Hepatitis Experiments, MKULTRA, Research misconduct and fraud.

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Unit 4

Ethical considerations: Vulnerable populations, Principles of ethical recruitment, inclusion and exclusion criteria and their ethical implications.

Conflict of interests (COI): Types, examples, and ethical and legal implications of COI.

Dr. Nitu Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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Unit 5

The Indian Perspective of Ethics in Clinical research, examples of unethical practices in India

Introduction to CDSCO and DCGI, Ethics committee, Types of ethics committee, Review process of a study by the Ethics Committee

Registration and re-registration of Ethics Committee, violations of ethics approval rules and regulations, DSMB, SUGAM portal

LEARNING RESOURCE MATERIAL

Textbooks:

- Principles of Research Methodology and Ethics in Pharmaceutical Sciences an application guide for students and researchers. Edited By Vikas Anand Saharan, Hitesh Kulhari, Hemant R Jadhav, Published August 30, 2024 by CRC Press
- The Oxford Textbook of Clinical Research Ethics by Ezekiel J Emanuel (ed.) et al. 2023
- A textbook of pharmacovigilance and clinical research. Published by Career Point Ltd.

Journals:

- Journal of Intellectual Property Rights
- The Journal of Clinical Ethics
- American Medical Association Journal of Ethics
- Clinical Ethics
- Journal of Clinical Trials & Patenting

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Highlight the role of patents in pharmaceutical research, their impact on drug pricing, and access to medicines.	3	2	3	2	3	2	3	2
CO2	Evaluate ethical concerns in patenting biotechnology and life-saving drugs, balancing public health and commercial interests.	3	2	3	2	3	2	3	2
CO3	Explain technology transfer, licensing, and intellectual property management in research and industry.	3	2	3	3	3	2	3	3
CO4	Understand autonomy, beneficence, non-malfeasance, and justice, along with frameworks like the Belmont Report and Declaration of Helsinki	3	2	3	3	3	2	3	3
CO5	Highlight the importance of voluntary participation and protecting vulnerable populations.	3	2	3	3	3	2	3	3
CO6	Identify unethical practices like data falsification and plagiarism and stresses transparency and	3	2	3	3	3	2	3	3

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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Dehradun

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	reproducibility in research.								

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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CMCR516 Clinical Data Management (4 Cr)

Course Description:

Understanding and implementing data management principles is critical for any scientific domain. This course is about methodical organization of health data in digital form. Clinical Data Management (CDM) is a critical phase in clinical research, which leads to generation of high-quality, reliable, and statistically sound data from clinical trials / investigations. Clinical data management enables you to integrate and analyze medical data to make patient care more efficient, and extract insights that can improve medical outcomes, drastically reduce time for drug to reach market, while protecting the security and privacy of the data. The course deals with data management systems, information retrieval, alignment and analysis. It also imparts knowledge of online/offline clinical data management tools. The teaching focuses on interactive sessions and will involve considerable periods of computer-based work.

Course outcomes

At the end of the course the student will be able to:

- Understanding of quality data management and metrics and best practices for quality data management.
- Familiarity with CDM processes, Data collection modalities, electronic data capture, Storage, Retrieval and validation.
- Application of data, data preparation and discrepancy management

Course Content & Structure

Unit I

Clinical Data Management (CDM) and its significance. Need for high quality data. Datamining, Surveys. Clinical trials. Multicenter studies. Global health Research data planning: wise investment. Important concept *'garbage in garbage out'*. Designing the project in advance. Data Management Plan. **CDM Process**: Data collection, database designing, data-entry, data validation, discrepancy management, medical coding, data extraction, database locking. Data collection: source, kind of data and collection method. Designing Case Report Form (CRF), CRF annotation, electronic data capture fundamentals. Validated instruments for data collection, basic concept, and verification for contextual use. Medical coding, terminologies, and ontologies

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Unit II

Quality assurance. Benefits of data quality management. Definition 'high quality data'. Specifics and metrics of quality assessment. Data quality management best practices: Data preparation framework, Understanding data. Data cleansing- discrepancy management. Data validation – testing for errors. Transformation and enriching data. Data storage and retrieval. Data governance. monitoring, reporting, and enhancing data quality. Periodic quality assessment. Data tracking guidelines, quality control measures. Audit trail and monitoring. SOPs for technical components, processes, operations: standard templates, workflow.

Unit III

Dr. Nikku Yadav
Incharge Dept. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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Data processing and Analysis. Analytical tools: Fundamentals of Biostatistics and Bioinformatics. Data classification, data distribution, descriptive methods for categorical and continuous data. Response variables. Basic statistical parametric and non-parametric tests. Comparison of populations, correlation, and regression. Probability and Normal Distributions. Anova. Sample Size estimation.
Use of survival analysis in clinical research. Estimation of survival curve (Kaplan-Meier estimate).

Unit IV

Brief Introduction to MySQL. Working knowledge Excel, SPSS.Tools for CDM CDMS. Commercial tools ORACLE CLINICAL, CLINTRIAL, MACRO, RAVE, and eClinical Suite. Open-source tools OpenClinica, openCDMS, TrialDB, and PhOSCo. Functions of tools IT and basic Machine Learning tools in CDM. Safety Adverse Events reconciliation. Roles and responsibilities in CDM

Unit V

Standards and regulatory compliances for data management and electronic data systems. Electronic Data Capture (EDC) and EDC Concepts. Standardization of Study processes. Standard terminologies CDISC suite of standards: Data collection CDASH, Data tabulation: SDTM/SEND. LOINC, Health Level7 : HL7, ICD-9/ICD-10/IC-0-3, SNOMED-CT, GCDMP Institutional Review Board approval. Human subjects protection- Guiding principles. Health information privacy. Information security management (E-Govt Act). CIRB, HIPAA, and FISMA1
GCP and 21 CFR Part 1

LEARNING RESOURC MATERIAL

Primary Text books:

- "Clinical Data Management" – Richard K. Rondel, Sheila A. Varley, Colin F. Webb (2023, 3rd Edition)
- "Principles of Clinical Data Management" – Lisa M. Danehower, Stephen J. Bennett (2022, 2nd Edition)
- "Clinical Trials Data Management: A Practical Approach" – Eleanor McFadden (2023, 4th Edition)

Reference Books:

- "Clinical Trials and Data Management: A Regulatory Perspective" – M. U. R. Naidu (2023, 2nd Edition)
- "Good Clinical Data Management Practices (GCDMP) Guidelines" – Society for Clinical Data Management (SCDM) (2024, Latest Edition)

Internet:

- National center for biotechnology information, www.ncbi.nlm.nih.gov
- Medidata, http://www.mdsol.com/products/rave_capture.htm
- ClinPlus, http://www.clinplus.com/products/clinical-data-management/Drug Bank, www.drugbank.caProgeny, http://www.progenygenetics.com/clinical/

Reference Material (Journals, Handout)

- Journal of Clinical Research
- Journal of Clinical Research & Bioethics
- Clinical Research & Regulatory Affairs

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4. Laboratoy equipment: Computer, Printer, Internet

Dr. Nikhu Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understanding of quality data management and metrics and best practices for quality data management.	3	3	3	2	3	3	3	2
CO2	Familiarity with CDM processes, Data collection modalities, electronic data capture, Storage, Retrieval and validation.	2	3	3	2	3	3	3	2
CO3	Application of data, data preparation and discrepancy management	2	3	3	2	3	3	3	2

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Dr. Nikku Yadav
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CMCR517 Environmental & Regulatory Physiology (4 Cr)

Course Description

This course emphasizes on the understanding of the body systems working independently as well as in coordination with environment to bring balance in physiological process. Course also explores how organisms body responds to various external stresses imposed by fluctuations in the environment. Unit topics include environmental challenges, organisms-environment interference; various types of messengers, the body's internal control viz., thermoregulation, osmoregulation, nutrient levels (digestion and excretion), homeostasis as well as the neural and hormonal regulation of these systems. Also includes, physiology of reproduction, neurons, and behavior.

Course Outcome: After successful completion of this course, students should be able to

- familiarize with various aspects of regulatory physiology & biological body systems.
- understand interaction of organisms with their immediate environment, life sustaining strategies, role of environmental cues & messenger in maintaining the information flow among organism & surroundings
- understand the types of chemical, hormonal messengers, their synthesis in body, diverse modes of actions, applications and neuronal coordination

Course contents

Unit I- General Physiology: Structure and function of cell organelles, Cell to cell communication, Transport across cell membrane, Homeostasis and its maintenance, Membrane Potentials. (RMP Action Potential)

Unit II-Body fluids: Body water and Body fluids, measurement of body fluid, composition and functions of blood, functions of blood cells (rbc, wbc, platelets), blood clotting, blood group

Unit III- Endocrine: Classification of hormones, Mechanism of action of steroid, Protein and amine hormones, Role of hypothalamus in control of pituitary, Role of Synthesis, secretion, functions of Thyroid Hormone. Applied of Thyroid hormone. Functions of Adrenal gland Hormones & applied. Functions of Insulin and applied.

Unit IV- Nervous System Structure of neuron and type, Mechanism of impulse conduction, Synapse structure and properties, Neurotransmitter classification, Functions of different part of Brain and spinal cord, Autonomic nervous system, Functions of hypothalamus (Temperature, circadian rhythm and feeding behavior)

Unit V- Reproductive System: Puberty- Definition, changes during puberty, Menstrual cycle- Phases and hormonal regulation, Spermatogenesis and its regulation, Contraceptives, Physiological changes in Pregnancy.

Following lab practical's are planned:

- Determination of blood types or antibodies to blood group antigens by agglutination

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Incharge Dept. of Clinical Research
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- Separation of serum from whole blood
- Isolation of RBC from whole blood and preparation of permanent slide
- Quantitative estimation of blood glucose level using glucometer
- To prepare thin smears of blood film and staining the blood film.
- Effect of Pre and Post exercise on blood pressure and pulse rate using electronic sphygmomanometer
- To estimate the level of dietary iodine in the given sample.
- To detect the level of iodine in the given biological sample (urine).
- Quantitative estimation of cholesterol in the given sample.
- Separation of Tyrosine-derived hormones using TLC and Paper chromatography
- Assessment of thyroid status: through hormonal measurements using ELISA.

LEARNINGRESOURCEMATERIAL

1.Primary Textbooks:

- "Guyton and Hall Textbook of Medical Physiology" John E. Hall (2023, 14th Edition)
- "Ganong's Review of Medical Physiology" – Kim E. Barrett, Susan M. Barman, Scott Boitano (2023, 26th Edition)
- "Berne & Levy Physiology" – Bruce M. Koeppen, Bruce A. Stanton (2022, 7th Edition)

Reference books:

- "Medical Physiology: Principles for Clinical Medicine" – Rodney A. Rhoades, David R. Bell (2022, 6thEdition)

"Textbook of Human Physiology for Medical Students" – Indu Khurana (2023, 3rd Edition)

Internet resources

http://intl-ajpregu.physiology.org/.

2. Secondary (Monograph, Reports etc.). None

3. Reference Material (Journals, Handout)

Journals-

- American Journal of Physiology -Endocrinology and Metabolism
- American Journal of Physiology – Gastroenterology and Liver
- American Journal of Psychiatry
- Best Practice & Research: Clinical Endocrinology & Metabolism
- European Journal of applied Physiology
- European Journal of Endocrinology
- Human Reproduction

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4. Laboratory equipment

Centrifuges, colorimeter, pH meter, electronic balance, hot air oven, magnetic stirrer, glucometer, sphygmomanometer, weighing machine, microscope.

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
Allied Health PG Programmes
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Familiarize with various aspects of regulatory physiology & biological body systems.	3	2	3	2	3	3	2	3
CO2	Understand interaction of organisms with their immediate environment, life sustaining strategies, role of environmental cues & messenger in maintaining the information flow among organism & surroundings	3	2	2	2	3	2	2	3
CO3	Understand the types of chemical, hormonal messengers, their synthesis in body, diverse modes of actions, applications and neuronal coordination	3	2	3	2	3	3	2	3

Vice Principal
(Allied Health PG Programmes)
SHIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Himalayan Institute of Medical Sciences
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Course Code and Title: CMCR518 Basics of Pharmaceutics (4 Cr)

Course Description: This course deals with the novel drug delivery systems, approaches, criteria for selection of polymers and drugs and their formulation and evaluation. Also deals with various pre formulation elements, industrial management and GMP considerations, Pilot Plant Scale Up Techniques, Stability testing, sterilization and packaging of dosage forms. This course will impart knowledge and skills in generic drug development, various regulatory filings the approval process, and concept of generics across the globe.

Course outcomes:

- Demonstrate basic understanding of preparation, manufacturing, and packaging of pharmaceutical dosage forms.
- Explain basic principles of formulation of pharmaceutical dosages with knowledge of their physicochemical properties.
- Explain basic steps of converting raw material into finished goods in manufacturing pharmaceutical dosage forms.
- Describe the evaluation process to ensure quality of dosage forms.
- Describe Current Good Manufacturing Practice (cGMP) and its compliance in Pharmaceutical Industry.

Unit 1:

General introduction to pharmaceutics

Brief introduction to different branches of pharmacy.

Pharmacopoeias: Introduction to IP, BP, USP

Dosage forms: Introduction to dosage forms, classification and definitions

Prescription: Definition, Parts of prescription, handling of Prescription and Errors in prescription. **Posology:** Definition, Factors affecting posology. Pediatric dose calculations based on age, body weight and body surface area.

Different route of drug administration

Unit 2

Pre formulation Studies: Introduction to pre formulation, goals and objectives, study of physicochemical characteristics of drug substances.

Physical properties: Physical form (crystal & amorphous), particle size, shape, flow properties, solubility profile (pKa, pH, partition coefficient), polymorphism

Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

BCS classification of drugs & its significant

Role of excipients in drug formulations: Classification of binders, disintegrants, preservatives, solvents, and emulsifiers

Unit 3

Pharmaceutical dosage forms

Brief introduction about following –

Solid dosage forms- Tablet, Capsules,

Liquid dosage forms- Monophasic liquids: Eardrops, Nasal drops, Syrups, Elixirs, Liniments and Lotions. Biphasic liquids: Suspensions, Emulsions

Semisolid dosage forms: Ointments, pastes, creams and gels.

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
Allied Health PG Programmes
HIMS, SRHU
Dehradun-248016

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Unit 4

Quality Assurance and Quality Management concepts: Definition and concept of Quality control, Quality assurance and GMP

Total Quality Management (TQM): Definition, elements.

ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines.

ICH stability testing guidelines

Unit 5

Impurities in pharmaceutical substances: Sources and types of impurities, principle involved in the limit test for Chloride, Sulphate, Iron, Arsenic, Lead and Heavy metals

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.

Details of laboratory experiments to be considered for intensive writing and hands on work

LEARNING RESOURCE MATERIAL

Primary Text books:

- Aulton's Pharmaceutics: The Design and Manufacture of Medicines edited by Kevin M.G. Taylor (4th Edition, published in 2021).
- Applied Physical Pharmacy by W. Cary Mobley, Mansoor M. Amiji, and Thomas J. Cook (3rd Edition, published in 2021).
- Drug Safety Evaluation, 4th Edition by Shayne Cox Gad and Dexter W. Sullivan Jr. (published in December 2022).
- Fundamentals of Drug Development by Jeffrey S. Barrett (1st Edition, published in July 2022).

Reference books:

- Drug Metabolism Handbook: Concepts and Applications in Cancer Research, 2nd Edition by Ala F. Nassar, Paul F. Hollenberg, JoAnn Scatina, Soumen Kanti Manna, and Su Zeng (published in November 2022).

Reference materials (Journals):

- Pharmaceutics
- Pharmaceuticals
- Journal of Pharmacy and Pharmaceutical Sciences
- International Journal of Pharmaceutics
- European Journal of Pharmaceutics and Biopharmaceutics
- Journal of Pharmaceutical Sciences
- Asian Journal of Pharmaceutical Sciences
- Drug Development and Industrial Pharmac

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Demonstrate basic understanding of preparation, manufacturing, and packaging of pharmaceutical dosage forms.	3	2	3	2	3	3	3	2
CO2	Explain basic principles of formulation of pharmaceutical dosages with knowledge of their physicochemical properties	3	2	3	2	3	3	3	2
CO3	Explain basic steps of converting raw material into finished goods in manufacturing pharmaceutical dosage forms.	3	3	3	2	3	3	3	2
CO4	Describe the evaluation process to ensure quality of dosage forms.	3	3	3	2	3	3	3	2
CO5	Describe Current Good Manufacturing Practice (cGMP) and its compliance in Pharmaceutical Industry.	3	3	3	2	3	3	3	2

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(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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CMCR519: Population Studies

Course Description: This course provides an in-depth understanding of Population Studies, focusing on demographic concepts, population trends, and patterns at global and national levels. It covers various methods of population analysis, including fertility, mortality, migration, and population projection techniques. Students will learn about the composition and structure of populations, including age, sex, and dependency ratios. The course also explores data sources such as SRS, NFHS, and NSS, along with associated data quality issues. It emphasizes the link between population and development, including national policies and health committee recommendations.

Course outcome:

- Understand the history, scope, and significance of Population Studies along with global and national population trends and demographic concepts.
- Identify and evaluate various sources of population data, including civil registration, SRS, NSS, WFS, DHS, and NFHS, and understand types and sources of errors in population data.
- Apply appropriate methods to analyze population growth and change, including arithmetic, geometric, exponential growth rates, and use of mathematical and component methods for population projection.
- Analyze population composition and structure with a focus on spatial and temporal distribution, age and sex composition, demographic dividend, and various dependency ratios.
- Evaluate fertility, mortality, and migration indicators and understand their determinants and measurement, including computation of fertility rates, life expectancy, and migration patterns.
- Examine the relationship between population and development using various indices (HDI, PQLI, SDI) and understand national health policies and recommendations of key health committees.

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UNIT I: Introduction to Population Studies and Sources of Data

History and scope of Population Studies. Population trends, global variation in population size and growth, Current Population Scenario in India and States. Basic demographic concepts, components of population change. Sources of Population data. Civil registration, Sample Registration System (SRS), National Sample Surveys (NSS), World Fertility Survey (WFS), Demographic Health Surveys (DHS), National Family Health Surveys (NFHS), Types and sources of errors in population data, etc

UNIT II: Methods of Population Analysis

Himalayan Institute of Medical Sciences Dean -cum- Principal

Dr. Nikku Yadav
Incharge Dept. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
Allied Health PG Programmes
HIMS, SRHU
Jolly Grant, Dehradun-248016

Arithmetic, Geometric and Exponential growth rates, decadal growth rate doubling time, concept of population stabilization and net reproduction rate, Crude and Standardized methods for fertility and mortality estimates. Location of event in time and the Lexis diagram. Method of population projection: mathematical methods of population projection (linear, exponential, polynomial, and logistic growth curves for population projection), component method of population projection, etc.

UNIT III: Population Composition and Change

Spatial and temporal changes in the size and distribution of population-global perspective with focus on India, Age and sex structure of population, Composition of India's population. Population ageing: concepts and measures, and components. demographic dividend, sex-ratio, sex-ratio at birth, child-women ratio, median age, age sex pyramid, dependency ratio (child dependency ratio, old dependence ratio, total dependency ratio).

Unit –IV- Fertility, Mortality, and Migration

Fertility: Fertility Indicators: sources of data and their computation, Crude Birth Rate (CBR), General Fertility Rate (GFR), Age Specific Fertility Rate (ASFR), Age Specific Marital Fertility Rate (ASMFR), Total Fertility Rate (TFR), Gross Reproduction Rate (GRR), Net Reproduction Rate (NRR), Determinants of Fertility.

Mortality: Basic concept and measures of mortality, Infant Mortality Rate (IMR), Under-five mortality Rate, Maternal Mortality Rate (MMR), Causes of Deaths Statistics. Life expectancy. Life Table and Model Life Table.

Migration: Types of migration: internal and international trends, Patterns, and differentials of Internal and international migration. Direct and indirect measures of migration.

Unit V-Population Development and Related Policies

Concepts of Development and its Measures: Human Development Index (HDI), Physical Quality of Life Index (PQLI), Social Development Index (SDI), Millennium Development Goals (MDG), Sustainable Development Goals (SDG), NITI Ayog. Recommendations of various Experts Committee viz., Bhore Committee, Mudaliar Committee, Chadha Committee, Mukherjee Committee, Jungalwalla Committee, Kartar Singh Committee, Shrivastava Committee, Bajaj Committee etc., National Heath Mission (NHM)Policies, Programmes and Legislations in India: related to Age at Marriage, Medical Termination of Pregnancy, Sex Selected Abortion (PCPNDT Act), COTPA Act-2003 (Tobacco Control Act), Policies and Programme related to Reproductive and Child Health, etc. Family Planning Methods, Communicable and Non-Communicable Diseases, Programme Global Issues and Challenges in Population and Health: Concept of global health, global demographic, health and epidemiological Transition, UN World Population Conferee

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant Dehradun-248016

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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the history, scope, and significance of Population Studies along with global and national population trends and demographic concepts.	3	1	2	2	2	1	2	3
CO2	Identify and evaluate various sources of population data, including civil registration, SRS, NSS, WFS, DHS, and NFHS, and understand types and sources of errors in population data.	3	3	3	1	2	2	3	2
CO3	Apply appropriate methods to analyze population growth and change, including arithmetic, geometric, exponential growth rates, and use of mathematical and component methods for population projection.	3	3	3	1	2	3	2	3
CO4	Analyze population composition and structure with a focus on spatial and temporal distribution, age and sex composition, demographic dividend, and various dependency ratios.	3	2	2	2	2	2	2	3
CO5	valuate fertility, mortality, and migration indicators and understand their determinants and measurement, including computation of fertility rates, life expectancy, and migration patterns.	3	3	3	1	2	3	2	3
CO6	Describe Current Good Manufacturing Practice (cGMP) and its compliance in Pharmaceutical Industry.	3	2	3	3	2	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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(Allied Health PG Programmes)
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Jolly Grant, Dehradun-248016

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CMCR601 Biopharmaceuticals& Drug Development (4 Cr)

Course Description:

The aim of this subject is to introduce students to them a in theoretical concepts and experimental designs in pharmaceutical and agro -food technology, and their contribution to protection and enhancement of human health. This course would provide the students with an understanding of the role and development of biotechnology in the field of pharmaceutical sciences and agro food technology, and also discusses the current status of research being pursued in these areas.

Course outcome

- Describe Biopharmaceuticals and Drug development process.
- Have a thorough knowledge and enforceability of development, research and production of pharmaceutical products (Demonstration)
- Demonstrate the understanding of awareness of and national, international health problems related pharmaceutical biotechnology.

Course Structure and Contents

UNIT I

Introduction to biopharmaceuticals: history, definition & sources, use of biopharmaceuticals in ancient tradition, classification of biopharmaceuticals, biopharmaceutical products viz., blood components, blood factors, thrombolytic agents, hormones, hematopoietic growth factors, therapeutic enzymes etc

UNIT II

Biogenetics and biosimilars: definition, generics and its advantages, bio generics and biosimilars, protein-based biopharmaceuticals, approved follow-on proteins/ biosimilars, characteristics of proteins/ biosimilars, target products for fob(follow-on biologicals)/ biosimilars development, industries dealing with biogenetics its market value, world scenario, Indian scenario

UNIT III

Recombinant biopharmaceuticals: Introduction to recombinant DNA technology, key signaling proteins erythropoietin, growth hormone, biosynthetic human insulin and its analogues, custom-designed monoclonal antibodies, use of transgenic models-benefits & risks. Production of biopharmaceuticals & their application, production and application of therapeutic proteins - factor VIII, growth hormones, DNA vaccines, insulin, cytokines - interferon, interleukins I & II, tumor necrosis factor (TNF), monoclonal antibodies, large-scale production - bioreactors.

UNIT IV

Drug development: new drug discovery & development, designing clinical trials, clinical research phase studies, the investigational new drug process, FDA IND review team, NDA filing, FDA approval

UNIT V

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(Allied Health PG Programmes)
HIMS, SRHU
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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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Future Trends and Challenges in Biopharmaceuticals, Gene therapy, RNA-based therapeutics, and CRISPR technology, Personalized medicine and pharmacogenomics, Nanotechnology in biopharmaceuticals, Challenges in pricing, patent protection, and global access to biologics

Details of laboratory experiments (Tentative)

- Lab analysis of different drugs available in market
- Collection of data on drug allergies in different groups of individuals
- Pharmacokinetics and Pharmacodynamics for biologics (Dry lab)
- Recovery and downstream processing of any biopharmaceutical (Dry lab)
- Preparation of Pharmaceutical solutions, Emulsions, Suspensions
- Qualitative and quantitative estimation of different drugs available in market
- Stability of various industrial food products
- Extraction of enzymes used in food processing
- Report visits to Biopharmaceutical Industry

LEARNING RESOURCE MATERIAL

Primary (Textbooks):

a) Drug Discovery and Development by Raymond Hill and Duncan Richards (3rd Edition, published in 2020).
b) Fundamentals of Drug Development by James Swarbrick and James C. Boylan (1st Edition, published in 2021).
c) Biopharmaceutics: Applications in Drug Development by H. P. Rang and M. M. Dale (1st Edition, published in 2022).

Reference books:

- Development of Biopharmaceutical Drug-Device Products by Jeffrey K. Aronson and Brian R. Smith (1st Edition, published in 2023).
- Recent Advances in Drug Discovery and Development edited by Sandeep Kumar Vyas (published in 2024).

Reference Material (Journals):

- Journal of Biopharmaceutics and Biotechnology
- Biopharmaceutics & Drug Disposition
- Current Pharmaceutical Biotechnology
- Journal of Biosimilars
- Journal of Agricultural and Food Chemistry
- Web Resources:
- MOOC Resource(s): (Skaggs School of Pharmacy, UC San Diego, USA) - Drug Discovery, Development & Commercialization
- USFDA - Science & Research (Drugs

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
Allied Health PG Programmes
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean -cum- Principal

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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Describe Biopharmaceuticals and Drug development process.	3	2	3	2	3	3	3	3
CO2	Have a thorough knowledge and enforceability of development, research and production of pharmaceutical products (Demonstration)	3	3	3	2	3	3	3	3
CO3	Demonstrate the understanding of awareness of and national, international health problems related pharmaceutical biotechnology.	3	2	3	3	3	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR602 Quality Assurance & Quality Control in Clinical Research (3 Cr)

Course Description

The aim of the subject is to introduce students to the main theoretical concepts and in the conduct of Pharmaceutical and clinical research. The syllabus provides short discourse about the emergence of QA/QC as a formalized discipline, its developments, and its present status by considering how is been practiced starting from basic laboratory experimental work to present issues pertaining to whole and large scale productions.

Course Outcomes:

- Discuss understanding of importance of Quality Assurance and Quality Control in Clinical investigations, translational as well as observational.
- Demonstrate the understanding of Cognizance with process of quality data generation, protocol compliance, documentation, monitoring in keeping with GCP guidelines.
- Demonstrate the understanding of Regulatory compliances (Audits/ inspections etc)

Course Structure and Contents

Unit I

Introduction to QC, QA & GCP Audits: Introduction to Quality in Clinical Research, Process Mapping in Clinical trials, QA and QC in Clinical Research, QA Activities, QA Planning, QA SOPs, practical exercises and Interactive sessions- designing a process map etc, tools of audits, auditors - who and what are they? preparing for an audit, conduct of an audit, cro audit, practical case scenarios in audits

Unit II

Prospective pathway to drug discovery: Principles of drug discovery and development. clinical research process. Development and informational content for investigational new drugs application (IND), new drug application (NDA), abbreviated new drug application (ANDA), supplemental new drug application (SNDA), ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Unit III

Regulatory Inspections: FDA Inspections- Preparation, Conduct, reporting and recording of inspections, EMEA Inspections- preparation, conduct, reporting of inspections, MHRA Inspections- preparation, conduct, reporting of inspections, ANVISA Inspections, IEC/IRB Inspections, DCGI Inspections, conduct of a mock inspection, differences between FDA and EMEA Inspections, Frauds, Misconduct and Errors, Practical Scenarios in Regulatory Inspections

Unit IV

Dr. Nikku Nabar
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Emerging concepts of quality assurance for drugs, introduction, hazard analysis and critical control points (HACCP) methodology. pharmaceutical quality systems (PQS), quality review and quality documentation, regulatory control, regulatory drug analysis, interpretation of analytical data.

Unit V

Drug evaluation models: scope, limitations, high throughput screening (HTS), ethical considerations, protocol designing and its execution, GLP, requirement of animal care facility and role of statistics, evaluation of analgesic antipyretic and anti-inflammatory drugs , anti-diabetic, antihypertensive , anticancer agents etc

Details of laboratory experiments to be considered for intensive writing and hands on work

1. Designing of SOPs for QA/QC work
a. Protocol
b. Investigator brochure
c. CRF
d. Screening form
e. Informed consent
2. Isolation of Active components from Medicinal Plants
3. Virtual High Throughput screening of Druggable compounds using S/W.
4. Biochemical Estimations of Body fluids used in clinical investigation of Drugs.
5. Develop test procedure using dissolution method for in-vivo and in-vitro quality testing of drug.
6.Standardization and validation of basic Analytical Instruments used in Clinical investigation

LEARNING RESOURCE MATERIAL

Primary Text books:

- Quality Assurance and Quality Control in the Analytical Chemical Laboratory: A Practical Approach, Piotr Konieczka, Jacek Namieśnik, 2nd Edition (2020)
- Good Clinical Practice: Standard Operating Procedures for Clinical Researchers, Josef Kolman, Paul Meng, Graeme Scott, 2nd Edition (2020)
- Fundamentals of International Clinical Research, Richard Chin, 2nd Edition (2019)

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Reference Textbooks:

- Principles of Good Clinical Practice, Michael J. McGraw, Karen E. Stout, 2nd Edition (2018)
- Clinical Trials Handbook, Shayne Cox Gad, 2nd Edition (2021)

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean -cum- Principal

- The CRC's Guide to Coordinating Clinical Research, Karen E. Woodin, John C. Schneider, 4th Edition (2021

Reference material (Journals):

- Quality Assurance Journal (Published by Wiley)
- Good Clinical Practice Journal (GCPj)
- Quality Management in Health Care
- Clinical Trials: Journal of the Society for Clinical Trials
- Journal of Clinical Research Best Practices
- Drug Information Journal (DIA Journal)
- Regulatory Toxicology and Pharmacology
- Journal of Pharmaceutical Sciences

Internet:

- American Chemical Society, www.acs.org
- Chemical Abstracts Service, www.cas.org
- International Union for Pure and Applied Chemistry (IUPAC), iupac.org
- International Union of Pharmacology (IUPHAR) Database www.iuphar-db.org
- Drug Bank, www.drugbank.ca
- PubChem, www.pubchem.ncbi.nlm.nih.go

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Institute of Medical Sciences
Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Discuss understanding of importance of Quality Assurance and Quality Control in Clinical investigations, translational as well as observational.	3	2	3	2	3	3	3	3
CO2	Demonstrate the understanding of Cognizance with process of quality data generation, protocol compliance, documentation, monitoring in keeping with GCP guidelines.	3	3	3	2	3	3	3	3
CO3	Demonstrate the understanding of Regulatory compliances (Audits/ inspections etc)	3	3	3	2	3	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248011

Himalayan Institute of Medical Sciences
Dean cum-Principal

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CMCR603 Regulatory Affairs (4Cr)

Course Description: This course the student is familiarized with the regulatory rules, regulations practiced in clinical research & biopharmaceutical industry. Students will required to carry out case studies & review the process in above topic in Indian & overseas CR & biopharmaceutical industries. As pharmaceutical sector is growing rapidly, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies.

Course outcome:

- Understand the role of a medical products regulatory affairs specialist and the dynamic nature of the regulatory field.
- Learn the laws and regulations that apply to the development, testing and production of medical products, including biologics, drugs, biotechnology-derived therapeutics, vaccines, and medical devices.
- Explore post-market issues and requirements such as inspections, reporting and enforcement

Course Structure and Contents

This course, being in the form of a case study, is unstructured, continues & no end term will be proposed. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the case study. Assisted by the internal supervisor, student develops a study design and plans for its timely execution. The student generates data and/or data mines and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life case study with a problem-solving approach.

Course Contents

Unit 1: Introduction to regulatory affairs, Overview of Regulatory Affairs and its importance in the healthcare industry, Role of Regulatory Affairs professionals in drug development and approval, Global regulatory bodies: FDA (USA), EMA (Europe), CDSCO (India), MHRA (UK), PMDA (Japan), TGA (Australia), Regulatory framework for pharmaceuticals, biologics, medical devices, and cosmetics

Unit 2: Drug Development and Regulatory Submission, drug discovery & development process, preclinical and clinical trials (Phase I-IV), Investigational New Drug (IND) application, New Drug Application (NDA) and Abbreviated New Drug Application (ANDA), Biologic License Application (BLA) and biosimilar regulations, orphan drug regulations and expedited approval pathways

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Unit 3: Regulatory Guidelines and Compliance, ICH Guidelines (International Council for Harmonisation): ICH Q (Quality), ICH S (Safety), ICH E (Efficacy), Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP), Pharmacovigilance regulations (Adverse drug reaction monitoring and reporting), Post-marketing surveillance and Risk Management Plans (RMP), Drug labeling, packaging, and advertising regulations

Unit 4: Medical Devices and Combination Products Regulations, Medical device classification and approval pathways (Class I, II, III), Regulatory framework for medical devices: 21 CFR Part 820 (FDA), EU MDR (European Medical Device Regulation), In-vitro Diagnostic (IVD) regulations, Clinical evaluation of medical devices, Combination products: Regulations and approval processes

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Unit 5: Regulatory Affairs in Emerging Markets & Future Trends, Regulatory requirements in India, China, Brazil, South Africa, Russia, and ASEAN countries Harmonization initiatives: WHO, ASEAN, and BRICS regulatory frameworks, Digital health regulations (AI in healthcare, telemedicine, e-submissions), Evolving trends in regulatory science, personalized medicine, and gene therapy, Career opportunities and certifications in Regulatory Affairs (RAPS, RAC, CQA, PMP)

LEARNING RESOURCE MATERIAL

Primary Text Books:

- "Fundamentals of International Regulatory Affairs" – Regulatory Affairs Professionals Society (RAPS) (2023, 6th Edition)
- "Fundamentals of US Regulatory Affairs" – Regulatory Affairs Professionals Society (RAPS) (2023, 15th Edition)
- "Drug Regulatory Affairs: Fundamentals, Applications, and Industry Perspectives" – Siaw-Teng Liaw, Abdullah G. Assiri (2023, 2nd Edition)

Reference Books:

- "New Drug Development: A Regulatory Overview" – Mark Mathieu (2023, 9th Edition)
- "FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics" – David Mantus, Douglas J. Pisano (2023, 4th Edition)

Journals-

- Bioequivalence Journal
- Pharmaceutical Analysis Journal
- Pharmacovigilance Journal
- Journal of Pharmaceutical Regulatory Affairs

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the role of a medical products regulatory affairs specialist and the dynamic nature of the regulatory field.	3	2	3	3	3	3	3	3
CO2	Learn the laws and regulations that apply to the development, testing and production of medical products, including biologics, drugs, biotechnology-derived therapeutics, vaccines, and medical devices.	3	3	3	3	3	3	3	3
CO3	Explore post-market issues and requirements such as inspections, reporting and enforcement	3	3	3	3	3	3	3	3

Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR 604 Introduction to Clinical & Pharmaco-Epidemiology (3Cr)

Course Description

This course guides the students to explore the epidemiological concepts i.e., the disease patterns, determinants, and frequency of health-related events. Students will be able to gauge the impact of different exposure and treatments and exposures on disease outcome A deeper insight into health policies, disease prevention, systematic reviews, and patient data registry development will be sought. By the end, they will gain analytical skills to assess public health challenges, contribute to research, and support policy initiatives for improved healthcare outcomes.

Course Outcomes

At the end of the course the student is expected to:

- Have gained and understanding epidemiology of diseases of public health importance in India.
- Formulate strategies for disease screening and prevention
- Analyse and direct health policies and guidelines
- become well versed in systematic reviews and metanalysis methods
- have acquired data preparation and data analysis skills from available data in patient registries.
- understand the pharmacoepidemiology & Pharmacoeconomics

Course Content and Structure

UNIT I

Epidemiology of diseases of public health importance. Basic epidemiology of communicable and non-communicable diseases. Infectious disease epidemiology and epidemics. Patterns, causes and effects of tuberculosis, HIV-AIDS, diabetes and hypertension in patient populations and association with exposures/ treatments and their health outcomes. Case Studies of evidence-based practices in diseases. Application of epidemiological data in public health decision-making

UNIT II

Patterns and impact of environmental deficiencies. Patterns, causes and effects of Iron, Protein energy and Iodine deficiency in patient populations and association with exposures/ treatments and their health outcomes. Case studies of evidence-based practices in deficiency disorders. Application of epidemiological data in public health decision-making

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UNIT III

Disease Screening and Prevention. Screening and diagnostic tests, differences and criterion for selection,Lead Time, Types of Screening. Validity and reliability of screening

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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tests (Sensitivity, Specificity, predictive values, Receiver Operator Curve. Yield of a screening test.

UNIT IV

Pharmaco-epidemiology: Pharmacovigilance and drug safety, Dose-effect relationship, Dose-response relationship, Pharmaco-epidemiological methodologies, pharmaceutical policy analysis.

UNIT V Pharmacoeconomics: Introduction to Pharmacoeconomics, Definition and Importance of Pharmacoeconomic studies, Introduction to pharmacoeconomic analysis Health Care and Market Failure

LEARNING RESOURCE MATERIAL

Text books

- Park, K. (2025) Parks Textbook of Preventive and Social Medicine. 28th Edition, M/S Banarsidas Bhanot Publishers, Jabalpur.
- Rajvir Bhalwar (2023). Textbook of Community Medicine. Wolters 128luwer india Pvt Ltd.

Reference Books

- Rashmi Kundapur, Maroof Amir Khan, Kakkar, R., Sheth, A. and Nidhi Mangrola (2024). Textbook of Community Medicine. Jaypee Brothers Medical Publishers Pvt Limited.
- Gordis, L. (2014). Epidemiology. 5th ed. Philadelphia, PA: Elsevier/Saunders.

E Resources

- CDC PUBLIC HEALTH 101 SERIES. https://www.cdc.gov/training-publichealth101/php/training/introduction-to-epidemiology.html
- NPTEL/ Swayam
- NCBI, www.ncbi.nlm.nih.gov

Journals, Handout

Nature, Science, Journal of public health, Journal of Epidemiology, American Journal of Epidemiology

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(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

Dr. Nikka Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Have gained and understanding epidemiology of diseases of public health importance in India.	3	2	2	2	3	3	3	3
CO2	Formulate strategies for disease screening and prevention	3	3	2	2	3	3	3	3
CO3	Analyse and direct health policies and guidelines	3	3	3	3	3	3	3	3
CO4	Become well versed in systematic reviews and metanalysis methods	3	3	3	2	3	3	3	3
CO5	Have acquired data preparation and data analysis skills from available data in patient registries	3	3	2	2	3	3	3	3
CO6	understand the pharmacoepidemiology & Pharmacoeconomics	3	1	2	1	3	3	2	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR605 Research Methodology (4Cr)

Course Description: This course is designed to familiarize students with what, why and how of research. It broadly describes identification of a problem, the right question(s)to be asked to ensure problem solving, research design, relevant statistical and other tools and techniques, quantification, measures, validation, accuracy, precision, bias, data reduction, data analysis, presentation, and publication of findings. Students will learn to identify original problems for research and to appreciate the importance of why and how research ought to be conducted.

Course outcomes:

- Understanding of the importance of research in societal growth and development
- Ability to identify original problems for research and develop research designs for problem solving
- Familiarity with research methodologies i.e., surveys, sampling, experimental, in clinical investigations
- Understanding of ethical and regulatory issues in scientific research
- Adequate skill in statistical tools, techniques, and their application to arrive at relevant conclusions
- Adequate skill in basic software used in data collection, compilation, storage, retrieval, and data analysis.

Unit 1: Foundations of Research Methodology: Definition, Scope, and Importance of Research in Clinical Sciences, Characteristics of Good Research, Types of Research: Descriptive, Analytical, Applied, and Fundamental Research

Philosophical Underpinnings: Paradigms: Positivism, Interpretivism, Pragmatism, Ethical Considerations in Clinical Research, Principles of Research Integrity

Unit 2: Research Design and Methods: Observational Studies: Case-Control, Cohort, Cross-Sectional Experimental Studies: Randomized Control Trials, Quasi-Experimental Designs, Mixed-Method Research Sampling Methods: Types of Sampling: Probability and Non-Probability, Determination of Sample Size, Sampling Bias and Strategies to Minimize It Measurement Tools and Techniques: Development and Validation of Questionnaires, Scales: Likert, Semantic Differential, Visual Analog

Unit 3: Data Collection and Management: Primary Data: Interviews, Focus Groups, Surveys Secondary Data: Literature Review, Registry Data, Clinical Records, Data Collection Techniques, Data Quality and Management: Ensuring Data Accuracy and Completeness, Tools for Data Entry and Cleaning, Softwares for Data Management, Case Study on Data Collection Challenges in Clinical Research

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Unit 4: Data Analysis and Interpretation: Statistical Concepts: Descriptive Statistics: Measures of Central Tendency and Dispersion, inferential statistics: hypothesis testing, p-values, confidence intervals, software for statistical analysis: introduction to SPSS, R, STATA,

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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interpreting outputs from statistical software, data visualization: creating charts and graphs: bar, pie, boxplot, use of software for visualization: tableau, excel, ethical reporting of data

Unit 5: Writing and Dissemination of Research: Structure of Research Writing: writing a thesis, dissertation, and journal article, IMRAD Format: introduction, methods, results, and discussion, referencing styles: APA, MLA, Vancouver, Publishing and Presenting Research: choosing the right journal: impact factor, scope, writing a cover letter and responding to reviewer comments, poster and oral presentations case study on successful research translation into practice

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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LEARNING RESOURCE MATERIAL

Prescribed Texts:

- NPTEL/ Swayam
- NCBI, www.ncbi.nlm.nih.gov
- MEGA, http://www.megasoftware.net/
- Kothari, C. R., and Gaurav Garg. *Research Methodology: Methods and Techniques*. 4th ed., New Age International Publishers, 2019.
- Cooper, Donald R., and Pamela S. Schindler. *Business Research Methods*. 12th ed., McGraw-Hill Education, 2018.
- Sekaran, Uma, and Roger Bougie. *Research Methods for Business: A Skill-Building Approach*. 8th ed., Wiley, 2020.

Reference Books:

- Booth, Wayne C., Gregory G. Colomb, and Joseph M. Williams. *The Craft of Research*. 4th ed., University of Chicago Press, 2016.
- Bryman, Alan. *Social Research Methods*. 5th ed., Oxford University Press, 2016.

Internet Reference:

- eGradeSchool, http://www.egradschool.edu.au/whategsaoffe/researchmeth.jsp
- ipc.gov.in
- cdsco.gov.in
- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

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HIMS, SRHU
Jolly Grant, Dehradun-248016

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understanding of the importance of research in societal growth and development	3	2	3	3	3	3	3	3
CO2	Ability to identify original problems for research and develop research designs for problem solving	3	3	3	2	3	3	3	3
CO3	Familiarity with research methodologies i.e., surveys, sampling, experimental, in clinical investigations	3	3	2	2	3	3	3	3
C04	Understanding of ethical and regulatory issues in scientific research	2	3	3	3	3	2	3	3
CO5	Adequate skill in statistical tools, techniques and their application to arrive at relevant conclusions	3	3	2	2	3	3	3	3
CO6	Adequate skill in basic software used in data collection, compilation, storage, retrieval and data analysis.	2	3	2	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR606Pharmacovigilance (4 Cr)

Course Description:

The main purpose of this course is educated students all about drug safety, the needs and importance of pharmacovigilance. It provides a thorough understanding of the basic concepts of drug safety and risk management throughout the process of drug development and its life cycle in the open market either as a patent or generic drug. This exposure prepares students to understand and appreciate the various types and grades of Adverse Events.

Learning Outcome

After completion of this course, student will:

- Explain classification of adverse events / adverse drug reactions.
- Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval.
- Describe the various pharmacovigilance methods and PMS methodologies
- Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)
- Understand ongoing benefit / risk assessment throughout the life cycle of a medicine.
- Understand the basics of signal detection and management

Course Content and Structure

UNIT I

Pharmacovigilance: definitions, overview and scope, importance, thalidomide disaster and post-thalidomide era; current status, need and objectives; drugs withdrawn from the market, WHO drug monitoring program and Uppsala Monitoring Centre (UMC), pharmacovigilance global perspective.

UNIT II

Introduction to adverse drug reactions: definitions and classification of ADRs, detection and reporting, management of adverse drug reactions, adverse drug reaction reporting: introduction to reporting systems; spontaneous reporting system; reporting to regulatory authorities; Adverse event case processing & principles, sources of individual case safety reports, guidelines for reporting ADRs in biomedical literature.

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UNIT III

Pharmacovigilance Methods: Passive surveillance, active surveillance, and stimulated reporting.

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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PMS methodologies - comparative observational studies, descriptive studies, drug utilization studies, case studies, cohort studies, vaccine safety surveillance studies.

UNIT IV

Benefit-Risk Assessment: Actual vs perceived risk and benefits, factors affecting benefit-risk balance; methods of risk minimization, PSUR and its reporting, PBRER, International expedited reporting, pharmacovigilance planning guidelines.

UNIT V

Signal Detection: Signal generation, sources and methods of signal detection, automated quantitative signal detection, UMC signaling process, PV database software (Aris, Argus, etc.) for case report management.

Details of laboratory experiments (Tentative)

- Real life case studies on different diseases in relation to pharmacovigilance.
- Accurately filling suspected ADR reporting form
- Monitoring of ADRs
- Reporting of ADRs using vigiflow

LEARNING RESOURCE MATERIAL

Prescribed Texts:

- Pharmacovigilance: Principles and Practice, I. Ralph Edwards, Marie Lindquist, 2nd Edition (2023).
- Good Pharmacovigilance Practices: A Guide for the Pharmaceutical Industry, M. N. Kumar, P. V. P. Chowdary, 1st Edition (2022)

Mann's Pharmacovigilance, Elizabeth B. Andrews, Nicholas Moore, 3rd Edition (2019).

Reference Books:

- Pharmacovigilance: A Practical Approach, Thao Doan, Nicholas Moore, 1st Edition (2021).

Pharmacovigilance: Critique and Ways Forward, Patrick Waller, Mira Harrison-Woolrych, 1st Edition (2020)

Internet Reference:

- ipc.gov.in
- cdsco.gov.in
- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.int

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(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Explain classification of adverse events / adverse drug reactions.	3	2	3	2	3	2	3	2
CO2	Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval.	3	3	3	2	2	2	3	3
CO3	Describe the various pharmacovigilance methods and PMS methodologies	3	3	3	2	3	3	3	3
C04	Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)	2	3	3	2	3	2	3	3
CO5	Understand ongoing benefit / risk assessment throughout the life-cycle of a medicine.	3	3	3	2	3	3	3	3
CO6	Understand the basics of signal detection and management	3	3	3	2	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR 650 Research Project

Course Description: Student will undertake a research project on a topic of his/her choice as discussed with tutor. Topic selection depending on student inclination and proficiency and expertise available. The project can also be a part of the departmental/ collaborative on-going research programs. Work can commence in 2nd semester and the report submitted towards the end of 3rd semester followed by a presentation and defense of the findings to the tutor.

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Get hold of principles and hands-on relevant techniques of biomedical research viz. disease genesis, diagnostics & management.	3	2	3	2	3	3	2	3
CO2	Be able to prepare technical documents (protocol, informed consent, clinical report form, clinical study report).	2	3	3	3	2	2	3	2
CO3	Be well-versed with wet/dry lab methodologies and field activity.	3	3	3	2	3	3	2	3
C04	Get knowledge for data generation, integration & statistical analysis using software.	2	3	2	2	3	2	3	3
CO5	Be able to design and interpret clinical case studies using medico informatics tools.	3	3	3	2	3	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR651 Intensive study of a disease: Etiology, Diagnostics, Therapeutics (4 Cr)

Course Description: This course would provide the students with an understanding and an in-depth study of a disease. This course would also impart knowledge to students regarding different aspects of a disease analyzing the latest Biomedical & Clinical Research literature available. This course helps the students get well versed with the various advanced, clinical, proteomics and genomics analysis of diseases

Course Outcomes:

- Explain the fundamental causes and pathophysiology of specific diseases.
- Identify genetic, environmental, infectious, and lifestyle-related factors contributing to disease development.
- Analyze epidemiological data to determine disease prevalence, incidence, and risk factors.
- Describe the cellular and molecular mechanisms leading to disease onset and progression.
- Understand how biochemical and immunological processes contribute to disease pathology.
- Differentiate between acute and chronic disease progression and their systemic effects.

Unit 1: Introduction to Disease Pathophysiology: Definition and classification of diseases (infectious, genetic, autoimmune, metabolic, neoplastic, etc.), Concepts of homeostasis, cellular adaptation, and disease progression, role of inflammation, immune response, and oxidative stress in disease development, Overview of epidemiology and disease surveillance

Unit 2: Etiology and Risk Factors
Genetic and hereditary factors in disease development, environmental and lifestyle-related causes (diet, smoking, pollution, occupational exposure) pathogen-induced diseases: bacterial, viral, fungal, and parasitic infections, role of hormonal imbalances, metabolic dysfunctions, and autoimmune mechanisms

Unit 3: Diagnostic Approaches and Investigations, Clinical evaluation: signs, symptoms, and differential diagnosis
Laboratory investigations: Blood tests, biochemical markers, microbiological cultures
Imaging techniques: X-ray, MRI, CT scan, PET scan, ultrasound
Molecular and genetic diagnostic tools: PCR, ELISA, flow cytometry, gene sequencing
Emerging diagnostic technologies: AI-assisted diagnostics, biosensors, liquid biopsy

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Unit 4: Therapeutic Strategies and Management Pharmacological interventions: Drug classes, mechanisms, and clinical applications Non-pharmacological treatments: Physiotherapy, lifestyle modifications, diet therapy, Surgical and interventional procedures: Indications and advancements in surgery, Immunotherapy, gene therapy,

Dr. Nikku Yadav
Incharge Dept. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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and personalized medicine, Role of nanomedicine and regenerative medicine in disease management

Unit 5: Case Studies and Future Perspectives, In-depth analysis of specific diseases (e.g., cancer, diabetes, cardiovascular diseases, autoimmune disorders), Patient case discussions and evidence-based treatment approaches, Challenges in disease prevention, treatment resistance, and emerging threats (e.g., antimicrobial resistance, new pandemics), Future trends in precision medicine, AI-driven healthcare, and global disease control strategies.

LEARNING MATERIAL

Primary textbooks:

- "Robbins & Cotran Pathologic Basis of Disease" – Vinay Kumar, Abul K. Abbas, Jon C. Aster (2024, 11th Edition)
- "Harrison's Principles of Internal Medicine" – Dennis L. Kasper, Anthony S. Fauci, Stephen L. Hauser, Dan L. Longo, J. Larry Jameson, Joseph Loscalzo (2022, 21st Edition)
- "The Molecular Basis of Cancer" – John Mendelsohn, Peter M. Howley, Mark A. Israel, Joe W. Gray, Craig B. Thompson (2023, 5th Edition)
- Reference Text books:
- Goodman & Gilman's: The Pharmacological Basis of Therapeutics" – Laurence L. Brunton, Randa Hilal-Dandan, Björn C. Knollmann (2023, 14th Edition)
- "Cancer Immunotherapy: Principles and Practice" – Lisa H. Butterfield, Howard L. Kaufman, Francesco M. Marincola (2022, 3rd Edition

Internet references:

- Clinical Chemistry
- The Journal of Molecular Diagnostics
- Radiology
- Nature Reviews Drug Discovery
- Journal of Translational Medicine
- The Lancet Oncolog

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Explain the fundamental causes and pathophysiology of specific diseases.	3	2	3	2	3	3	2	3
CO2	Identify genetic, environmental, infectious, and lifestyle-related factors contributing to disease development.	3	2	3	2	3	3	2	3
CO3	Analyze epidemiological data to determine disease prevalence, incidence, and risk factors.	2	3	2	2	3	3	2	3
CO4	Describe the cellular and molecular mechanisms leading to disease onset and progression.	3	2	3	2	3	3	2	3
CO5	Understand how biochemical and immunological processes contribute to disease pathology.	3	2	3	2	3	3	2	3
CO6	Differentiate between acute and chronic disease progression and their systemic effects.	3	2	3	2	3	3	2	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR652 Pharmacovigilance Elective (4 Cr)

Course Description:

The main purpose of this course is educated students all about drug safety, the needs and importance of pharmacovigilance. It provides a thorough understanding of the basic concepts of drug safety and risk management throughout the process of drug development and its life cycle in the open market either as a patent or generic drug. This exposure prepares students to understand and appreciate the various types and grades of Adverse Events.

Course Outcome:

- Explain classification of adverse events / adverse drug reactions.
- Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval
- Describe the various pharmacovigilance methods and PMS methodologies
- Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)
- Understand ongoing benefit / risk assessment throughout the life cycle of a medicine.
- Understand the basics of signal detection and management

Unit I: Introduction and recapitulation of ADRs and PV

Terminology of Adverse Medication Related Events, regulatory terminology

- Types of ADRs and aims and goals of Pharmacovigilance
- WHO Adverse Reaction Terminology, MedDRA and Standardization MedDRA Queries, WHO Drug Dictionary, Eudravigilance Medicinal Product Dictionary
- Vaccine pharmacovigilance, adverse event following immunization, Haemovigilance and materiovigilance
- Global safety monitoring systems

Unit II: Establishing PV Programme

- Establishing in a Hospital, Establishment and Operation of Drug Safety Department in Industries, CROs, Establishing a National Programme.
- Regulatory guidelines and laws, SOPs in PV, PV auditing and inspection, Regulatory aspects in PV
- Effective communication in PV, communication in drug safety, crisis management, communication with Regulatory Agency, Health care facilities & media.
- CIOMS-CIOMS working Groups, CIOMS Form

Unit III: Drug safety evaluation in special population

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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HIMS, SRHU
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- Pharmacogenetics and Pharmacogenomics in relation to ADRs
- Drug safety evaluation in special population
- Pediatrics
- Pregnancy and lactation
- Geriatrics

Unit IV: Pharmacovigilance in clinical trials

- Pharmacovigilance in different phases of clinical trials
- Roles of sponsor, PI and IEC/IRB
- Timelines for reporting ADRs

Unit V: Good Pharmacovigilance Practices

- Pharmacovigilance and pharmacoepidemiology in risk management
- Expedited Reporting Criteria, format and content of PSUR & PBRER
- Quality system in pharmacovigilance
- PV Database and Signal Detection, Risk Assessment &management.
- Developing a pharmacovigilance plan

Prescribed Texts:

- Pharmacovigilance: Principles and Practice, I. Ralph Edwards, Marie Lindquist, 2nd Edition (2023).
- Good Pharmacovigilance Practices: A Guide for the Pharmaceutical Industry, M. N. Kumar, P. V. P. Chowdary, 1st Edition (2022)
- Mann's Pharmacovigilance, Elizabeth B. Andrews, Nicholas Moore, 3rd Edition (2019).

Reference Books:

- Pharmacovigilance: A Practical Approach, Thao Doan, Nicholas Moore, 1st Edition (2021).
- Pharmacovigilance: Critique and Ways Forward, Patrick Waller, Mira Harrison-Woolrych, 1st Edition (2020)

Internet Reference:

- ipc.gov.in
- cdsco.gov.in
- www.trialscentral.org/
- www.fda.gov/oc/gcp/
- www.who.in

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Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Explain classification of adverse events / adverse drug reactions.	3	2	2	3	3	3	2	3
CO2	Understand the safety reporting requirements (according to the type of adverse event / reaction) pre- and post-approval	2	3	3	3	3	3	3	3
CO3	Describe the various pharmacovigilance methods and PMS methodologies	3	3	2	3	3	3	2	3
CO4	Describe reporting of individual case safety reports (ICSRs) and periodic safety update reports (PSUR)	2	3	2	3	3	3	3	3
CO5	Understand ongoing benefit / risk assessment throughout the life-cycle of a medicine.	3	3	3	3	3	3	3	3
CO6	Understand the basics of signal detection and management	3	3	2	3	3	3	2	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR653 Medical Writing (4Cr)

Course Description: Through this course the student is familiarized with the technical documentation required in medical research conducted to allow safety and efficacy for any health interventions. Student makes an in-depth study of various regulatory guidelines viz., ICH, USFDA, MHRA, ICMR and simultaneously acquires skills in designing, developing, archiving documents in conformity thereof e.g. protocol, ICD, CRF, SOPs, Clinical study report, Dossier filing etc.

Course outcomes:

- Define medical writing and its role in healthcare, pharmaceuticals, and research.
- Differentiate between various types of medical documents (regulatory, scientific, educational, promotional).
- Write well-structured clinical study reports, research articles, and systematic reviews.
- Prepare patient information leaflets, drug monographs, and medical communication materials.
- Follow guidelines from regulatory agencies (FDA, EMA, ICH, GPP3) in medical writing.
- Adhere to ethical considerations, including plagiarism, data integrity, and authorship guidelines.

Unit 1: Introduction to Medical Writing: Definition, scope, and importance of medical writing, Types of medical writing: Regulatory writing, scientific writing, and medico-marketing writing, Ethics in medical writing and publication, plagiarism, and copyright issues in medical writing, Understanding target audiences (healthcare professionals, researchers, patients, regulatory authorities)

Unit 2: Scientific and Research Writing, Structure of scientific articles: IMRAD format (Introduction, Methods, Results, Discussion), Writing research proposals, theses, and dissertations, systematic reviews and meta-analyses, writing case reports and case series, Referencing styles (Vancouver, APA, Harvard) and reference management tools (EndNote, Mendeley, Zotero)

Unit 3: Regulatory and clinical writing, overview of regulatory documents (Clinical Study Protocols, Investigator's Brochure, Clinical Study Reports), Common Technical Document (CTD) format in drug development, writing Informed Consent Forms (ICFs) and Patient Information Leaflets (PILs), Pharmacovigilance writing: Adverse event reporting, Risk Management Plans (RMPs), Good Clinical Practice (GCP) guidelines in medical writing

Unit 4: Medical Communication and Healthcare Journalism, writing for medical blogs, newsletters, and magazines, medical journalism and writing for public awareness, Communicating complex medical information to non-experts, Writing healthcare-related

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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press releases and social media content, Ethical considerations in public health communication

Unit 5: Practical aspects and career opportunities in medical writing, tools and software for medical writing (grammarly, PubMed, AI writing tools), writing abstracts and preparing presentations for conferences, grant writing and funding proposals, freelance and corporate career opportunities in medical writing, effective editing and proofreading strategies for medical manuscripts

Primary Textbookss

- "Writing in the Biological Sciences: A Comprehensive Resource for Scientific Communication" – Angelika H. Hofmann (2023, 4th Edition)
- "How to Write and Publish a Scientific Paper" – Barbara Gastel, Robert A. Day (2022, 9th Edition)
- "The Craft of Scientific Writing" – Michael Alley (2024, 5th Edition)

Reference books:

- "Regulatory Writing for the Pharmaceutical Industry" – Rahul G. Patel (2023, 1st Edition)
- "Medical Writing: A Guide for Clinicians, Educators, and Researchers" – Robert B. Taylor (2022, 3rd Edition)
- "Scientific and Medical Writing: A Guide to Effective Communication" – Daniel W. Byrne (2023, 3rd Edition)

Reference Material (Journals, Hand-outs)-

Journals-

- Medical Writing (MEW)
- Science Editor
- Journal of Technical Writing and Communication (JTWC)
- Regulatory Focus
- Applied Clinical Trials
- Journal of Research Administration (JRA)
- Research Integrity and Peer Review

Himalayan Institute of Medical Sciences
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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Define medical writing and its role in healthcare, pharmaceuticals, and research.	3	2	2	3	3	3	2	3
CO2	Differentiate between various types of medical documents (regulatory, scientific, educational, promotional).	3	3	2	3	3	3	3	3
CO3	Write well-structured clinical study reports, research articles, and systematic reviews.	3	3	3	3	3	3	3	3
CO4	Prepare patient information leaflets, drug monographs, and medical communication materials.	2	3	2	3	3	3	3	3
CO5	Follow guidelines from regulatory agencies (FDA, EMA, ICH, GPP3) in medical writing.	3	3	3	3	3	3	3	3
CO6	Adhere to ethical considerations, including plagiarism, data integrity, and authorship guidelines.	3	3	2	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR654 Regulatory affairs, manufacturing [drugs and medical devices] (4Cr)

Course Description: This course the student is familiarized with the regulatory rules, regulations practiced in clinical research &biopharmaceutical industry. Students will be required to carry out case studies & review the process in above topic in Indian & overseas CR & biopharmaceutical industries.

Course Outcomes:

- Understand Regulatory Frameworks
- Apply Good Manufacturing Practices (GMP)
- Comprehend the drug development and approval process
- Evaluate medical device regulations
- Manage regulatory submissions & documentation
- Ensure compliance & risk management
- Understand ethical, legal & global aspects of regulatory affairs

Apply knowledge of risk management and quality assurance in pharmaceutical and medical device manufacturing.

Course Content & Structure

Unit I

Current Good Manufacturing Practices: Introduction, US Cgmp Part 210 and Part 211.EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.

Good Laboratory Practices: Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards.

UNIT II

Pharmaceutical industry developments: Legal requirements and Licenses for API and formulation industry, Plant location-Factors influencing. Plant layout: Factors influencing, Special provisions, Storage space requirements, sterile and aseptic area layout. Production planning: General principles, production systems, calculation of standard cost, process planning, routing, loading, scheduling, dispatching of records, production control.

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Unit III

Aseptic process technology: Manufacturing, manufacturing flowcharts, in process-quality control tests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder, Solution (Small Volume & large Volume). Process Automation in Pharmaceutical Industry: With specific reference to manufacturing of sterile semisolids, Small Volume

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Parenterals & Large Volume Parenterals (SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP), Sterilization in Place (SIP), Prefilled Syringe, Powdered Jet, Needle Free Injections, and Form Fill Seal Technology (FFS). Lyophilization technology: Principles, process, equipment.

UNIT IV

Non sterile manufacturing process technology: manufacturing, manufacturing flowcharts, in process-quality control tests for following Non-Sterile solid dosage forms: Tablets(compressed & coated), Capsules (Hard & Soft). Process Automation in Pharmaceutical Industry with specific reference to Manufacturing of tablets and coated products, Improved Tablet Production: Tablet production process, granulation and pelletization equipment's, continuous and batch mixing, rapid mixing granulators, rota granulators, spheronizers and marumerisers, and other specialized granulation and drying equipment's.

Unit V

Containers and closures for pharmaceuticals: Types, performance, assuring quality of glass; types of plastics used, Drug plastic interactions, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil /plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment, flexible packaging, product package compatibility, transit worthiness of package, Stability aspects of packaging. evaluation of stability of packaging material.

Primary Textbooks

- Fundamentals of International Regulatory Affairs, Regulatory Affairs Professionals Society (RAPS), 8th Edition (2023)
- FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David Mantus, 4th Edition (2022)
- Global Regulatory Affairs for Medical Devices, Sharon A. Olson, 1st Edition (2022)

Reference books:

- The Regulatory Affairs Handbook, Martin Rothman, Stephen Ferguson, 2nd Edition (2023)
- New Drug Development: A Regulatory Overview, Mark Mathieu, 9th Edition (2022)
- **Reference Material (Journals, Hand-outs)-**

Journals-

- Regulatory Affairs Journal (RAJ Pharma & RAJ Devices)
- Regulatory Toxicology and Pharmacology
- Pharmaceutical Regulatory Affairs: Open Access
- Journal of Regulatory Science
- Food and Drug Law Journal (FDLJ)
- Expert Review of Clinical Pharmacology

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Dr. Nikki Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand Regulatory Frameworks	3	3	3	2	3	3	3	2
CO2	Apply Good Manufacturing Practices (GMP)	3	3	3	3	3	3	3	3
CO3	Comprehend the Drug Development and Approval Process	3	3	3	3	3	3	3	3
CO4	Evaluate Medical Device Regulations	3	3	3	3	3	3	3	3
CO5	Manage Regulatory Submissions & Documentation	3	3	3	3	3	3	3	3
CO6	Ensure Compliance & Risk Management	3	3	3	3	3	3	3	3
CO7	Understand Ethical, Legal& Global Aspects of Regulatory Affairs	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR655 Analytical tools for Pharmaceutical Industry (4Cr)

Course Description: : This course provides knowledge of analytical techniques such as titrimetric, chromatographic, spectroscopic, electrophoretic, and electrochemical and their corresponding methods that have been applied in the analysis of pharmaceuticals.

Course Outcomes:

- Understand the Role of Analytical Tools in the Pharmaceutical Industry
- Apply Chromatographic and Spectroscopic Techniques
- Perform Drug Assay and Stability Testing
- Utilize Advanced Analytical Techniques
- Develop Problem-Solving Skills for Analytical Challenges
- Ensure Regulatory Compliance in Pharmaceutical Analysis

Course Contents and Structure

UNIT – I - Introduction to pharmaceutical analysis and techniques: Scope and range of modern pharmaceutical analysis. Listing of various techniques, with a broad discussion on their applications.

UNIT – II Ultraviolet (UV) and visible spectroscopy: a) Energy levels and selection rules: Definitions, molecular orbital approach for energy absorption, various modes of transitions. b) Correlation of structural variation with UV absorption: Factors influencing the position and intensity of absorptions, Inductive and resonance effects, the effect of the ring size, influence of stereochemical factors. c) Predicting UV absorption: Woodward-Fieser,Fieser-Kuhn, and Nelson rules. d) Other factors: Non-conjugative effect, solvent effect,S-Cis band. e) Principles of multicomponent analysis in UV and its applications.

UNIT –III- Infrared (IR) spectroscopy: a) Characteristic regions of the spectrum: Various modes of vibrations,Energy levels. b) Correlation of structure with IR spectra: Influence of substituents, ring size. hydrogen bonding, vibrational coupling, and field-effect on frequency. c) Applications: Spectral interpretation with examples, the role of deconvolution in FT-IR data interpretation. d. Quantitative IR spectroscopy.

UNIT – IV- Nuclear Magnetic Resonance (NMR)spectroscopy: a) Fundamentals: Physical basis, magnetic nuclei, resonance, relaxation processes, signal-sensitivity. b) Instrumentation: Continuous-Wave (CW) instrument, Pulsed Fourier Transform (FT) instrument, Functions, Relation with sensitivity, sampling. c)1H NMR, correlation of structure with spectra: Chemical environment and shielding, chemical shift and origin of its concept, reference compound, local diamagnetic shielding, and magnetic anisotropy, relation with chemical shift, chemical and magnetic non-equivalence, spin-spin splitting and its origin, Pascal's triangle, coupling constant, mechanism of coupling, integral, NMR solvents and their residual peaks, protons on heteroatoms, quadrupole broadening and decoupling, the effect of conformations and stereochemistry on the spectrum, Karplus relationship, diastereomeric protons, Heteronuclear coupling to F and P, virtual

Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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coupling, long-range coupling-epi, peri, bay effects. Shift reagents mechanism of action, spin decoupling, and double resonance. Explanation of spectra of some compounds and drugs.

UNIT – V- Mass spectrometry (MS): a) Basic principles of Mass Spectrometry. b) Instrumentation: Ionization techniques: Electron ionization, Chemical ionization, Atmospheric pressure ionization (Electrospray ionization, APCI, and APPI), other sources: MALDI, ICP, etc. c) Mass Analyzers: Quadrupole, Time of flight, Ion traps, LIT, FTICR, Orbitrap, High-Resolution Mass Spectrometry. d) Hyphenated Mass Spectrometry: GC/MS, HPLC/UPLC-MS and Tandem Mass Spectrometry (Product ion scan, Precursor ion scan, neutral loss scan, SIM and MRM) e) Interpretation of mass spectra: Isotopes and ion abundances, the Fragmentation pattern of organic molecules with different functional groups, Qualitative analysis, Quantitative analysis. F) Applications: Application of mass spectrometry in Pharmacology/Toxicology, Environmental Monitoring/Analysis and Organic chemistry (Structure elucidation of organic molecules, A brief outline of metabolomics study including the scope of biomarkers study

LEARNING RESOURCE MATERIAL

Primary Text Books:

- Analytical Techniques in the Pharmaceutical Sciences, Anette Müllertz, Yvonne Perrie, Thomas Rades, 1st Edition (2020)
- Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists, David G. Watson, 5th Edition (2022)
- Handbook of Modern Pharmaceutical Analysis, Satinder Ahuja, Stephen Scypinski, 3rd Edition (2021)

Reference Books-

- Analytical Method Validation and Instrument Performance Verification, Churgin Sam, 2nd Edition (2020)
- Quality Control in the Pharmaceutical Industry, Murray Sam, 2nd Edition (2023)

Journals-

- Journal of pharmaceutical and Biomedical Analysis
- European Journal of Pharmaceutical Sciences
- Drug Design, Development and Therapy
- International Journal of Pharmaceutics
- Asian Journal of Pharmaceutical Sciences

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the Role of Analytical Tools in the Pharmaceutical Industry	3	2	3	3	2	3	3	3
CO2	Apply Chromatographic and Spectroscopic Techniques	3	3	3	3	3	3	3	3
CO3	Perform Drug Assay and Stability Testing	3	3	3	3	3	3	3	3
C04	Utilize Advanced Analytical Techniques	3	3	3	3	3	3	3	3
CO5	Develop Problem-Solving Skills for Analytical Challenges	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
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CO6	Ensure Regulatory Compliance in Pharmaceutical Analysis	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR656: Clinical Data Integration and Analysis (CDIA) (4 Cr)

Course Description: This course apprises students with the various methods & statistical procedures of mining, management and analysis of clinical studies-based data.

Course outcome:

- Apprises students with the various methods & statistical procedures of mining, management, and analysis of clinical studies-based data.
- Become conversant in CDM processes, data management and validation plans
- Use statistical tools and techniques in data management and analysis
- Design surveys and develop independent projects
- Application of data, data preparation and discrepancy management

UNIT I

Clinical Data Management (CDM) and its significance. Need for high quality data. Datamining. Clinical investigations. Survey research, experimental research, Clinical trials.

UNIT II

Quality data management. Garbage-in garbage-out, Benefits of data quality management. Specifics and metrics of quality assessment. Database designing, data collection & data-entry. data validation, testing for errors, discrepancy management, database locking.

UNIT III

Data integration. Multi-centric resources. Importance of data integration.
Data quality management best practices. Transformation and enriching data. Data storage and retrieval. Challenges of data integration (data from legacy systems, data from new systems, external data, wrong integration software)

UNIT IV

Tools for data integration and analysis
Brief Introduction and applications to Software tools viz., Excel, SPSS, R, Python, MYSQL Role of IT in healthcare data integration and research

UNIT V

Data analysis (descriptive, diagnostic, predictive and prescriptive)
Statistical tools in data analysis. Normal and skewed distribution. Comparison of populations. Correlations Regression analysis
Basic parametric and non- parametric tests.

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LEARNING RESOURCE MATERIAL
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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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- "Healthcare Data Integration and Interoperability" – John D. Halamka, Paul Cerrato (2023, 2nd Edition)
- "Interoperability and Data Analytics in Healthcare" – P. D. Verheij, M. A. Olsen (2024, 1st Edition)
- "FHIR, HL7, and Healthcare Data Standards" – Grahame Grieve, Josh Mandel (2023, 1st Edition)

Reference book-

- "Big Data and Artificial Intelligence in Healthcare" – Arjun Panesar (2023, 2nd Edition)
- "Clinical Data Science: Data Analysis and AI for Healthcare" – Christian Lovis, Mark Sendak (2024, 1st Edition)
- "Machine Learning for Healthcare Analytics" – Michael R. Berthold, Rosaria Silipo (2023, 3rd Edition)

Internet references-

Journals-

- Journal of the American Medical Informatics Association (JAMIA)
- International Journal of Medical Informatics
- Health Informatics Journal
- npj Digital Medicine
- Journal of Biomedical Informatics
- Artificial Intelligence in Medicine

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Apprises students with various methods & statistical procedures for clinical data analysis	3	3	3	3	3	3	3	3
CO2	Become conversant in CDM processes, data management, and validation plans	3	3	3	3	3	3	3	3
CO3	Use statistical tools and techniques in data management and analysis	3	3	3	3	3	3	3	3
CO4	Design surveys and develop independent projects	3	3	3	3	3	3	3	3
CO5	Application of data, data preparation, and discrepancy management	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

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CMCR657 Clinical Trial Management (4 Cr)

Course Description

This course will examine the current guidelines and regulations for conducting clinical trials especially in emerging countries. It will review Good Clinical Practice and how to plan and execute clinical development plans. At the end of this course, participants should be able to understand how clinical trial programmers are conducted and explore how international best practices may be applied in low- and middle-income countries.

This is an extensive course, designed for the Pharma professionals/Life Sciences/Medical Practitioners aspiring to work in the field of clinical research or allied professions like central labs, CROs, sponsor company & pharmacovigilance. The program provides complete overview and practical environment in the field of clinical research. The program would candidates to upgrade their knowledge about ICH GCP Guidelines, regulatory issues and other major aspects of clinical trials management. Program would help pharma professionals/life sciences/medical practitioners in developing career in the field of clinical research

Course Outcomes:

- After completion this course student will
- Learn the process for managing biomedical product development for FDA approval
- Gain an in-depth understanding of the clinical trials process through a modular, operations-focus approach
- Acquire project management skills needed to successfully manage human clinical trials
- Gain a global perspective on clinical trials management to better respond to the growing industry across the globe
- Learn how to respond to ethical issues inherent in clinical trials
- Discover how to use statistical methods to monitor clinical trial outcomes and make decisions
- Gain practical knowledge through real-world case studies and team projects in product development
- Learn from instructors with industry expertise in clinical trials management

Course Structure and Contents

Unit I: General introduction to clinical trials, phases and designs, factors influencing human participation in clinical trials, Ethics guidelines

Unit II- Roles & responsibilities of investigator, sponsor, CRC, CRA, CRO, Essential documents and regulatory submission

Unit III- ICH GCP guidelines, difference between E6(R2) and E6(R3) guidelines, ethics committee, Clinical trial monitoring and auditing.

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Unit IV- Data management and biostatistics, regulatory affairs in clinical research, pharmacovigilance

Unit V- Project management - based on project management body of knowledge, Clinical project management overview, Clinical trial management software.

LEARNING RESOURCE MATERIAL

Primary textbooks-

- Clinical Trials Handbook, Shayne Cox Gad, 2nd Edition (2021)
- A Practical Guide to Managing Clinical Trials, JoAnn Pfeiffer, Cris Wells, 2nd Edition (2022)
- Clinical Trials: Study Design, Endpoints, and Biomarkers, Drug Safety, and FDA and ICH Guidelines, Tom Brody, 3rd Edition (2020)

Reference book-

- Managing Clinical Trials: A Guide to Effective Practice, Annie Andritsch, Julianne Kirkland, 1st Edition (2023)
- Clinical Research Compliance Manual: An Essential Guide for Human Research Protections Programs, John Steiner, 4th Edition (2022)
- Clinical Research Coordinator Handbook, Deborrah Norris, 4th Edition (2021)

Internet references-

- Friedman, Furberg, and DeMets. Fundamentals of Clinical Trials (4th Edition). Springer, 2010. Free text available online at http://dx.doi.org/10.1007/978-1-4419-1586-3
- Machin and Fayers. Randomized Clinical Trials: Design, Practice and Reporting. Wiley-Blackwell, 2010 Piantadosi S.
- Clinical Trials: A Methodologic Perspective (2nd Edition). New Jersey: John Wiley & Sons, 2005.

Journals-

- Open Access Journal of Clinical Trials
- Contemporary Clinical Trials
- Journal of Clinical Trials
- International Journal of Clinical Trials
- Journal of Clinical Research and Clinical Trial

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Learn the process for managing biomedical product development for FDA approval	3	3	3	3	3	3	3	3
CO2	Gain an in-depth understanding of the clinical trials process through a modular, operations-focus approach	3	3	3	3	3	3	3	3
CO3	Acquire project management skills needed to successfully manage human clinical trials	3	3	3	3	3	3	3	3
CO4	Gain a global perspective on clinical trials management to better respond to the growing industry across the globe	3	3	3	3	3	3	3	3
CO5	Demonstrate the ethical principles, regulations, and guidelines governing clinical trials, such as ICH-GCP, FDA, EMA, and CDSCO regulations.	3	3	3	3	3	3	3	3
CO6	Learn from instructors with industry expertise in clinical trials management	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
Allied Health PG Programmes
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

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CMCR659 Medical coding (4Cr)

Course Description

This course introduces the student with ICD Codes, CPT codes & HCPC for supplies/DME and procedures. Outpatient/inpatient coding and physician practice coding. The student will also understand coding from a reimbursement perspective and Utilize appropriate coding in anesthesia, surgery, radiology, pathology, and medical services and Electronic health records (EHR) systems.

Course Outcome

- Demonstrate a thorough understanding of CPT, ICD-10-CM, and HCPCS coding.
- Accurately code a variety of medical procedures, diagnoses, and services.
- Code from Progress notes, Operative reports, Pathology reports, and Radiology reports.
- Ensure compliance with healthcare regulations and standards.
- Apply coding knowledge to real-world scenarios through practical exercises and case studies.

Course Structure and Contents

Unit 1: Introduction to Medical Coding: Overview of medical coding and its importance in healthcare, Healthcare documentation and medical records, role of medical coders in insurance claims, billing, and compliance, Basics of HIPAA regulations and patient confidentiality

Unit 2: Medical Terminology and Anatomy for Coding: Fundamentals of medical terminology (prefixes, suffixes, root words), understanding human anatomy and physiology for accurate coding, Common diseases, conditions, and medical procedures, Pharmacology basics for coding medications

Unit 3: Coding Systems and Classification: ICD (International Classification of Diseases) Coding, ICD-10-CM (Clinical Modification), ICD-10-PCS (Procedure Coding System), CPT (Current Procedural Terminology) coding, evaluation, and management (E/M) coding, Surgery, anesthesia, radiology, and pathology coding, HCPCS (Healthcare Common Procedure Coding System) Coding, Level I and Level II codes, Durable medical equipment (DME) coding

Unit 4: Medical Billing and Reimbursement Process: Basics of medical billing and claim submission, CMS (Centers for Medicare & Medicaid Services) guidelines, Revenue cycle management (RCM) and insurance policies, Denials, rejections, and appeals process, Fraud, abuse, and compliance in coding

Unit 5: Advanced Coding Concepts and Career Preparation: Modifiers and coding guidelines for complex cases, Risk adjustment coding (HCC) and DRG coding, Electronic

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Health Records (EHR) and coding automation, certification preparation (CPC, CCS, CCA) for AAPC and AHIMA exams, career opportunities and trends in medical coding

LEARNING RESOURCE MATERIAL

Primary Text books-

- Step-by-Step Medical Coding, Carol J. Buck, 2024 Edition
- ICD-10-CM Expert for Physicians, AAPC, 2024 Edition
- CPT Professional, American Medical Association (AMA), 2024 Edition

Reference books-

- HCPCS Level II Professional, American Medical Association (AMA), 2024 Edition
- Medical Coding ICD-10-CM, AAPC, 2024 Edition

Reference materials (Journals):

- Journal of AHIMA (American Health Information Management Association)
- AAPC Healthcare Business Monthly
- Perspectives in Health Information Management
- Medical Coding & Billing Magazine
- Healthcare Financial Management (HFMA Journal)
- Medical Economics Journal

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research (Allied Health)
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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Principal

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the Basics of Medical Coding	3	2	2	2	1	3	3	2
CO2	Apply Medical Terminology and Anatomy in Coding	3	3	2	2	1	3	3	3
CO3	Navigate ICD-10 CM, CPT, and HCPCS Coding Systems	3	3	3	3	2	3	3	3
CO4	Ensure Accuracy And Compliance in Coding	3	3	3	3	2	3	3	2
CO5	Analyze and Abstract Medical Records for Coding	3	3	3	3	2	3	3	3
CO6	Understand Medical Billing and Reimbursement Processes	3	3	3	2	3	3	3	3
CO7	Use Medical Coding Software and Tools	3	3	3	3	3	3	3	2

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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Principal

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CMCR660 Quality Assurance & Quality Control in Clinical Trials (4Cr)

Course Description

The aim of the subject is to introduce students to the main theoretical concepts and in the conduct of Pharmaceutical and clinical research. The syllabus provides short discourse about the emergence of QA/QC as a formalized discipline, its developments, and its present status by considering how is being been practiced starting from basic laboratory experimental work to present issues pertaining to whole and large scale productions.

Course Outcomes:

- Understand Healthcare Systems & Policies
- Develop Leadership & Management Skills
- Apply Financial & Economic Principles in Healthcare
- Address Public Health & Ethical Considerations
- Improve Healthcare Operations & Quality Management
- Enhance Communication & Teamwork in Healthcare Settings
- Utilize Health Information Systems & Technology

Course Structure and Contents

Unit I

Introduction to QC, QA & GCP Audits: Introduction to Quality in Clinical Research, Process Mapping in Clinical trials, QA and QC in Clinical Research, QA Activities, QA Planning, QA SOPs, Practical exercises and Interactive sessions- Designing a process Map etc, Tools of Audits, Auditors - Who and What are they? Preparing for an Audit, Conduct of an Audit, CRO Audit, Practical Case Scenarios in Audits

Unit II

Prospective Pathway to Drug Discovery: Principles of drug discovery and development. clinical research process. Development and informational content for investigational new drugs application (IND), new drug application (NDA), abbreviated new drug application (ANDA), supplemental new drug application (SNDA), ICH Guidelines: purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines

Unit III

Regulatory Inspections: FDA Inspections- Preparation, Conduct, Reporting and Recording of Inspections, EMEA Inspections- Preparation, Conduct, Reporting of Inspections, MHRA Inspections- Preparation, Conduct, Reporting of Inspections, ANVISA Inspections, IEC/IRB Inspections, DCGI Inspections, Conduct of a Mock inspection, Differences between FDA and EMEA Inspections, Frauds, Misconduct and Errors, Practical Scenarios in Regulatory Inspections

Unit IV

Vice Principal (Allied Health PG Programmes) HIMS, SRHU Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences Dean -cum- Principal

Dr. Nikku Yadav Incharge Deptt. of Clinical Research Himalayan Institute of Medical Sciences Swami Rama Himalayan University Dehradun

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Emerging concepts of quality assurance for drugs, introduction, hazard analysis and critical control points (HACCP) methodology. pharmaceutical quality systems (PQS), quality review and quality documentation, regulatory control, regulatory drug analysis, interpretation of analytical data.

Unit V

Drug evaluation models: scope, limitations, high throughput screening (HTS), ethical considerations, protocol designing and its execution, GLP, requirement of animal care facility and role of statistics, evaluation of analgesic antipyretic and anti-inflammatory drugs, anti-diabetic, antihypertensive , anticancer agents etc.

Details of laboratory experiments to be considered for intensive writing and hands on work

1. Designing of SOPs for QA/QC work

a. Protocol
b. Investigator brochure
c. CRF
d. Screening form
e. Informed consent

2. Isolation of Active components from Medicinal Plants.
3. Virtual High Throughput screening of Druggable compounds using S/W.
4. Biochemical Estimations of Body fluids used in clinical investigation of Drugs.
5. Develop test procedure using dissolution method for in-vivo and in-vitro quality testing of drug.
6.Standardization and validation of basic Analytical Instruments used in Clinical investigation

LEARNING RESOURCE MATERIAL

Primary textbooks:

- Principles of Good Clinical Practice, Michael J. McGraw, Karen E. Stout, 2nd Edition (2018)
- Quality Assurance and Quality Control in the Analytical Chemical Laboratory: A Practical Approach, Piotr Konieczka, Jacek Namieśnik, 2nd Edition (2020)
- Good Clinical Practice: Standard Operating Procedures for Clinical Researchers, Josef Kolman, Paul Meng, Graeme Scott, 2nd Edition (2020)

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

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Reference books:

- Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections, Vera Mihajlovic-Madzarevic, 1st Edition (2021)
- Quality Management in Clinical Trials: A Guide for Effective Implementation, Fiona M. L. O'Neill, 1st Edition (2023)
- Clinical Trials and Good Clinical Practice, David Machin, Simon Day, Sylvan Green, 2nd Edition (2020)

Internet:

- American Chemical Society, www.acs.org
- Chemical Abstracts Service, www.cas.org
- International Union for Pure and Applied Chemistry (IUPAC), iupac.org
- International Union of Pharmacology (IUPHAR) Database www.iuphar-db.org
- Drug Bank, www.drugbank.ca
- PubChem, www.pubchem.ncbi.nlm.nih.gov

Dr. Nikhu Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand Healthcare Systems & Policies	3	3	2	2	3	3	3	2
CO2	Develop Leadership & Management Skills	3	2	3	2	3	3	2	2
CO3	Apply Financial & Economic Principles in Healthcare	3	2	3	3	3	3	2	2
CO4	Address Public Health & Ethical Considerations	3	3	3	3	2	3	3	3
CO5	Improve Healthcare Operations & Quality Management	3	2	3	3	3	3	3	2
CO6	Enhance Communication & Teamwork in Healthcare Settings	3	3	3	2	3	3	2	3
C07	Utilize Health Information Systems & Technology	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)

Himalayan Institute of Medical Sciences
Dean
-cum-
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CMCR661 Introduction to healthcare management (4Cr)

Course Description: This course provides knowledge about managing healthcare projects using tools and techniques. This course also describes the role of the regulatory professional in medical writing and biomedical research. And provides basic strategies for crafting an effective document: SOPs, CT Protocol, ICD, CRF, data management plan, and clinical study report.

Course Outcomes:

- Understand Healthcare Systems & Policies
- Develop Leadership & Management Skills
- Address Public Health & Ethical Considerations
- Apply Financial & Economic Principles in Healthcare
- Improve Healthcare Operations & Quality Management
- Enhance Communication & Teamwork in Healthcare Settings
- CO7: Utilize Health Information Systems & Technology

Course Contents and Structure

UNIT – I Introduction Concept of Hospitals – Planning and Design of a Hospital (Building & Physical Layout) – space Required for Separate Functions – Different types 14 of Hospitals – problems and constrains in different type of hospitals – history of hospital development – departmentation and organization structure of different types of hospitals.

UNIT – II Departmentation in Hospital Organization – Structure – Vertical & Horizontal – Clinical & Non – clinical – supportive & Ancillary Service Departments.

UNIT – III Management and Organization of Clinical Services Organization and Administration of various clinical services – Outpatient service – Inpatient Services – Emergency Services – Operation Theater – ICUs - super Specialty Service including their utilization study – Nursing Care and Ward Management.

UNIT – IV Organization and Management of Utility Services Organizing and Managing Facility Support Services – Laundry – Housekeeping – Pest control managing the Estate (Hospital Security) – Recent trends in disaster Management – Hospital Engineering Services (Plumbing, electricity, Civil, A/c, Lifts)- Ambulance Service.

UNIT – V Evaluation of Hospital And Health Services Accreditation – Setting of objective – Health indicators – applying Economic concepts to Service Evaluation – Assessing Patient Satisfaction – Techniques of Hospital Service Evaluation – Indicators of Hospital Efficiency and Effectiveness – Evaluation of Quality of Hospital Services – Management of Hazard and Safety in a Hospital Setup – Nursing Services in a Hospital – current – Issues in Hospital Management – Telemedicine – Bio Medical Waste Management – Organ Transplantation – Rehabilitation Services – Health Insurance and Managing Health Care – Medical audit – Hazard and Safety in a hospital Setup.

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
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Dean
-cum-
Principal

LEARNING RESOURCE MATERIAL

Primary Textbooks:

- Introduction to Health Care Management, Sharon B. Buchbinder, Nancy H. Shanks, Dale Buchbinder, 4th edition (2020)
- Cellucci, Leigh W., et al. *Essentials of Health Care Management*. 1st ed., Health Administration Press, 2021.
- McLaughlin, Daniel B., and Julie M. Hays. *Healthcare Operations Management*. 4th ed., Health Administration Press, 2022.

Reference books:

- Shortell, Stephen M., and Arnold D. Kaluzny. *Health Care Management: Organization Design and Behavior*. 6th ed., Cengage Learning, 2021.
- Darr, Kurt, and Jonathan S. Rakich. *Managing Health Services Organizations and Systems*. 7th ed., Health Professions Press, 2023.

Internet references-

1.https://corporatefinanceinstitute.com/resources/knowledge/strategy/operations-management/

2. https://managementhelp.org/operationsmanagement/

3. https://hbr.org/topic/operations-management

Journals-

- Journal of healthare management
- International journal of healthcare management
- Hands on Activities
- Journal of Hospital Management and Health Policy
- British Journal of Healthcare Management

Himalayan Institute of Medical Sciences Dean -cum- Principal

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand Healthcare Systems & Policies	3	3	2	2	3	3	3	2
CO2	Develop Leadership & Management Skills	3	2	3	2	3	3	2	2
CO3	Address Public Health & Ethical Considerations	3	3	3	3	2	3	3	3
CO4	Apply Financial & Economic Principles in Healthcare	3	2	3	3	3	3	2	2
CO5	Improve Healthcare Operations & Quality Management	3	2	3	3	3	3	3	2
CO6	Enhance Communication & Teamwork in Healthcare Settings	3	3	3	2	3	3	2	3
CO7	Utilize Health Information Systems & Technology	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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CMCR662 Pharmaceutical Business Development (4 Cr)

Course Description: This course apprises students with the skills needed to develop new business opportunities and enhance existing pharmaceutical business.

Course outcome:

After completion of course, student will:

- Understand the history and development of the pharmaceutical industry.
- Introduce the framework of the industry - research, development, manufacture and distribution of pharmaceutical products on an international level.
- Understand the role of Business Development within different types of pharmaceutical companies.
- To understand the different types of agreements used in the industry.
- To develop an understanding of the basic legal concepts with emphasis on application in a pharmaceutical and biotechnology business development and licensing context.
- To develop an understanding of the value and limitations of IPRs in encouraging innovation with emphasis on the use and application of IPRs in a pharmaceutical and biotechnology business development and licensing context.

Course Structure and Contents

This course, being in the form of a case study, is unstructured, continues & no end term will be proposed. Depending on student interest, proficiency and expertise available the student identifies a question to be addressed in the case study. Assisted by the internal supervisor, student develops a study design and plans for its timely execution. The student generates data and/or data mines and employs methods (after validation) to achieve the desired objectives. Students are generally advised to pursue real life case study with a problem-solving approach.

Course Contents-

UNIT I- : Introduction to Business Development in Pharmaceutical Marketing: Understanding the Pharmaceutical Marketing Landscape, role and responsibilities of a Business Development Manager, Ethical Considerations in Business Development.

UNIT II- Evolution of Indian Pharmaceutical Industry Different Evolution Phases of Indian Pharmaceutical Industry, Present status of Indian Pharma Industry (Present value, Key Players, Indian Bulk Drug Market).

UNIT III- Legal Issues In Business Development Contracts: Pharmaceutical Licensing Agreements, Alternative Arrangements for Marketing, Promotion and Exploitation of Pharmaceutical Products.

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Dr. Nikku Yadav
Charge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
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UNIT IV- Intellectual Property: Introduction to Intellectual Property Rights, Patents, Pharmaceutical Associated Intellectual Property Rights, Licensing and Exploitation of Intellectual Property Rights.

UNIT V- Case Studies and Practical Applications: Simulated Business Development Scenarios, Case Studies in Pharmaceutical Business Development, Real-world Application of Business Development Strategies

LEARNING RESOURCE MATERIAL

Primary textbooks-

- Pharmaceutical Lifecycle Management: Making the Most of Each and Every Brand, Tony Ellery, Neal Hansen, 2nd Edition (2020).
- Pharmaceutical Competitive Intelligence for the Regulatory Affairs Professional, Martin Austin, 1st Edition (2021)
- Pharmaceutical Market Access in Developed Markets, Ed Schoonveld, 3rd Edition (2023)

Reference books-

- Pharmaceutical Business Development: A Global Perspective, Metha Neermul, 1st Edition (2022)
- Pharmaceutical and Biomedical Project Management in a Changing Global Environment, Scott D. Babler, Daniele Fresca, 1st Edition (2021)

Journals-

- The Academy of Management Annals
- Pharmaceutical Development & Technology
- International Journal of Pharmaceutical and Healthcare Marketing
- Business Development & Licensing Journal For the Pharmaceutical Licensing Groups
- Research & Reviews: A Journal of Pharmaceutical Management
- Journal of Pharmaceutical Innovation

Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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-cum-
Principal

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the history and development of the pharmaceutical industry.	3	2	2	1	2	3	2	1
CO2	Introduce the framework of the industry - research, development, Manufacture and distribution of pharmaceutical products on an international level.	3	3	3	2	3	3	3	2
C03	Understand the role of Business Development within different types of Pharmaceutical companies.	3	3	3	2	3	3	3	3
C04	To understand the different types of agreements used inthe industry.	2	3	3	3	3	2	3	3
CO5	To develop an understanding of the basic legal concepts with emphasis on application in a pharmaceutical and biotechnology business development and licensing context.	2	3	3	3	3	2	3	3
CO6	To develop an understanding of the value and limitations of IPRs in encouraging innovation with emphasis on the use an application of IPRs in pharmaceutical and biotechnology business development and licensingcontext.	2	3	3	3	3	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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-cum-
Principal

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CMCR663 Health Analytics (4 Cr)

Course Description:

Health Analytics is an interdisciplinary field that applies data science, statistical techniques, and machine learning to healthcare data for improving decision-making, patient outcomes, and operational efficiency. This course provides students with the knowledge and skills to collect, analyze, and interpret health data using modern analytical tools and technologies.

Course Outcomes:

- Collect, clean, and manage healthcare datasets for analysis.
- Apply statistical and machine learning methods to healthcare problems.
- Use visualization techniques to communicate insights effectively.
- Assess the impact of analytics on healthcare decision-making and policy.
- Understand data security, privacy, and compliance in health analytics.

Course Contents and Structure

- Introduction to Healthcare Data Analytics- Electronic Health Records– Components of EHR- Coding Systems- Benefits of EHR- Barrier to Adopting HER Challenges- Phenotyping Algorithms.
- Challenges in Healthcare Data Analysis, Acquisition Challenges, Pre-processing, Transformation
- Social Media Analytics for Healthcare. Advanced Data
- Analytics for Healthcare: Review of clinical trials, Prediction Models. Statistical Prediction Models, Alternative Clinical Prediction Models, Survival Models, Predictive Models for Integrating Clinical and Genomic Data, Data Analytics for Pervasive Health, Fraud Detection in Healthcare, Pharmaceutical Discoveries and Clinical Decision Support Systems.

Teaching Methodology

Direct classroom teaching, discussion, case study, quiz, homework, assignment, project work, video, animation etc.

LEARNING RESOURCE MATERIAL

Primary Textbooks

- Health Analytics: Gaining the Insights to Transform Health Care, Jason Burke, 2nd Edition (2021)
- Big Data and Health Analytics, Katherine Marconi, Harold Lehmann, 1st Edition (2020)

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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- Healthcare Analytics for Quality and Performance Improvement, Trevor L. Strome, 1st Edition (2023)

Reference books:

- Health Informatics: A Systems Perspective, Gordon D. Brown, Tamara T. Stone, Timothy B. Patrick, 2nd Edition (2022)
- Predictive Analytics in Healthcare: A Data Mining Approach, Cynthia McKinney, Robert Stokes, 1st Edition (2022)

Reference Material (Journals, Hand-outs)-

Journals-

1. Healthcare analytics
2. Health care analysis
3. International Journal of Big Data and Analytics in Healthcare (IJBDAH)
4. International Journal of Applied Health Care Analytics
5. Journal of Healthcare Informatics Research

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
alayan Institute of Medical Sciences
Nami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Collect, clean, and mange healthcare datasets for analysis.	3	3	2	3	3	3	3	2
CO2	Apply statistical and machine learning methods to healthcare problems.	3	3	3	3	3	3	3	3
CO3	Use visualization techniques to communicate insights effectively.	3	3	3	2	3	3	3	3
CO4	Assess the impact of analytics on healthcare decision making and policy	3	3	3	3	3	3	3	3
CO5	Understand data security, privacy, and compliance in health analytics.	3	3	2	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun

Himalayan Institute of Medical Sciences
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CMCR664 QA and QC in pharmaceutics (4Cr)

Course Description: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Course Outcome:

- Understand Various aspects of quality control and quality assurance in pharmaceutical industries.
- Familiarized with important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.
- Understand the importance of documentation and responsibilities of QA & QC departments.
- Understand the scope of quality certifications applicable to pharmaceutical industries.

Course Content & Structure

Unit I

Introduction: Concept and evolution and scopes of Quality Control and Quality Assurance, Good Laboratory Practice, GMP, Overview of ICH Guidelines - QSEM, with special emphasis on Qseries guidelines. Good Laboratory Practices: Scope of GLP, Definitions, Quality assurance unit, protocol for conduct of non-clinical testing, control on animal house, report preparation and documentation. CPCSEA guidelines.

UNIT II

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER) Pharmaceutical Inspection Convention (PIC), WHO and EMEA covering: Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction, and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination and Good Warehousing Practice.

Unit III

Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), Developing specification (ICH Q6 and Q3), purchase specifications and maintenance of stores for raw materials. In process quality control and finished products quality control for following dosage forms in Pharma industry according to Indian, US and British pharmacopoeias: tablets, capsules, ointments, suppositories, creams, parenteral, ophthalmic and surgical products (How to refer pharmacopoeias).

UNIT IV

Documentation in pharmaceutical industry: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles- How to maintain,

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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-cum-
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retention and retrieval etc. Standard operating procedures (How to write), Master Batch Record, Batch Manufacturing Record, Quality audit plan and reports. Specification and test procedures, Protocols, and reports. Distribution records. Electronic data handling. Concepts of controlled and uncontrolled documents. Submission documents for regulators DMFs, as Common Technical Document and Electronic Common Technical Documentation (CTD, eCTD). Concept of regulated and non-regulated markets.

Unit V

Manufacturing operations and controls: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, charge-in of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging, reprocessing, salvaging, handling of waste and scrap disposal. Introduction, scope, and importance of intellectual property rights. Concept of trademark, copyright, and patents.

Primary Textbooks

- Good Manufacturing Practices for Pharmaceuticals, Joseph D. Nally, 7th Edition (2022)
- Pharmaceutical Quality by Design: A Practical Approach, Walkiria Schlindwein, Mark Gibson, 1st Edition (2022)
- Pharmaceutical Quality Assurance and Quality Control, Dipak Kumar Sarker, 1st Edition (2021)

Reference books:

- Handbook of Quality Control in Pharmaceuticals, Sarwar Beg, Sneh Punia, 1st Edition (2023)
- Pharmaceutical Quality Control Lab Guidebook: Regulations, Standards, and Best Practices, Lukasz Wygladacz, 1st Edition (2021

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Reference Material (Journals, Hand-outs)-

Journals-

- Healthcare analytics
- Health care analysis
- International Journal of Big Data and Analytics in Healthcare (IJBDAH)
- International Journal of Applied Health Care Analytics
- Journal of Healthcare Informatics Research

Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean -cum- Principal

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand Various aspects of quality control and quality assurance In pharmaceutical industries.	3	3	2	3	3	3	3	2
CO2	Familiarized with important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.	3	3	3	3	3	3	3	3
CO3	Understand the importance of documentation and responsibilities of QA & QC departments.	3	3	3	2	3	3	3	3
CO4	Understand the scope Of Quality certifications applicable to pharmaceutical industries.	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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GEEs101: Introduction to Artificial Intelligence

Course Description:
This course introduces fundamental concepts of Artificial Intelligence (AI), including problem-solving, search strategies, knowledge representation, machine learning, and applications of AI in various fields.

Course outcomes:

- Understand fundamental AI concepts, algorithms, and applications, including search strategies, machine learning, and knowledge representation.
- Develop AI-based solutions using programming tools like Python and apply AI techniques in natural language processing, computer vision, and decision-making.
- Critically evaluate the ethical and societal implications of AI and explore emerging trends shaping its future.

Unit 1: Introduction to AI, Definition and History of AI, Applications of AI in Various Domains, Strong AI vs. Weak AI, Ethics and Challenges in AI, Introduction to Robotics and AI in Autonomous Systems
Unit 2: Problem Solving and Search, State Space Representation, Uninformed Search Strategies: BFS, DFS, Uniform Cost Search, Informed Search Strategies: A*, Greedy Best-First Search
Adversarial Search: Minimax Algorithm, Alpha-Beta Pruning
Unit 3: Knowledge Representation and Reasoning, Logic and Propositional Logic, First-Order Logic (FOL), Rule-Based Systems and Expert Systems, Uncertainty Handling: Bayesian Networks, Fuzzy Logic
Unit 4: Machine Learning Basics: Introduction to Machine Learning (Supervised, Unsupervised, Reinforcement Learning), Decision Trees, Naïve Bayes Classifier, Artificial Neural Networks and Deep Learning Basics, Clustering Algorithms: K-Means, Hierarchical Clustering
Unit 5: AI Applications and Future Trends, AI in Healthcare, Finance, and Business, AI Ethics, Bias, and Explain ability
Future of AI: AGI, Quantum AI

LEARNING MATERIALS:
Primary Textbooks:

- Russell, Stuart, and Peter Norvig. *Artificial Intelligence: A Modern Approach*. 4th ed., Pearson, 2020.
- Poole, David L., and Alan K. Mackworth. *Artificial Intelligence: Foundations of Computational Agents*. 2nd ed., Cambridge University Press, 2017.
- Murphy, Kevin P. *Machine Learning: A Probabilistic Perspective*. 1st ed., MIT Press, 2012.

Reference books:

- Bishop, Christopher M. *Pattern Recognition and Machine Learning*. 1st ed., Springer, 2006.
- Goodfellow, Ian, Yoshua Bengio, and Aaron Courville. *Deep Learning*. 1st ed., MIT Press, 2016.

Internet references:

- **Artificial Intelligence (AI Journal)**
- Journal of Artificial Intelligence Research (JAIR)
- IEEE Transactions on Pattern Analysis and Machine Intelligence (TPAMI)
- Machine Learning Journal
- Neural Networks
- IEEE Transactions on Neural Networks and Learning Systems (TNNLS)
- xpert Systems with Applications
- Journal of Machine Learning Research (JMLR)

Dr. Nikhil Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean

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SWAMI RAMA HIMALAYAN UNIVERSITY

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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand fundamental AI concepts, algorithms, and applications	3	2	1	1	3	3	2	3
CO2	Develop AI-based solutions using programming tools	3	3	2	1	3	3	2	3
CO3	Critically evaluate ethical and societal implications of AI	3	1	2	3	2	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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GEMs101: Principles of Management

Course Description: This course introduces the fundamental principles and practices of management, including planning, organizing, leading, and controlling. It explores management theories, decision-making processes, leadership styles, and organizational behavior.

Course outcomes:

Understand the fundamental principles, functions, and roles of management in organizations.

- Apply planning, organizing, leading, and controlling (POLC) concepts to real-world business scenarios.
- Analyze different management theories and their relevance in modern business environments.
- Develop decision-making, leadership, and strategic thinking skills for effective management.
- Evaluate ethical, social, and global challenges in management and propose responsible solutions.

Course Content:

Unit 1: Introduction to Management: definition, nature, and scope of management functions of management: planning, organizing, leading, controlling evolution of management thought: classical, behavioral, and modern approaches, roles and skills of a manager

Unit 2: Planning and Decision-Making: Importance and types of planning, strategic planning vs. tactical planning, steps in the planning process, decision-making process, and techniques, organizing and organizational structure: principles of organization, types of organizational structures (functional, divisional, matrix, etc.)

Unit 3: Authority, responsibility, and delegation, organizational culture and change management. business ethics and corporate social responsibility (csr): ethical issues in management, corporate governance and business ethics, social responsibility of organizations, sustainable business practices

Unit 4: Leadership and Motivation: Leadership Theories: Trait, Behavioral, Contingency, Transformational, Motivation Theories: Maslow's Hierarchy, Herzberg's Two-Factor Theory, McGregor's Theory X and Theory Y, Leadership Styles and Their Impact on Organizations, Communication in Management

Unit 5: Controlling and Performance Management: Importance of control in management types of control: preventive, concurrent, feedback performance measurement techniques (kpis, balanced scorecard), quality management and six sigma

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Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean -cum- Principal

LEARNING MATERIAL

Primary Textbooks:

- Jones, Gareth R., and Jennifer M. George. *Contemporary Management*. 12th ed., McGraw-Hill, 2022.
- Bateman, Thomas S., Scott Snell, and Robert Konopaske. *Management: Leading & Collaborating in a Competitive World*. 14th ed., McGraw-Hill, 2022.
- Koontz, Harold, and Heinz Weihrich. *Essentials of Management: An International Perspective*. 11th ed., McGraw-Hill, 2020.

Reference books:

- Griffin, Ricky W. *Principles of Management*. 13th ed., Cengage Learning, 2022.
- Kinicki, Angelo, and Brian Williams. *Management: A Practical Introduction*. 10th ed., McGraw-Hill, 2023.

Internet References:

- Academy of Management Journal (AMJ)
- Journal of Management (JOM)
- Harvard Business Review (HBR)
- Strategic Management Journal (SMJ)
- Journal of Business Research (JBR)
- Leadership Quarterly (LQ)
- Journal of Organizational Behavior (JOB)
- International Journal of Management Reviews (IJMR)

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the fundamental principles, functions, and roles of management in organizations.	3	2	2	2	3	3	2	2
CO2	Apply planning, organizing, leading, and controlling (POLC) concepts to real-world business scenarios.	3	3	3	2	3	3	2	3
CO3	Analyze different management theories and their relevance in modern business environments.	3	2	3	2	3	3	3	2
CO4	Develop decision-making, leadership, and strategic thinking skills for effective management.	3	3	3	3	3	3	2	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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GESs102: Gender inequality and gender studies

Course Description:

This course explores gender as a social construct and examines gender inequality in various social, cultural, economic, and political contexts. It introduces key theories in gender studies, feminist movements, intersectionality, and policies addressing gender discrimination. The course also analyzes gender roles, representation in media, and global perspectives on gender justice.

Course outcomes:
Understand key concepts, theories, and frameworks related to gender inequality and gender studies.

- Analyze historical and contemporary gender disparities across social, economic, political, and cultural domains.
- Examine the role of institutions, policies, and media in shaping gender norms and identities.
- Critically evaluate intersectionality and the impact of gender on diverse communities, including marginalized groups.
- Develop informed perspectives on gender equity and propose strategies for social change and advocacy.

Course content:
Unit 1: Introduction to Gender Studies: Definition of gender vs. sex, understanding gender as a social construct key concept: patriarchy, feminism, gender identity, and sexual orientation historical overview of gender studies

Unit 2: Theories of Gender and Feminism: Feminist Theories: Liberal, Radical, Marxist, Intersectional Masculinity Studies and Gender Performativity (Judith Butler)
Intersectionality (Kimberlé Crenshaw) and Its Impact on Gender Discourse

Unit 3: Gender and Social Institutions: family and gender roles, education and gender bias, workplace and the gender pay gap, gender and political representation, LGBTQ2+ rights and challenges, gender and religion gender inequality in society: gender-based violence (domestic violence, sexual harassment, human trafficking), reproductive rights and healthcare disparities

Unit 4: Gender and Law: International Gender Equality Policies (CEDAW, SDGs, etc.)
Gender Laws: Equal Pay Act, Anti-Harassment Laws, Maternity Rights
Future Directions for Gender Equality

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Unit 5: Case Studies on Gender Justice Movements
Gender Representation in Media and Culture: Gender stereotypes in films, advertising, and literature, The Role of social media in gender movements, women in leadership and public life

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean -cum- Principal

Contemporary Debates and Future Perspectives: gender and technology (ai bias, digital gender divide), gender in conflict and war

LEARNING MATERIAL

Primary textbooks:

- Butler, Judith. *Gender Trouble: Feminism and the Subversion of Identity*. 2nd ed., Routledge, 2020.
- Rippon, Gina. *The Gendered Brain: The New Neuroscience That Shatters the Myth of the Female Brain*. 1st ed., Bodley Head, 2019.
- Connell, Raewyn, and Rebecca Pearse. *Gender: In World Perspective*. 4th ed., Polity Press, 2021.

Reference books:

- Messerschmidt, James W., et al., editors. *Gender Reckonings: New Social Theory and Research*. 1st ed., NYU Press, 2018.
- Srinivasan, Amia. *The Right to Sex: Feminism in the Twenty-First Century*. 1st ed., Farrar, Straus and Giroux, 2021.

Internet References:

- Gender & Society
- Feminist Theory
- Signs: Journal of Women in Culture and Society
- Gender, Work & Organization
- Journal of Gender Studies
- Feminist Media Studies
- International Feminist Journal of Politics
- Gender, Place & Culture

Dr. Nikka Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand key concepts, theories, and frameworks related to gender inequality and gender studies.	3	2	2	2	3	3	2	3
CO2	Analyze historical and contemporary gender disparities across social, economic, political, and cultural domains.	3	2	3	2	3	3	2	3
CO3	Examine the role of institutions, policies, and media in shaping gender norms and identities.	3	2	3	3	3	2	3	3
Co4	Critically evaluate intersectionality and the impact of gender on diverse communities, including marginalized groups.	3	2	3	3	3	2	3	3
CO5	Develop informed perspectives on gender equity and propose strategies for social change and advocacy.	3	2	3	3	3	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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GESs102 Mental Health & Well being

Course Description: Mental Health & Wellness is a course designed to reinforce and empower a student's overall mental health, especially in times of crisis or trauma. This course is designed to help students cope with difficult situations, self-soothe, and manage conflicting emotions. It seeks to give students the tools they need to keep their mind and well-being safe and sound.

Course outcomes: Understand the fundamental concepts of mental health, well-being, and psychological resilience.

- Identify common mental health disorders, their causes, symptoms, and available treatment approaches.
- Analyze the impact of social, cultural, and environmental factors on mental health and well-being.
- Apply stress management, mindfulness, and self-care techniques to promote personal and community well-being.
- Evaluate mental health policies, stigma reduction strategies, and the role of mental health advocacy in society

Course Contents and Structure

Unit I-CONCEPT OF MENTAL HEALTH: Importance of mental health reducing the stigma of mental illness, characteristics and causes of poor mental health, ethical and legal aspects of treatment, ethical principles from the apa , achieving mental health and role of teachers.

Unit II- CONCEPT OF MENTAL WELLBEING: Indicators of Mental Wellbeing : hope , self-care , personal responsibility , positive relationship with others , purpose in life , productivity , clarity of thinking , emotion , cognition. Indicators of Emotional Wellbeing : eliminating negative emotions , bouncing back from difficulties , saying 'no' without feeling guilty, being able to relax , talking with someone about emotional concerns , sharing feelings with others.

Unit III- STRESS AND COPING: Nature and sources of stress; personal and social mediators of stress; effects of stress on physical and mental health; coping and stress management. risk factors in mental illness : genetic predispositions , homelessness and unemployment , alcohol and other drug use , discrimination and other racial injustice , family conflict and domestic violence , stressful life events

Unit IV: ABNORMAL BEHAVIOR: Meaning, causes and classification, historical background, major figures in early history of abnormal behavior, mental health problems in India, historical development of mental asylums in India, current mental health initiatives in India, future directions for mental health in India.

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Unit V: HEALTH MANAGEMENT: Health enhancing behaviours: exercise, nutrition, meditation, yoga; health compromising behaviours (alcoholism, smoking, internet addiction); techniques for improving mental wellbeing : effective , affordable and feasible

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

strategies to promote , protect and restore mental wellbeing. counselling , psychotherapy , assertiveness training , relaxation technique , biofeedback

LEARNING RESOURCE MATERIAL

Primary textbooks:

- Bessel van der Kolk. *The Body Keeps the Score: Brain, Mind, and Body in the Healing of Trauma*. Updated ed., Penguin, 2023.
- Gabor Maté. *The Myth of Normal: Trauma, Illness, and Healing in a Toxic Culture*. 1st ed., Avery, 2023.
- Lori Gottlieb. *Maybe You Should Talk to Someone: A Therapist, HER Therapist, and Our Lives Revealed*. Revised ed., Houghton Mifflin Harcourt, 2024.

Reference books:

- Johann Hari. *Stolen Focus: Why You Can't Pay Attention—and How to Think Deeply Again*. 1st ed., Crown Publishing, 2023.
- Nicole LePera. *How to Meet Your Self: The Workbook for Self-Discovery*. 1st ed., Harper Wave, 2024.

Internet References:

- Journal of Mental Health – Taylor & Francis
- BMC Psychiatry – BioMed Central
- JAMA Psychiatry – American Medical Association
- The Lancet Psychiatry – Elsevier
- International Journal of Mental Health Systems – Springer
- World Psychiatry – World Psychiatric Association
- Journal of Affective Disorders – Elsevier
- Psychological Medicine – Cambridge University Press
- Clinical Psychology Review – Elsevier

Annual Review of Clinical Psychology – Annual Review

Dr. Nikita Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Himalayan Institute of Medical Sciences
Dean
-cum-
Principal

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REGISTRAR
SWAMI RAMA HIMALAYAN UNIVERSITY

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S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand the fundamental concepts of mental health, well-being, and psychological resilience.	3	2	2	2	3	3	2	3
CO2	Identify common mental health disorders, their causes, symptoms, and available treatment approaches.	3	2	3	2	3	3	2	3
CO3	Analyze the impact of social, cultural, and environmental factors on mental health and well-being	3	2	3	3	3	2	3	3
CO4	Apply stress management, mindfulness, and self-care techniques to promote personal and community well-being.	3	2	3	3	3	2	3	3
CO5	Evaluate mental health policies, stigma reduction strategies, and the role of mental health advocacy in society.	3	2	3	3	3	2	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun

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GEMS102 Innovation, Business Models and Entrepreneurship

Course Description: This course provides learners with a foundational understanding of the business environment in which entrepreneurs operate. It explores methods for launching a new venture, including developing organizational and business plans and formulating strategies for growth. Designed to engage students in the entrepreneurial journey, the course offers insights into the entrepreneur's role and characteristics while equipping them with essential skills for effective venture planning and success.

Course outcomes:

- Understand key concepts of innovation, business models, and entrepreneurship in various industries.
- Analyze different types of innovation and their role in creating competitive advantages.
- Develop and evaluate business models using frameworks such as the Business Model Canvas.
- Identify opportunities, assess risks, and formulate strategies for launching and scaling a startup.
- Apply entrepreneurial thinking to solve real-world business challenges and drive sustainable growth.

Course Contents and Structure

Unit-1: Evolution, Characteristics, Nature, Types, Functions of Entrepreneur - distinction between an entrepreneur and a manager, concept, growth of entrepreneurship in India, the entrepreneurial perspective, the entrepreneurial decision process, types of startups, role of entrepreneur's economic development, the future of entrepreneurs, entrepreneurial process, manager vs entrepreneur decision making, intrapreneurship.

Unit-2: Entrepreneurial feelings, entrepreneur background and characteristics, motivation role models and support systems, male versus female entrepreneurship, entrepreneurs versus inventors, the nature of international entrepreneurship, international versus domestic entrepreneur.

Unit-3: Entrepreneur, Theories of entrepreneurship: economic, classical, neo classical, Austrian market process, psychological, personality traits, need for achievement, sociological, anthropological entrepreneurial, opportunity based entrepreneurship theory, resource based entrepreneur, financial capital/ liquidity, social capital or social network theory.

Unit-4: Clarence Danhof Classification, arthur h. cole classification, classification on the basis of ownership, classification based on the scale of the enterprise, entrepreneurial motivation, entrepreneurial motivation – the needs framework, manifest needs theory.

Unit-5: Sources of new Idea, methods of generating ideas, creative problem solving, opportunity recognition, product planning and development, opportunity recognition,

business structure, creating a business plan, market size analysis, e-commerce and startups, financial support for business plan, regulations to set up a and laws, legal issues in setting up the organization, patents, business methods patents, trademarks, copyrights, trade secrets, licensing, product safety and liability, insurance, contracts.

LEARNING RESOURCE MATERIAL

Primary textbooks:

- Eric Ries. *The Startup Way: How Modern Companies Use Entrepreneurial Management to Transform Culture and Drive Long-Term Growth*. 1st ed., Currency, 2023.
- John Bessant and Joe Tidd. *Innovation and Entrepreneurship*. 5th ed., Wiley, 2024.
- D. S. Pugh and D. J. Hickson. *Management Worldwide: The Impact of Societal Culture on Organizations Around the Globe*. 3rd ed., Penguin, 2023.

Reference books:

- Alexander Osterwalder and Yves Pigneur. *The Invincible Company: How to Constantly Reinvent Your Organization with Inspiration From the World's Best Business Models*. 1st ed., Wiley, 2023.
- Scott D. Anthony, Paul Cobban, Natalie Painchaud, and Andy Parker. *Eat, Sleep, Innovate: How to Make Creativity an Everyday Habit Inside Your Organization*. 1st ed., Harvard Business Review Press, 2024

Internet resources:

- Journal of Business Venturing
- Entrepreneurship Theory and Practice
- Research Policy
- Innovation: Management, Policy & Practice
- Journal of Product Innovation Management
- Small Business Economics
- Technovation
- Journal of Innovation and Entrepreneurship

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

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Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Understand key concepts of innovation, business models, and entrepreneurship in various industries.	3	2	2	2	3	3	2	3
CO2	Analyze different types of innovation and their role in creating competitive advantages.	3	3	3	2	3	3	2	3
CO3	Develop and evaluate business models using frameworks such as the Business Model Canvas.	3	3	3	2	3	3	3	3
CO4	Identify opportunities, assess risks, and formulate strategies for launching and scaling a startup.	3	3	3	3	3	3	2	3
CO5	Apply entrepreneurial thinking to solve real-world business challenges and drive sustainable growth.	3	3	3	3	3	3	3	3

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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CMCR700

Course Description: Student will undertake a project on a topic of his/her choice in the relevant area of specialization advised by the internal supervisor. An external supervisor may be involved, preferably from industry, research institute, or University other than SRHU depending on student inclination and proficiency and expertise available.

Course outcome (COs) mapping with Program Outcomes (POs) & Program Specific Outcomes (PSOs)

S. NO	Course Outcomes	PO1	PO2	PO3	PO4	PO5	PSO1	PSO2	PSO3
		Basic Researcher & critical thinker	Data manager	Professional	Communicator	Lifelong Learner	Clinical Trial Design & Execution	Regulatory Affairs & Ethical Compliance	Translational & Evidence-Based Research
CO1	Identify a research problem, formulate research questions, and define objectives.	3	2	2	1	2	3	2	3
CO2	Develop a research methodology, including experimental design and data collection strategies.	3	3	3	2	2	3	3	3
CO3	Conduct independent research while adhering to ethical and regulatory guidelines.	3	3	3	2	2	3	3	3

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CO4	Analyze and interpret research findings using statistical tools and methodologies.	3	3	2	1	3	3	2	3
CO5	Write a well-structured dissertation with all key components.	2	3	2	3	3	3	3	3
CO6	Present research findings through oral presentations, posters, or seminars.	2	2	2	3	3	2	2	3
CO7	Apply research ethics, including plagiarism, data integrity, and responsible conduct.	3	3	3	2	3	3	3	3
CO8	Demonstrate problem-solving skills and critical thinking in addressing challenges.	3	3	2	2	3	3	3	3
CO9	Contribute to scientific knowledge through research publications and innovations.	3	3	3	3	3	3	3	3
CO10	Develop professional competencies such as time management and teamwork.	3	2	2	3	3	3	2	3

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LOG BOOK

The students shall maintain a record log book of the work carried out by them during the period of training. The log book shall be maintained as recommended by the department, checked, and assessed periodically, signed by the faculty regularly and checked and signed by the HOD at the end of every month.

Sample Logbook page in MSc Clinical Research

Sub Item: Assignments/ Seminars/ Hands on activity (Dry/ Wet/ Field)/ Self Directed Learning

1	2	3	4	5	6	7	8
Competency # addressed	**Name of Activity**	**Date completed: dd-mm-yyyy**	**Attempt at activity** First or Only (F) Repeat (R) Remedial (Re)	**Rating** Below (B) expectations Meets (M) expectations Exceeds (E) expectations	**Decision of faculty** Completed (C) Repeat (R) Remedial (Re)	**Initial of faculty and date**	**Feedback Received** Initial of learner

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ASSESSMENT

The assessment opportunities shall be broadly divided into:

- Formative assessment/ Internal assessment
- Summative assessment/ End term assessment

Assessment	Type		Modes of Assessment
Summative Assessment	**End Term Semester Examination (100 Marks, Weightage 60%)**		• Structured question • PBQ • Short answers questions (SAQ) • Answer in brief • Give reasoning
Formative Assessment	**Internal Assessment (100 Marks, Weightage 40%)**		
	Sessional I		**25%**
	Sessional II		**25%**
	Continuous Assessment		**50%**
	Continuous Assessment (50%)	**Hands on activity (30%)**	• Student Knowledge & clarity of thought analytical ability • Hands-on skills • Effort (Data generation, Data generation, Data log, analysis,) • Compilation of work & submission (within time limit) • DOAP • Viva Voce • Record maintenance, attitudinal assessment, and timely submission
		Assignments (5%)	• Student Knowledge & clarity of thought analytical ability, Originality • Regularity & Timely submission • Handling of QA
		Seminar (10%)	• Content originality • Critical thought • Way of presentation/ body Language/ Presentation skills • Handling of QA/ Viva Voce
		Logbook/ Efforts (5%)	• Day to day assessment • Daily skill assessment

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In brief: In accordance with UGC MERP guidelines Learning Assessment Components comprise a combination of Internal assessment and End term examination. The weightage % distribution of marks generally follows 40:60 ratio (Internal Assessment vs End term examination).

Dr. Nikku Yadav
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Continuous assessment is conducted utilizing Performance-based Rubrics with varied % weightage distribution on the scale of 1-5.

Eligibility criteria to appear in University Examination

1. **Attendance:** A student must have a minimum of 75% attendance of total actual academic/working days.
2. In accordance with UGC MERP guidelines Learning Assessment Components comprise a combination of Continuous assessment and End term examination. The weightage % distribution of marks generally follows 40:60 ratio (Continuous vs End term)
3. Continuous assessment is conducted utilizing Performance-based Rubrics with varied % weightage distribution on the scale of 1-5
4. To render students' industry-ready, a great emphasis is laid on hands-on real time activities and application rather than didactic teaching alone. Accordingly, assessment criterion is customized, based on course-specific requirements. Learning assessment Components for both are further prescribed in well-defined Course Structures for each course (Table 1 above)
5. Student must secure at least 50% marks of total marks assigned for Internal Assessment.

Learning Assessment Components (LAC) of Continuous assessment.

Fundamental Course/ Core Course / Degree Specific Elective Course/ Generic Elective Course/ Ability Enhancement Compulsory Course/ Skill Enhancement Course: Each LAC derives from performance-based Rubrics specific to the requirement of particular course, hence may vary. Assessed generally on a scale of 1-5 or letter grades each, as preferred by Tutor (Table 1 above)

I. Assignment -5 % Weightage

II. Hands on activity (Dry/ Wet/ Field) -30% Weightage

III. Seminar 10% Weightage

IV. Effort/ Logbook/ Portfolio 5% Weightage

Research Project/Elective Report/ Dissertation:

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LAC Continuous Assessment 100			
Data generation/mining, Data log, analysis, proficiency in skills being learnt. Assessed by periodic observation/ Seminars	Critical thinking & Imagination as revealed in periodic writings/ seminars/ discussions	Précis of related high impact research articles (2 best of 4)	Effort
40	30	20	10
LAC End Term Assessment (Summative) 100			
Report/ Thesis 60	**Presentation with Viva Voce 40**		
Data, Content, inferences, clarity, reasoning, review of literature, timely submission	Subject knowledge as revealed from: Ability to explain & Clarity of Thought	Grasp: Answers to Questions	Expression & Body language
60	20	15	5

QUESTION PAPER PATTERN

End term examination in general is conducted thru question papers deriving from all 5 Units with equal distribution comprising 4 kinds of question/ Unit viz., 1. Very Short Answer Questions – 2 marks, 2. Short Answer/Diagrammatic/Flowchart-Based Questions – 4 marks, 3. Structured Questions – 10 marks and Long Answer/Essay-Type Questions – 15 marks. Questions range from simple to complex challenging and represent the entire syllabus.

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END SEMESTER EXAMINATION (DECEMBER 2024)

Programme MSc Clinical Research Semester IIIrd /Academic Year:.....

Course Name: Biopharmaceuticals; Drug Development **Course Code: CMCR601**

Time allotted: 3 Hours **Max Marks: 100**

Note: Read all the instruction carefully.

Q.1 Attempt all **[10x2]**

a) Define thrombolytic agents with examples.
b) Define ANDA
c) Write the manufacturer of growth hormone (minimum 5).
d) Differentiate between biogenetics and biosimilars.
e) What is the function of erythropoietin?
f) What is DNA cloning?
g) Define biopharmaceuticals
ı What are monoclonal antibodies? Name the four types of MABs.
ı Differentiate between NDA and INDA.
h) What is the principle of recombinant DNA technology.

Q.2 Short notes/ Short answer (attempt any five out of Seven) **[5x4]**

a)	Elaborate the various types and applications of cytokines.	[CO2]
b)	Discuss the components of blood.	[CO1]
c)	Write a short note on biosynthetic human insulin and its analogs.	[CO2]
d)	Define Biopharmaceuticals also give their classification.	[CO1]
e)	Discuss the applications, advantages, and disadvantages of transgenic organisms.	[CO3]
f)	What are the responsibilities of FDA IND review team?	[CO1]
g)	Explain the DNA vaccine production process.	[CO3]

Q.3 Structured question (attempt any three out of four) **[3x10]**

a)	Describe the process of new drug discovery and development.	[CO3]
b)	What is a bioreactor? Explain the types and application of bioreactors.	[CO3]
c)	Define drug. Discuss the various sources of drugs with examples.	[CO1]
d)	Briefly explain production & types of insulin.	[CO2]

Q.4 Long Answer/ Easy type (Attempt any two out of three) **[2x15]**

a)	What are monoclonal antibodies? Discuss its types, applications and production.	[CO2]
b)	Give an account on the introduction of recombinant DNA technology. Also explain the production and applications of human recombinant erythropoietin.	[CO3]
c)	What are clinical research phase studies? Also explain the process of clinical trial designing.	[CO1]

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EXTERNAL EXPERTS PANEL FOR BOS MSC CLINICAL RESEARCH

S.No.	Name of Examiners/ Designation & Institute	Mobile No	Email address
1.	Dr. Manisha Bisht Additional Professor Department of Pharmacology AIIMS, Rishikesh	8475000263	manishabisht@yahoo.co.in
2.	Dr Suman Bala Professor & Head, Department of Pharmacology SGRRIM & HS, Dehradun	9456539173	yashsuman2000@gmail.com
3.	Dr. Saurabh Kumar Banerjee Dean School of Pharmaceutical Management The IIHMR University, Jaipur	8890398067	saurabh@iihmr.edu.in
4	Dr Nidhi Aggarwal Associate Professor, Centre for Clinical and Translational Research Jamia Hamdard University New Delhi	9818334770	nidhiagarwal@jamiahamdard.ac.in
5	Dr Ginpreet Kaur Professor, Department of Pharmacology, SPP School of Pharmacy & Technology Management, SVKM'S NMIMS University, Mumbai	9323398699;8169166082	ginpreet.kaur@nmims.edu, ginpreet.aneja@gmail.com
6	Prof Dr. Harvinder Popli Director, DPSRU Innovation and Incubation Foundation Delhi Pharmaceutical Science and Research University (DPSRU) New Delhi, India	+91-9899700704 /+91-1129552036	Popli.harvinder@dpsru.edu.in
7	Dr Lalitendu Mohanty Vice President, Clinical Research Department Panacea Biotec Ltd B-1 Extn./ A-27, Mohan Co-op. Industrial Estate, Mathura Road, New Delhi	+91 98119 23256	lalitendumohanty@panaceabiotec.com
8.	Dr Manoj Karwa Head, Clinical Trials and Pharmacovigilance Auriga Research Private Limited, 136, Sector-5, IMT Manesar, Gurugram, Haryana-122050	+91 93133 67656	manojkarwa@aurigaresearch.com

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

Vice Principal
(Allied Health Programmes)
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READING MATERIAL: LIST OF TEXTBOOKS, REFERENCE BOOKS & JOURNALS/ e RESOURCES

	Courses	Textbooks	Reference Books	Supplementary Books/ Online platforms, Links and other material
1	CMCR501 Biostatistics	1. Principles of Biostatistics, Marcello Pagano, Kimberlee Gauvreau, 3rd Edition (2022) 2. Biostatistics for the Biological and Health Sciences, Marc M. Triola, Mario F. Triola, 2nd Edition (2018)	1. Fundamentals of Biostatistics, Bernard Rosner, 8th Edition (2015) 2. Essentials of Biostatistics in Public Health, Lisa M. Sullivan, 3rd Edition (2017)	1. http://ocw.mit.edu/courses/biology/7-03-genetics-fall-2004/ 2. http://ocw.mit.edu/courses/biology/ 3. http://geneed.nlm.nih.gov 4. http://www.yourgenome.org 5. http://www.wellcome.ac.uk/en/genome/genesandbody/hg07f006.html
2	CMCR502 General Biochemistry	1. Lehninger Principles of Biochemistry (2021) 8th Edition: David L. Nelson & Michael M. Cox. 2. Biomolecules (2003) 3rd: S.R. Mishra	1. Enzymes: a Practical Introduction to Structure, Mechanism and Data Analysis (2002) 2nd Edition: Robert A. Copeland 2. Clinical Biochemistry (2016) 2nd Edition: Maheshwai Nanda	1. Biomolecules 2. Chem Bio Chem
3	CMCR503 Genetocs; Molecular Biology	1. Brooker RJ. Genetics: Analysis and Principles. 7th ed. New York: McGraw-Hill; 2023. 2. Krebs JE, Goldstein ES, Kilpatrick ST. Lewin's Genes XII. 12th ed. Burlington: Jones & Bartlett Learning; 2020. 3. Cox MM, Doudna J, O'Donnell M. Molecular Biology: Principles and Practice. 3rd ed. New York: W.H. Freeman; 2015.	1. Allison L. Fundamental Molecular Biology. 3rd ed. Hoboken: Wiley; 2021. 2. Cooper GM, Hausman RE. **The Cell: A Molecular Approach**. 8th ed. Sunderland: Sinauer Associates; 2022.	1. Nature Genetics 2. Genetics 3. American Journal of Human Genetics (AJHG) 4. Genome Research 5. PLoS Genetics
4	CMCR504/ CMCR511 Introduction to Clinical Research/ Clinical Trials	• Fundamental of Clinical Trials- Lawrence M. Friedman • Clinical Trials: A Practical Guide to Design, Anal Reporting • Introduction to Clinical Pharmacology- Edmun	1.Drug Safety from Molecule to Man (2017) 8th Edition - Park 2.Drugs From Discovery To Approval (2015) 3rd Edition - NG Rick 3.Clinical Trials A Practical Guide to Design, Analysis, and Reporting (2018) Kindle edition: Duolao Wang,	1. www.trialscentral.org/ 2. www.fda.gov/oc/gcp/ 3. www.who.int temporary Clinical Trials 2.Journal of Ayurveda and Integrative Medicine

Dr. Vikku Yadav
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		• Essentials of Medical Pharmacology 9th edition Tripathi • Fundamental of Clinical Trials (2019) 5th Edition- Lawrence M. Friedman • **"A Concise Guide to Clinical Trials"** by Allan Hackshaw (First Edition, 2024). • **"Clinical Trials"** edited by Timothy M. Pawlik and Julie A. Sosa (First Edition, 2020).	AmeetBakhai • Drug Safety From Molecule To Man (2017) 8th Edition - Park • "Fundamentals of Clinical Trials" by John I. Gallin, Frederick P. Ognibene, and Laura Lee Johnson (Fifth Edition, 2020). • Clinical Trials A Practical Guide to Design, Analysis, and Reporting (2018) Kindle edition: Duolao AmeetBakhai	https://nptel.ac.in/courses/127/106/127106137/ https://nptel.ac.in/courses/127/106/127106009/ http://ndl.iitkgp.ac.in/document/OFJCNlgyTDVVb3NGWlE5bUZWWDlITFJQTWdYVGEvWXdGQ3pDd0FUZGpJVT0 www.trialscentral.org/ www.fda.gov/oc/gcp/ www.who.int Contemporary Clinical Trials Clinical Trials: Journal of the Society for Clinical Trials Journal of Ayurveda and Integrative Medicine
5	CMCR505 Bioanalytical Techniques	• 1.Techniques in Microscopy and Cell Biology (2016) Kindle edition: Sharma VK Tata McGraw Hill • 2. Molecular biology of the cell (2018) 6th Edition: Alberts et al	1.Biochemical Technique: Theory & Practical (2015) 5th Edition: J.F. Robyt& B.J. White 2. Manual of Industrial Microbio. & Biotech (2017) 2nd Edition: Arnold L. Demain& Julian E. Davies	1 Journal of Analytical & Bioanalytical Techniques 2 Science
6	CMCR506 General Epidemiology	Principles of Epidemiology in Public Health Practice. Fifth Edition. CDC. • Epidemiology, by Leon Gordis, Elsevier Saunders publication	1.Epidemiology-Principles and Methods: Mac, Mahon & Pugh, 3. Community Medicine with Recent Advances: Suryakantha. 3.Park's Textbook of PSM (24th ed) by K.Park, Bhanot Publishers	Journal of Epidemiological Research • Journal of Epidemiology
7	CMCR512 Systems Pharmacology; Pre-Clinical Drug Development & Safety	• "Katzung's Basic & Clinical Pharmacology" by Bertram G. Katzung, Anthony J. Trevor, and Susan B. Masters (16th Edition, published in 2020). • "Pharmacology: A Patient-Centered Nursing Process Approach" by Joyce LeFever Kee, Evelyn R. Hayes, and Linda E. McCuistion (11th Edition, published in 2021).	• Drug Safety From Molecule To Man (2017) 8th Edition - Park "Goodman & Gilman's: The Pharmacological Basis of Therapeutics"	• www.trialscentral.org/ • www.fda.gov/oc/gcp/ • www.who.int • www.sciencedirect.com

Vice Principal (Allied Health PG Programmes) HIMS, SRHU Jolly Grant, Dehradun-248016

Dr. Nikku Yadav Incharge Deptt. of Clinical Research Himalayan Institute of Medical Sciences Swami Rama Himalayan University Dehradun

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		• "Pharmacology: An Introduction" by Henry Hitner and Barbara Nagle (7th Edition, published in 2020).		
8	CMCR513 Basic & Applied Immunology	• Basic Immunology: Functions and Disorders of the Immune System by Abul K. Abbas, Andrew H. Lichtman, and Shiv Pillai (7th Edition, published in 2020). • Immunobiology: The Immune System in Health and Disease by Charles A. Janeway Jr., Paul Travers, Mark Walport, and Mark J. Shlomchik (5th Edition, published in 2001). • The Immune System by Peter Parham (5th Edition, published in 2020).	• Clinical Immunology: Principles and Practice Hardcover (2018) 5th Edition: Robert R. Rich, Thomas A Fleisher • Immunology: A Short Course" by Richard Coico and Geoffrey Sunshine (7th Edition, published in 2020)	http://ndl.iitkgp.ac.in/document/SGhmbVpJeXkyWlA4OFBMVHBtUjMxTlM1UFhJUEhiamZseEpoSHRlcVNIOD0 http://ndl.iitkgp.ac.in/document/UGZCc1hPR3k3b2tUWllxK0k1TTFLcEo1ejhKSXJhSktqeVFkYnloNElEOD0
9	CMCR514 Basic & Applied Microbiology	• Microbiology (2024) 6thEdition: Michael Pelczar • Microbiology (2023)12th Edition: Dorothy Wood, Joanne Willey, Kathleen Sandman • Brock Biology of Microorganisms, Global Edition, (2024) 16th Edition: Michael T. Madigan	4. A Clinician's Dictionary of Pathogenic Microorganisms (2004) 5th Edition: James H. Jorgensen; Michael A. Pfaller 5. Fundamental Principles of Bacteriology (2017) 8th Edition: Salle A.J. 6. *Topley&*Wilson's *Microbiology and Microbial Infections*. 10th ed., HodderArnold ; ASM Press, 2005	International Journal of Medical Microbiology Journal of Applied Microbiology Journal of Clinical Microbiology Nature Microbiology

Vice Principal
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10	CMCR515 IPR;Ethics	• Principles of Research Methodology and Ethics in Pharmaceutical Sciences An Application Guide for Students and Researchers. Edited By Vikas Anand Saharan, Hitesh Kulhari, Hemant R Jadhav, Published August 30, 2024 by CRC Press • The Oxford Textbook of Clinical Research Ethics by Ezekiel J Emanuel (ed.) et al. 2023 • A textbook of pharmacovigilance and clinical research. Published by Career Point Ltd.	1. Ethics in Healthcare: A Philosophical Introduction Park (2018) Kindle edition: Ezio Di Nucci 2.Patient Care In Community Practice (2002) 2nd Edition Harman 3.Intellectual Property Rights (2014) : Pandey Neeraj, DharniKhushdeep	• Journal of Intellectual Property Rights • The Journal of Clinical Ethics • American Medical Association Journal of Ethics • Clinical Ethics • Journal of Clinical Trials & Patenting
11	CMCR516 Clinical Data Management	• "Clinical Data Management" – Richard K. Rondel, Sheila A. Varley, Colin F. Webb (2023, 3rd Edition) • "Principles of Clinical Data Management" – Lisa M. Danehower, Stephen J. Bennett (2022, 2nd Edition) • "Clinical Trials Data Management: A Practical Approach" – Eleanor McFadden (2023, 4th Edition)		1.National centre for biotechnology information, www.ncbi.nlm.nih.gov 2.Medidata, http://www.mdsol.com/products/rave_capture.htm 3.ClinPlus, http://www.clinplus.com/products/clinical-data-management/Drug Bank, www.drugbank.ca 4.Progeny, http://www.progenygenetics.com/clinical/
12	CMCR517 Environmental & Regulatory Physiology	• "Guyton and Hall Textbook of Medical Physiology" – John E. Hall (2023, 14th Edition) • "Ganong's Review of Medical Physiology" – Kim E. Barrett, Susan M. Barman, Scott Boitano (2023, 26th Edition)	• "Medical Physiology: Principles for Clinical Medicine" – Rodney A. Rhoades, David R. Bell (2022, 6th Edition) • "Textbook of Human Physiology for Medical Students" – Indu Khurana (2023, 3rd Edition)	http://intl-ajpregu.physiology.org/. • American Journal of Physiology - Endocrinology and Metabolism • American Journal of Physiology – Gastroenterology and Liver • American Journal of Psychiatry • Best Practice & Research: Clinical

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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		• "Berne & Levy Physiology" – Bruce M. Koeppen, Bruce A. Stanton (2022, 7th Edition)		Endocrinology & Metabolism • European Journal of Applied Physiology • European Journal of Endocrinology • Human Reproduction
13	CMCR518 Basics of Pharmaceutics	• Aulton's Pharmaceutics: The Design and Manufacture of Medicines edited by Kevin M.G. Taylor (4th Edition, published in 2021). • Applied Physical Pharmacy by W. Cary Mobley, Mansoor M. Amiji, and Thomas J. Cook (3rd Edition, published in 2021). • Drug Safety Evaluation, 4th Edition by Shayne Cox Gad and Dexter W. Sullivan Jr. (published in December 2022). • Fundamentals of Drug Development by Jeffrey S. Barrett (1st Edition, published in July 2022).	• Drug Metabolism Handbook: Concepts and Applications in Cancer Research, 2nd Edition by Ala F. Nassar, Paul F. Hollenberg, JoAnn Scatina, Soumen Kanti Manna, and Su Zeng (published in November 2022).	• Pharmaceutics • Pharmaceuticals • Journal of Pharmacy and Pharmaceutical Sciences • International Journal of Pharmaceutics • European Journal of Pharmaceutics and Biopharmaceutics • Journal of Pharmaceutical Sciences • Asian Journal of Pharmaceutical Sciences • Drug Development and Industrial Pharmacy
14	CMCR601 Biopharmaceutical & Drug Development	• Drug Discovery and Development by Raymond Hill and Duncan Richards (3rd Edition, published in 2020). • Fundamentals of Drug Development by James Swarbrick and James C. Boylan (1st Edition, published in 2021). • Biopharmaceutics: Applications in Drug Development by H. P. Rang and M. M. Dale (1st Edition, published in 2022).	• Development of Biopharmaceutical Drug-Device Products by Jeffrey K. Aronson and Brian R. Smith (1st Edition, published in 2023). • Recent Advances in Drug Discovery and Development edited by Sandeep Kumar Vyas (published in 2024).	• Journal of Biopharmaceutics and Biotechnology • Biopharmaceutics & Drug Disposition • Current Pharmaceutical Biotechnology • Journal of Biosimilars • Journal of Agricultural and Food Chemistry • Web Resources: • MOOC Resource(s): (Skaggs School of Pharmacy, UC San Diego, USA) - Drug Discovery, Development & Commercialization • USFDA - Science & Research (Drugs)

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(Allied Health PG Programmes)
HMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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15	CMCR602 Quality Assurance & Quality Control in Clinical Research	• Quality Assurance and Quality Control in the Analytical Chemical Laboratory: A Practical Approach, Piotr Konieczka, Jacek Namieśnik, 2nd Edition (2020) • Good Clinical Practice: Standard Operating Procedures for Clinical Researchers, Josef Kolman, Paul Meng, Graeme Scott, 2nd Edition (2020) • Fundamentals of International Clinical Research, Richard Chin, 2nd Edition (2019)	• Principles of Good Clinical Practice, Michael J. McGraw, Karen E. Stout, 2nd Edition (2018) • Clinical Trials Handbook, Shayne Cox Gad, 2nd Edition (2021) • The CRC's Guide to Coordinating Clinical Research, Karen E. Woodin, John C. Schneider, 4th Edition (2021)	• Quality Assurance Journal (Published by Wiley) • • Good Clinical Practice Journal (GCPj) • • Quality Management in Health Care • • Clinical Trials: Journal of the Society for Clinical Trials • • Journal of Clinical Research Best Practices • • Drug Information Journal (DIA Journal) • • Regulatory Toxicology and Pharmacology • • Journal of Pharmaceutical Sciences Internet: • American Chemical Society, www.acs.org • Chemical Abstracts Service, www.cas.org • International Union for Pure and Applied Chemistry (IUPAC), iupac.org • International Union of Pharmacology (IUPHAR) Database www.iuphar-db.org • Drug Bank, www.drugbank.ca • PubChem,

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Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikita Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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				www.pubchem.ncbi.nlm.nih.gov
16	CMCR603 Regulatory Affairs	• "Fundamentals of International Regulatory Affairs" – Regulatory Affairs Professionals Society (RAPS) (2023, 6th Edition) • "Fundamentals of US Regulatory Affairs" – Regulatory Affairs Professionals Society (RAPS) (2023, 15th Edition) • "Drug Regulatory Affairs: Fundamentals, Applications, and Industry Perspectives" – Siaw-Teng Liaw, Abdullah G. Assiri (2023, 2nd Edition)	• "New Drug Development: A Regulator Overview" – Mark Mathieu (2023, 9th Edition) • "FDA Regulatory Affairs: A Guide fo Prescription Drugs, Medical Devices, an Biologics" – David Mantus, Douglas J. Pisan (2023, 4th Edition)	• Bioequivalence Journal • Pharmaceutical Analysis Journal • Pharmacovigilance Journal • Journal of Pharmaceutical Regulator Affairs
17	CMCR604 Clinical and ,Pharamaco Epidemiology	• 1.Health Psychology: A Textbook (2012). (5th ed.) : Ogden, J. • 2.Textbook of Pharmacoepidemiology, 2nd Edition 2013. Editors: Strom BL, Kimmel SE, Hennessy S	• Pharmacoepidemiology and Pharmacovigilance: Synergistic Tools to Better Investigate Drug Safety. By Sabrina Nour and Gilles Plourde. Academic Press; 2019 • Essentials of Medical Pharmacology. By KD. Tripathi. Jaypee Brothers Medical Publishers. 8th edition; 2019	• https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146182/ https://courses.lumenlearning.com/boundless-psychology/chapter/introduction-to-health-psychology/
18	CMCR605 Research Methodology	• Kothari, C. R., and Gaurav Garg. *Research Methodology: Methods and Techniques*. 4th ed., New Age International Publishers, 2019. • Cooper, Donald R., and Pamela S. Schindler. *Business Research Methods*. 12th ed., McGraw-Hill Education, 2018. • Sekaran, Uma, and Roger Bougie. *Research Methods for Business: A Skill-Building Approach*. 8th ed., Wiley, 2020.	• Booth, Wayne C., Gregory G. Colomb, and Joseph M. Williams. *The Craft of Research*. 4th ed., University of Chicago Press, 2016. • Bryman, Alan. *Social Research Methods*. 5th ed., Oxford University Press, 2016.	• NPTEL/ Swayam • NCBI, www.ncbi.nlm.nih.gov • MEGA, http://www.megasoftware.net/ •eGradeSchool, http://www.egradschool.edu.au/whategsaoffe/researchmeth.jsp
19	CMCR606	• Pharmacovigilance: Principles and Practice, I. F	• Pharmacovigilance: A Practical Approach, Thao	• ipc.gov.in

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(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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	Pharmacovigilance	Edwards, Marie Lindquist, 2nd Edition (2023). • Good Pharmacovigilance Practices: A Guide fo Pharmaceutical Industry, M. N. Kumar, P. V. P. 1st Edition (2022) • Mann's Pharmacovigilance, Elizabeth B. Andrews, Nicholas Moore, 3rd Edition (2019).	Doan, Nicholas Moore, 1st Edition (2021). Pharmacovigilance: Critique and Ways Forward, Patrick Waller, Mira Harrison-Woolrych, 1st Edition (2020)	• cdsco.gov.in • www.trialscentral.org/ • www.fda.gov/oc/gcp/ • www.who.int
20	CMCR651 Intensive study of a disease: Etiology, Diagnostics, Therapeutics	• "Robbins & Cotran Pathologic Basis of Disease" – Vinay Kumar, Abul K. Abbas, Jon C. Aster (2024, 11th Edition) • "Harrison's Principles of Internal Medicine" – Dennis L. Kasper, Anthony S. Fauci, Stephen L. Hauser, Dan L. Longo, J. Larry Jameson, Joseph Loscalzo (2022, 21st Edition) • "The Molecular Basis of Cancer" – John Mendelsohn, Peter M. Howley, Mark A. Israel, Joe W. Gray, Craig B. Thompson (2023, 5th Edition)	• Goodman & Gilman's: The Pharmacological Basis of Therapeutics" – Laurence L. Brunton, Randa Hilal-Dandan, Björn C. Knollmann (2023, 14th Edition) • "Cancer Immunotherapy: Principles and Practice" – Lisa H. Butterfield, Howard L. Kaufman, Francesco M. Marincola (2022, 3rd Edition)	• Clinical Chemistry • The Journal of Molecular Diagnostics • Radiology • Nature Reviews Drug Discovery • Journal of Translational Medicine • The Lancet Oncology
21	CMCR652 Pharmacovigilance Elective	• Pharmacovigilance: Principles and Practice Edwards, Marie Lindquist, 2nd Edition (2023). • Good Pharmacovigilance Practices: A Guid Pharmaceutical Industry, M. N. Kumar, P. V. P. Cho Edition (2022) • Mann's Pharmacovigilance, Elizabeth B. Ar Nicholas Moore, 3rd Edition (2019).	• Pharmacovigilance: A Practical Approach, Thao Doan, Nicholas Moore, 1st Edition (2021). • Pharmacovigilance: Critique and Ways Forward, Patrick Waller, Mira Harrison-Woolrych, 1st Edition (2020)	• ipc.gov.in • cdsco.gov.in • www.trialscentral.org/ • www.fda.gov/oc/gcp/ • www.who.int
22	CMCR653 Medical Writing	• Writing in the Biological Sciences: A Comprehensive Resource for Scientific Communication" – Angelika H. Hofmann (2023, 4th Edition)	• "Regulatory Writing for the Pharmaceutical Industry" – Rahul G. Patel (2023, 1st Edition) • "Medical Writing: A Guide for Clinicians, Educators, and Researchers" – Robert B.	• Medical Writing (MEW) • Science Editor • Journal of Technical Writing and Communication (JTWC)

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
olly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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		• "How to Write and Publish a Scientific Paper" – Barbara Gastel, Robert A. Day (2022, 9th Edition) • "The Craft of Scientific Writing" – Michael Alley (2024, 5th Edition)	Taylor (2022, 3rd Edition) • "Scientific and Medical Writing: A Guide to Effective Communication" – Daniel W. Byrne (2023, 3rd Edition)	• Regulatory Focus • Applied Clinical Trials • Journal of Research Administration (JRA) • Research Integrity and Peer Review
23	CMCR654 Regulatory affairs, manufacturing [drugs and medical devices]	• Fundamentals of International Regulatory Affairs, Regulatory Affairs Professionals Society (RAPS), 8th Edition (2023) • FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics, Douglas J. Pisano, David Mantus, 4th Edition (2022) • Global Regulatory Affairs for Medical Devices, Sharon A. Olson, 1st Edition (2022)	• The Regulatory Affairs Handbook, Martin Rothman, Stephen Ferguson, 2nd Edition (2023) • New Drug Development: A Regulatory Overview, Mark Mathieu, 9th Edition (2022)	• Regulatory Affairs Journal (RAJ Pharma & RAJ Devices) • Regulatory Toxicology and Pharmacology • Pharmaceutical Regulatory Affairs: Open Access • Journal of Regulatory Science • Food and Drug Law Journal (FDLJ) Expert Review of Clinical Pharmacology
24	CMCR655 Analytical tools for pharmaceutical industry	• Analytical Techniques in the Pharmaceutical Sciences, Anette Müllertz, Yvonne Perrie, Thomas Rades, 1st Edition (2020) • Pharmaceutical Analysis: A Textbook for Pharmacy Students and Pharmaceutical Chemists, David G. Watson, 5th Edition (2022) • Handbook of Modern Pharmaceutical Analysis, Satinder Ahuja, Stephen Scypinski, 3rd Edition (2021)	• Analytical Method Validation and Instrument Performance Verification, Churgin Sam, 2nd Edition (2020) • Quality Control in the Pharmaceutical Industry, Murray Sam, 2nd Edition (2023)	• Journal of Pharmaceutical and Biomedical Analysis • European Journal of Pharmaceutical Sciences • Drug Design, Development and Therapy • International Journal of Pharmaceutics • Asian Journal of Pharmaceutical Sciences
25	CMCR656	• "Healthcare Data Integration and Interoperability" – John D. Halamka, Paul Cerrato (2023, 2nd Edition)	• "Big Data and Artificial Intelligence in Healthcare" – Arjun Panesar (2023, 2nd Edition)	• Journal of the American Medical Informatics Association (JAMIA) • International Journal of Medical Informatics

Vice Principal
(Allied Health PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
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		• "Interoperability and Data Analytics in Healthcare" – P. D. Verheij, M. A. Olsen (2024, 1st Edition) • "FHIR, HL7, and Healthcare Data Standards" – Grahame Grieve, Josh Mandel (2023, 1st Edition)	• "Clinical Data Science: Data Analysis and AI for Healthcare" – Christian Lovis, Mark Sendak (2024, 1st Edition) • "Machine Learning for Healthcare Analytics" – Michael R. Berthold, Rosaria Silipo (2023, 3rd Edition)	• Health Informatics Journal • npj Digital Medicine • Journal of Biomedical Informatics • Artificial Intelligence in Medicine
26	CMCR657 Clinical Trial Management	• Clinical Trials Handbook, Shayne Cox Gad, 2nd Edition (2021) • A Practical Guide to Managing Clinical Trials, JoAnn Pfeiffer, Cris Wells, 2nd Edition (2022) • Clinical Trials: Study Design, Endpoints, and Biomarkers, Drug Safety, and FDA and ICH Guidelines, Tom Brody, 3rd Edition (2020)	• Managing Clinical Trials: A Guide to Effective Practice, Annie Andritsch, Julianne Kirkland, 1st Edition (2023) • Clinical Research Compliance Manual: An Essential Guide for Human Research Protections Programs, John Steiner, 4th Edition (2022) • Clinical Research Coordinator Handbook, Deborrah Norris, 4th Edition (2021)	• Friedman, Furberg, and DeMets. Fundamentals of Clinical Trials (4th Edition). Springer, 2010. Free text available online at http://dx.doi.org/10.1007/978-1-4419-1586-3 • Machin and Fayers. Randomized Clinical Trials: Design, Practice and Reporting. Wiley-Blackwell, 2010 Piantadosi S. • Clinical Trials: A Methodologic Perspective (2nd Edition). New Jersey: John Wiley & Sons, 2005. **Journals-** • Open Access Journal of Clinical Trials • Contemporary Clinical Trials • Journal of Clinical Trials • International Journal of Clinical Trials • Journal of Clinical Research and Clinical Trials
27	CMCR659 Medical coding	• Step-by-Step Medical Coding, Carol J. Buck, 2024 Edition • ICD-10-CM Expert for Physicians, AAPC, 2024 Edition • CPT Professional, American Medical	• HCPCS Level II Professional, American Medical Association (AMA), 2024 Edition • Medical Coding ICD-10-CM, AAPC, 2024 Edition	• Journal of AHIMA (American Health Information Management Association) • AAPC Healthcare Business Monthly • Perspectives in Health Information Management

Vice Principal
(Allied Health & PG Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Dept. of Clinical Research
Himalayan Institute of Medical Sciences
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		Association (AMA), 2024 Edition		• Medical Coding & Billing Magazine • Healthcare Financial Management (HFMA Journal)
28	CMCR660 Quality Assurance & Quality Control in Clinical Trials	• Principles of Good Clinical Practice, Michael J. McGraw, Karen E. Stout, 2nd Edition (2018) • Quality Assurance and Quality Control in the Analytical Chemical Laboratory: A Practical Approach, Piotr Konieczka, Jacek Namieśnik, 2nd Edition (2020) • Good Clinical Practice: Standard Operating Procedures for Clinical Researchers, Josef Kolman, Paul Meng, Graeme Scott, 2nd Edition (2020)	• Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections, Vera Mihajlovic-Madzarevic, 1st Edition (2021) • Quality Management in Clinical Trials: A Guide for Effective Implementation, Fiona M. L. O'Neill, 1st Edition (2023) • Clinical Trials and Good Clinical Practice, David Machin, Simon Day, Sylvan Green, 2nd Edition (2020)	• American Chemical Society, www.acs.org • Chemical Abstracts Service, www.cas.org • International Union for Pure and Applied • Chemistry (IUPAC), iupac.org • International Union of Pharmacology (IUPHAR) Database www.iuphar-db.org • Drug Bank, www.drugbank.ca • PubChem, • www.pubchem.ncbi.nlm.nih.gov
29	CMCR661 Introduction to healthcare management	• Introduction to Health Care Management, Sharon B. Buchbinder, Nancy H. Shanks, Dale Buchbinder, 4th edition (2020) • Cellucci, Leigh W., et al. *Essentials of Health Care Management*. 1st ed., Health Administration Press, 2021. • McLaughlin, Daniel B., and Julie M. Hays. *Healthcare Operations Management*. 4th ed., Health Administration Press, 2022.	• Shortell, Stephen M., and Arnold D. Kaluzny. *Health Care Management: Organization Design and Behavior*. 6th ed., Cengage Learning, 2021. • Darr, Kurt, and Jonathan S. Rakich. *Managing Health Services Organizations and Systems*. 7th ed., Health Professions Press, 2023.	**Internet references-** 1.https://corporatefinanceinstitute.com/resources/knowledge/strategy/operations-management/ 2.https://managementhelp.org/operationsmanagement/ 3.https://hbr.org/topic/operations management **Journals-** • Journal of healthare management • International journal of healthcare management • Hands on Activities • Journal of Hospital Management and Health Policy • British Journal of Healthcare Management
30	CMCR662	• Pharmaceutical Lifecycle Management:	• Pharmaceutical Business Development: A	• The Academy of Management Annals

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(Allied Health & Programmes)
HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
Himalayan Institute of Medical Sciences
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	Pharmaceutical Business Development	Making the Most of Each and Every Brand, Tony Ellery, Neal Hansen, 2nd Edition (2020). • Pharmaceutical Competitive Intelligence for the Regulatory Affairs Professional, Martin Austin, 1st Edition (2021) • Pharmaceutical Market Access in Developed Markets, Ed Schoonveld, 3rd Edition (2023)	Global Perspective, Metha Neermul, 1st Edition (2022) • Pharmaceutical and Biomedical Project Management in a Changing Global Environment, Scott D. Babler, Daniele Fresca, 1st Edition (2021)	• Pharmaceutical Development & Technology • International Journal of Pharmaceutical and Healthcare Marketing • Business Development & Licensing Journal For the Pharmaceutical Licensing Groups • Research & Reviews: A Journal of Pharmaceutical Management • Journal of Pharmaceutical Innovation
31	CMCR 663 Health Analytics	• Health Analytics: Gaining the Insights to Transform Health Care, Jason Burke, 2nd Edition (2021) • Big Data and Health Analytics, Katherine Marconi, Harold Lehmann, 1st Edition (2020) • Healthcare Analytics for Quality and Performance Improvement, Trevor L. Strome, 1st Edition (2023)	• Health Informatics: A Systems Perspective, Gordon D. Brown, Tamara T. Stone, Timothy B. Patrick, 2nd Edition (2022) • Predictive Analytics in Healthcare: A Data Mining Approach, Cynthia McKinney, Robert Stokes, 1st Edition (2022)	• Healthcare analytics • Health care analysis • International Journal of Big Data and Analytics in Healthcare (IJBDAH) • International Journal of Applied Health Care Analytics • Journal of Healthcare Informatics Research
32	CMCR664 QA and QC in pharmaceutics	• Good Manufacturing Practices for Pharmaceuticals, Joseph D. Nally, 7th Edition (2022) • Pharmaceutical Quality by Design: A Practical Approach, Walkiria Schlindwein, Mark Gibson, 1st Edition (2022) • Pharmaceutical Quality Assurance and Quality Control, Dipak Kumar Sarker, 1st Edition (2021)	• Handbook of Quality Control in Pharmaceuticals, Sarwar Beg, Sneh Punia, 1st Edition (2023) • Pharmaceutical Quality Control Lab Guidebook: Regulations, Standards, and Best Practices, Lukasz Wygladacz, 1st Edition (2021	• Healthcare analytics • Health care analysis • International Journal of Big Data and Analytics in Healthcare (IJBDAH) • International Journal of Applied Health Care Analytics • Journal of Healthcare Informatics Research

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HIMS, SRHU
Jolly Grant, Dehradun-248016

Dr. Nikku Yadav
Incharge Deptt. of Clinical Research
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FINAL LETTER SIGNED BY ALL EXPERTS

Proposed detailed course, curriculum, and method of assessment in MSc Clinical Research program was discussed in detail. Suitable corrections were done and are accepted along with exhaustive list of recommended books.

Panels of External examiners with sufficient teaching experience have also been proposed.

S.no	Name	Signature
1	Dr. Nikku Yada, Incharge & Associate Professor, Department of Clinical Research	
2	Dr. Dilip Chandra Dhasmana Professor, Department of Pharmacology	
3	Dr Deep Shikha Professor, Department of Community Medicine	
4	Dr Ashwani Bhat Associate Professor, Dpartment of Neurology	
5	Dr Neha Sharma Associate Professor, Department of Community Medicine	
6	Dr Suman Bala Professor & Head, Department of Pharmacology SGRRIM & HS, Dehradun	
7	Dr Ginpreet Kaur Professor, Department of Pharmacology SPP School of Pharmacy & Technology Management	
8	Ms Ruchika Thapliyal Batch 2023 Senior Student	
9	Mr Ashutosh Dangwal Batch 2022 Alumni	

Dr. Nikku Yada
Incharge Deptt of Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun

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