॥ सा विद्या या विमुक्तये ॥

स्वामी रामानंद तीर्थ मराठवाडा विद्यापीठ, नांदेड

'ज्ञानतीर्थ', विष्णुपुरी, नांदेड – ४३१ ६०६ (महाराष्ट्र राज्य) भारत

SWAMI RAMANAND TEERTH MARATHWADA UNIVERSITY, NANDED

'Dnyanteerth', Vishnupuri, Nanded - 431 606 (Maharashtra State) INDIA

स्वामी रामानंद तीर्थ मराठवाडा विद्यापीठ, नांदेड

Established on 17th September, 1994, Recognized By the UGC U/s 2(f) and 12(B), NAAC Re-accredited with 'B++' grade

Fax : (02462) 215572

Phone: (02462)215542

Academic-1 (BOS) Section

website: srtmun.ac.

E-mail: bos@srtmun.ac.

विज्ञान व तंत्रज्ञान विद्याशाखे अंतर्गत राष्ट्रीय शैक्षणिक धोरण २०२० नुसार पदव्यूत्तर द्वितीय वर्षाचे अभ्यासक्रम (Syllabus) शैक्षणिक वर्ष २०२४–२५ पासून लागू करण्याबाबत.

प रि प त्र क

या परिपत्रकान्वये सर्व संबंधितांना कळविण्यात येते की, या विद्यापीठा अंतर्गत येणा–या सर्व संलग्नित महाविद्यालयामध्ये शैक्षणिक वर्ष २०२४–२५ पासून राष्ट्रीय शैक्षणिक धोरणानुसार पदव्यूत्तर द्वितीय वर्षाचे अभ्यासक्रम लागू करण्याच्या दृष्टीकोनातून विज्ञान व तंत्रज्ञान विद्याशाखे अंतर्गत येणा–या अभ्यासमंडळांनी तयार केलेल्या पदव्यूत्तर द्वितीय वर्षाच्या अभ्यासक्रमांना मा. विद्यापरिषदेने दिनांक १५ मे २०२४ रोजी संपन्न झालेल्या बैठकीतील विषय क्रमांक १५/५९–२०२४ च्या ठरावाअन्वये मान्यता प्रदान केली आहे. त्यानुसार विज्ञान व तंत्रज्ञान विद्याशाखेतील खालील एम. एस्सी द्वितीय वर्षाचे अभ्यासक्रम (Syllabus) लागू करण्यात येत आहेत.

1) M. Sc. II year Biotechnology (Affiliated College)
2) M. Sc. II year Biotechnology (Campus)
3) M. Sc. II year Bioinformatics (Sub Campus Latur)
4) M. Sc. II year Bioinformatics (Affiliated College)
5) M. Sc. II year Clinical Research (Affiliated College)
6) M. Sc. II year Botany (Campus)
7) M. Sc. II year Herbal Medicine
8) M. Sc. II year Boany (Affiliated College)
9) M. Sc. II year Geology (Campus)
10) M. Sc. II year Dairy Science
11) M. Sc. II year Electronics
12) M. Sc. II year Environmental Science
13) M. Sc. II year Environmental Science (Campus)
14) M. Sc. II year Geography (Campus)
15) M. Sc. II year Applied Mathematics
16) M. Sc. II year Mathematics
17) M. Sc. II year Mathematics (Campus)
18) M. Sc. II year Microbiology
19) M. Sc. II year Microbiology (Campus)
20) M. Sc. II year Statistics
21) M. Sc. II year Statistics (Campus)

सदरील परिपत्रक व अभ्यासक्रम प्रस्तुत विद्यापीठाच्या **www.srtmun.ac.in** या संकेतस्थळावर उपलब्ध आहेत. तरी सदरील बाब ही सर्व संबंधितांच्या निदर्शनास आणून द्यावी, ही विनंती.

'ज्ञानतीर्थ' परिसर,
विष्णुपुरी, नांदेड – ४३१ ६०६.
जा.क्र.:शै–१/एनइपी/विवत्रंविपदवी/२०२४–२५/१०९
दिनांक १२.०६.२०२४

डॉ. सरिता लोसरवार
सहा.कुलसचिव
शैक्षणिक (१–अभ्यासमंडळ) विभाग

प्रत : १) मा. आधिष्ठाता, विज्ञान व तंत्रज्ञान विद्याशाखा, प्रस्तुत विद्यापीठ.
२) मा. संचालक, परीक्षा व मुंल्यमापन मंडळ, प्रस्तुत विद्यापीठ.
३) मा. प्राचार्य, सर्व संबधित संलग्नित महाविद्यालये, प्रस्तुत विद्यापीठ.
४) मा. संचालक, सर्व संकुले परिसर व उपपरिसर, प्रस्तुत विद्यापीठ
५) सिस्टीम एक्सपर्ट, शैक्षणिक विभाग, प्रस्तुत विद्यापीठ. याना देवून कळविण्यात येते की, सदर परिपत्रक संकेतस्थळावर प्रसिध्द करण्यात यावे.

SWAMI RAMANAND TEERTH

MARATHWADA UNIVERSITY, NANDED

STRUCTURE AND SYLLABUS OF TWO-YEAR MASTERS PROGRAM IN SCIENCE

SUBJECT: CLINICAL RESEARCH

Under the Faculty of

Science and Technology

M. Sc. Second Year

(As per NEP-2020)

AFFILIATED COLLEGES

Effective From Academic Year 2024-2025

From the Desk of the Dean, Faculty of Science and Technology

Swami Ramanand Teerth Marathwada University, Nanded, enduring to its vision statement *"Enlightened Student: A Source of Immense Power",* is trying hard consistently to enrich the quality of science education in its jurisdiction by implementing several quality initiatives. Revision and updating curriculum to meet the standard of the courses at national and international level, implementing innovative methods of teaching-learning, improvisation in the examination and evaluation processes are some of the important measures that enabled the University to achieve the 3Es, the equity, the efficiency and the excellence in higher education of this region. To overcome the difficulty of comparing the performances of the graduating students and also to provide mobility to them to join other institutions the University has adopted the cumulative grade point average (CGPA) system in the year 2014-2015. Further, following the suggestions by the UGC and looking at the better employability, entrepreneurship possibilities and to enhance the latent skills of the stakeholders the University has adopted the Choice Based Credit System (CBCS) in the year 2018-2019 at graduate and post-graduate level. This provided flexibility to the students to choose courses of their own interests. To encourage the students to opt the world-class courses offered on the online platforms like, NPTEL, SWAYM, and other MOOCS platforms the University has implemented the credit transfer policy approved by its Academic Council and also has made a provision of reimbursing registration fees of the successful students completing such courses.

SRTM University has been producing a good number of high caliber graduates; however, it is necessary to ensure that our aspiring students are able to pursue the right education. Like the engineering students, the youngsters pursuing science education need to be equipped and trained as per the requirements of the R&D institutes and industries. This would become possible only when the students undergo studies with an updated and evolving curriculum to match global scenario.

Higher education is a dynamic process and in the present era the stakeholders need to be educated and trained in view of the self-employment and self-sustaining skills like start-ups. Revision of the curriculum alone is not the measure for bringing reforms in the higher education, but invite several other initiatives. Establishing industry-institute linkages and initiating internship, on job training for the graduates in reputed industries are some of the important steps that the University would like to take in the coming time. As a result, revision of the curriculum was the need of the hour and such an opportunity was provided by the New Education Policy 2020. National Education Policy 2020 (NEP 2020) aims at equipping students with knowledge, skills, values, leadership

qualities and initiates them for lifelong learning. As a result the students will acquire expertise in specialized areas of interest, kindle their intellectual curiosity and scientific temper, and create imaginative individuals.

The curriculum given in this document has been developed following the guidelines of NEP-2020 and is crucial as well as challenging due to the reason that it is a transition from general science based to the discipline-specific-based curriculum. All the recommendations of the Sukanu Samiti given in the NEP Curriculum Framework-2023 have been followed, keeping the disciplinary approach with rigor and depth, appropriate to the comprehension level of learners. All the Board of Studies (BoS) under the Faculty of Science and Technology of this university have put in their tremendous efforts in making this curriculum of international standard. They have taken care of maintaining logical sequencing of the subject matter with proper placement of concepts with their linkages for better understanding of the students. We take this opportunity to congratulate the Chairman(s) and all the members of various Boards of Studies for their immense contributions in preparing the revised curriculum for the benefits of the stakeholders in line with the guidelines of the Government of Maharashtra regarding NEP-2020. We also acknowledge the suggestions and contributions of the academic and industry experts of various disciplines.

We are sure that the adoption of the revised curriculum will be advantageous for the students to enhance their skills and employability. Introduction of the mandatory On Job Training, Internship program for science background students is praise worthy and certainly help the students to imbibe first-hand work experience, team work management. These initiatives will also help the students to inculcate the workmanship spirit and explore the possibilities of setting up of their own enterprises.

Dr. M. K. Patil,

Dean

Faculty of Science and Technology

Preamble:

The National Education Policy 2020 (NEP 2020) is formulated to revamp education system and lay down road map for new India. This policy is framed based on the fundamental pillars of access, equity, quality, affordability, and accountability and seeks to transform India into a thriving knowledge society and a global knowledge superpower.

Some of the important features of National Education Policy are increasing gross enrolment ratio in higher education, holistic and multidisciplinary education with multiple entry/exit options, establishment of academic bank of credit, setting up of multidisciplinary education and research Universities and National Research Foundation, expansion of open and distance learning to increase gross enrolment ratio, internationalization of education, motivated / energized and capable faculty, online and digital education and effective governance and leadership.

As per the National Education Policy, the Government of Maharashtra has proposed a model curriculum framework and an implementation plan for the State of Maharashtra. It is to suggest and facilitate the implementation of schemes and programs, which improve not only the level of academic excellence but also improve the academic and research environment in the state. The proposed curriculum framework endeavors to empower the students and help them in their pursuit for achieving overall excellence.

In view of NEP priority and in-keeping with its vision and mission, process of updating the curriculum is initiated and implemented in SRTM University at UG and PG level from the academic year 2023-2024.

Clinical Research plays a pivotal role in advancing medical knowledge, improving patient care, and shaping the future of healthcare. This preamble serves as an overview and introduction to the syllabus for a comprehensive clinical research course. The syllabus aims to provide students with a solid foundation in the principles, methodologies, and ethical considerations of clinical research. By achieving these goals, graduates of the M.Sc. Clinical Research program will be well-prepared to pursue successful careers in various sectors of the clinical research industry, including academia, pharmaceuticals, CROs, government agencies, and healthcare organizations. They will make significant contributions to the advancement of clinical research and evidence-based healthcare practices.

To ensure uniform curriculum and its quality at PG level, curriculum and syllabus of different Institutions and Universities is referred to serve as a base in updating the same. The comments or suggestions from all teachers, students and other stakeholders are welcome for upbringing this curriculum

Salient Features:

1. M.Sc. Clinical Research programs offer a comprehensive curriculum that covers various aspects of clinical research, including research methodologies, study design, data analysis, ethical considerations, regulatory compliance, and more. The curriculum is designed to provide students with a strong theoretical foundation and practical skills necessary for conducting high-quality clinical research studies.
2. Interdisciplinary Approach: Clinical research involves collaboration among professionals from diverse fields. M.Sc. Clinical Research program often adopts an interdisciplinary approach, bringing together faculty and students from different backgrounds such as medicine, pharmacy, nursing, and biostatistics, This fosters a multidisciplinary learning environment, allowing students to gain insights from various perspectives and develop effective teamwork skills.
3. Practical Training and Research Projects: M.Sc. Clinical Research program emphasizes practical training and hands-on experience. Students may have opportunities to participate in research projects, clinical trials, or internships, enabling them to apply their knowledge in real-world settings. This practical exposure enhances their research skills, critical thinking abilities, and prepares them for the challenges of the clinical research field.
4. Ethical Considerations and Regulatory Compliance: M.Sc. Clinical Research program emphasizes the importance of ethical conduct and compliance with regulatory guidelines in clinical research. Students learn about ethical principles, human subjects' protection, informed consent, and the ethical challenges faced in conducting research. They gain an understanding of regulatory frameworks and guidelines such as Good Clinical Practice (GCP) and the Institutional Review Board (IRB) process.
5. Faculty Expertise: M.Sc. Clinical Research program is often led by experienced faculty members who are experts in their respective fields. These faculty members bring their research experience and industry insights into the classroom, providing valuable guidance and mentorship to students. Their expertise contributes to the quality of education and helps students develop a strong foundation in clinical research.
6. Research Facilities and Resources: M.Sc. Clinical Research program provides students with access to state-of-the-art research facilities, laboratories, and resources necessary for conducting clinical research. Students can benefit from the latest technologies, software tools, and databases to analyze data and generate meaningful research outcomes.
7. Career Development Opportunities: M.Sc. Clinical Research program often offers career development support to students. This may include workshops on scientific writing,

presentation skills, job placement assistance, and networking opportunities with industry professionals. These initiatives enhance students' employability and help them transition into successful careers in clinical research.

8. Continuous Learning and Professional Growth: Clinical research is a rapidly evolving field, and M.Sc. Clinical Research program encourages students to engage in continuous learning and professional growth. They may provide opportunities for attending conferences, workshops, and seminars, as well as encourage students to contribute to scientific publications or present their research findings. These activities enable students to stay updated with the latest advancements and make valuable contributions to the field.

Program Educational Objectives:

The Objectives of this program are:

PEO1: To equip students with a comprehensive understanding of the principles and practices of clinical research.

PEO2: To develop critical thinking, problem-solving, and analytical skills required for conducting and interpreting clinical research studies.

PEO3: To foster ethical conduct and adherence to regulatory guidelines in clinical research.

PEO4: To enhance communication and teamwork skills necessary for collaborating with interdisciplinary research teams.

PEO5: To promote professional growth and continuous learning in the field of clinical research.

Program Outcomes:

The Outcomes of this program are:

By the end of the program, students should be able to:

PO1: Demonstrate in-depth knowledge of clinical research methodologies and regulatory requirements.

PO2: Design, plan, and conduct clinical research studies ethically and effectively.

PO3: Analyze and interpret research data using appropriate statistical methods.

PO4: Communicate research findings through oral presentations and written reports.

PO5: Collaborate with healthcare professionals and researchers to contribute to advancements in medical science.

Prerequisite:

Basic knowledge of medical terminology, statistics, and research methodologies is desirable. Applicants seeking admission to this program must have a Bachelor's degree in the relevant field (e.g. Life Sciences, Medicine, Pharmacy and Nursing) from any recognized institution.

Dr Sunita D Lohare

Chairman, BOS in Biotechnology and Bioinformatics,

Swami Ramanand Teerth Marathwada University,

Nanded-431606**.**

Details of the Board of Studies Members in the subject of Biotechnology, Bioinformatics and Clinical Research under the Faculty of Science & Technology, S.R.T.M. University, Nanded.

Sr No	Name of the Member	Designation	Sr No	Name of the Member	Designation
1	Dr Sunita Dhundiraj Lohare Shri Havgiswami Mahavidyalaya, Udgir, Dist -Latur Mob 9284161504	Chairman	2	Dr Babasaheb S Surwase School of Life Sciences SRTM University, Nanded 431606. Mob 9075829767	Member
3	Dr Pratap V. Deshmukh Nagnath Arts, Commerce and Science College, Aundha Nagnath, Dist. Hingoli Mob 9637202024	Member	4	Dr Komal S. Gomare Dept of Biotechnology, Dayanand Science College, Latur Mob 9284238413	Member
5	Dr Vaibhav D. Deshpande General Manager, Quality Corporate Office, Wockhardt, Mumbai Mob 9100988260	Member		--	
	Invitee Members				
6	Dr Laxmikant Kamble School of Life Sciences, SRTM University, Nanded 431606. Mob: 8669695555	Member	7	Dr M M V Baig Dept of Biotechnology, Yeshwant Mahavidyalaya, Nanded. Mob 9422170641	Member
8	Dr Sanjog T. Thul Environmental Biotechnology and Genomics Division, National Environmental and Engineering Research Institute (CSIR-NEERI). Nagpur. Mob 9881877072	Member	9	Dr Prashant Thakare Department of Biotechnology, SGB Amravati University, Amravati. Mob: 9822222822	Member
10	Dr Shivraj Hariram Nile Department of Food Science and Agriculture, National Agri-Food Biotechnology Institute (NABI), Mohali, Punjab. Mob 9561740707	Member	11	Dr Arun Ingale School of Life Sciences, North Maharashtra University, Umavinagar, Jalgaon. Mob: 9822708707	Member
12	Dr. Dhananjay S. Gond Department of Life Science, Swami Vivekanand Mahavidyalaya, Udgir. Mob: 98232 30378	Member	13	Dr Sunil Hajare Department of Biotechnology, New Model Degree College, Hingoli . Mob 8378878817	Member

Swami Ramanand Teerth Marathwada University, Nanded

Faculty of Science & Technology

Credit Framework and Structure of Two Year PG Program (NEP 2020)

Subject: M Sc Clinical Research (Affiliated Colleges) (R-2023)

Year & Level	Sem	Major Subject		RM	OJT / FP/CS (3-Cr)	Researh Project	Practicals (1-Cr)	Credits	Total Credits
		(DSC- 4 Cr)	(DSE- 3 Cr)						
1	1	SCLRC-401 Fundamentals of Clinical Operations SCLRC-402 Clinical Data Management SCLRC-403 Biostatistics for Clinical Research	SCLRE-401 Clinical Research and Pharmacovigilance **OR** SCLRE-403 Ethics in Medical Science	SVECR 401 Research Methodology (3-Cr)	--		SCLRP-401 Lab Course in Fundamentals of Clinical Operations SCLRP-402 Lab Course in Clinical Data Management SCLRP-403 Lab Course in Biostatistics for Clinical Research SCLRE-402 Lab Course in Clinical Research and Pharmacovigilance **OR** SCLRE-404 Lab Course in Ethics in Medical Science	22	44
	2	SCLRC-451 Clinical Study Design and Protocol Development SCLRC-452 Good Clinical Practices Guidelines SCLRC-453 Clinical Pharmacology	SCLRE-451 Clinical Research Quality Assurance **OR** SCLRE-453 Clinical Research Writing and Publication	---	SCLRX-451 (O/F/C)	--	SCLRP-451 Lab Course in Clinical Study Design and Protocol Development SCLRP-452 Lab Course in Good Clinical Practices Guidelines SCLRP-453 Lab Course in Clinical Pharmacology SCLRE-452 Lab Course in Clinical Research Quality Assurance **OR** SCLRE-454 Lab Course in Clinical Research Writing and Publication	22	
Exit option: Exit Option with PG Diploma in Clinical Research (After 2024-25)									
2	3	SCLRC-501 Regulatory Affairs SCLRC-502 Drug Design and Discovery SCLRC-503 Pharmacogenomics	SCLRE-501 Clinical Trial Operations **OR** SCLRE-503 Special Regulatory Process	--	--	Research Project SCLRR-501 (4-Cr)	SCLRP-501- Lab Course in Regulatory Affairs & Drug Design and Discovery. SCLRP-502 Lab Course in Pharmacogenomics SCLRE-502 Lab Course in Clinical Trial Operations **OR** SCLRE-504 Lab Course in Special Regulatory Process	22	44
	4	SCLRC-551 Project Management and Business Development SCLRC-552 Audit & Inspection	SCLRE-551 Epidemiological Principles in Clinical Research **OR** SCLRE-553 Reporting and Medical Writing	SVECP-551 Publication Ethics (2-Cr)	--	Research Project SCLRR-551 (6-Cr)	SCLRP-551 Lab Course in Project Management and Business Development SCLRP-552 Lab Course in Audit & Inspection SCLRE-552 Lab Course in Epidemiological Principles in Clinical Research **OR** SCLRE-554 Lab Course in Reporting and Medical Writing	22	
Total Credits		44	12	05	03	10	14		**88**

DSE indicates Department Specific Elective Course. Clinical Research student, in a particular semester, can opt either of these courses **OR** a course offered by the program of other Departments. DSC- Department Specific Core, OJT- On Job Training, FP- Field Project, CS- Case Study, RM- Research Methodology, Cr- Credit, VEC- Value Education Course, R- Revision, Credits of four semesters = 88, Total Marks of all four Semesters = 2200

M. Sc. Second Year Semester III (Level 7.0)

Teaching Scheme

Subject	Course Code	Course Name	Credits Assigned			Teaching Scheme	
			Theory	Practical	Total	Theory (Hrs/ week)	Practical (Hrs/ Week/ Batch)
Major (DSC)	SCLRC-501	Regulatory Affairs	04	--	04	04	--
	SCLRC-502	Drug Design and Discovery	04	--	04	04	--
	SCLRC-503	Pharmacogenomics	04	--	04	04	--
Elective (DSE)	SCLRE-501 SCLRE-503	Clinical Trial Operations **OR** Special Regulatory Process	03	--	03	03	--
Research Project	SCLRR-501	Research Project	--	04	04	--	08
DSC Practical	SCLRP-501	Lab Course in Regulatory Affairs and Drug Design and Discovery	--	01	01	--	02
	SCLRP-502	Lab Course in Pharmacogenomics	--	01	01	--	02
DSE Practical	SCLRE-502 SCLRE-504	Lab Course in Clinical Trial Operations **OR** Lab Course in Special Regulatory Process	--	01	01	--	02
		Total Credits	**15**	**07**	**22**	**15**	**14**

M. Sc. Second Year Semester III (Level 7.0)

Examination Scheme

[20% Continuous Assessment (***CA)*** and 80% End Semester Assessment (***ESA***)]

Subject	Course Code	Course Name	Theory				Practical		Total
			Continuous Assessment (CA)			ESA			
			Test I	Test II	Avg of (T1+T2)/2	Total	CA	ESA	
Major (DSC)	SCLRC-501	Regulatory Affairs	20	20	20	80	--	--	100
	SCLRC-502	Drug Design and Discovery	20	20	20	80	--	--	100
	SCLRC-503	Pharmacogenomics	20	20	20	80	--	--	100
Elective (DSE)	SCLRE-501 SCLRE-503	Clinical Trial Operations **OR** Special Regulatory Process	15	15	15	60	--	--	75
Research Project	SCLRR-501	Research Project	---	--	---	--	20	80	100
DSE Practical	SCLRP-501	Lab Course in Regulatory Affairs and Drug Design and Discovery	--	--	--	--	05	20	25
	SCLRP-502	Lab Course in Pharmacogenomics	--	--	--	--	05	20	25
DSE Practical	SCLRE-502 SCLRE-504	Lab Course in Clinical Trial Operations **OR** Lab Course in Special Regulatory Process	--	--	--	--	05	20	25

M. Sc. Second Year Semester IV (Level 7.0)

Teaching Scheme

Subject	Course Code	Course Name	Credits Assigned			Teaching Scheme	
			Theory	Practical	Total	Theory (Hrs/ Week)	Practical (Hrs/ Week/ Batch)
Major (DSC)	SCLRC-551	Project Management and Business Development	04	--	04	04	--
	SCLRC-552	Audit & Inspection	04	--	04	04	--
Elective (DSE)	SCLRE-551 **OR** SCLRE-553	Epidemiological Principles in Clinical Research **OR** Reporting and Medical Writing	03	--	03	03	--
Value Education Course (VEC)	SVECP-551	Publication Ethics	02	---	02	02	--
Research Project	SCLRR-551	Research Project	--	06	06	--	12
DSC Practical	SCLRP-551	Lab Course in Project Management and Business Development	--	01	01	--	02
	SCLRP-552	Lab Course in Audit & Inspection	--	01	01	--	02
DSE Practical	SCLRE-552 **OR** SCLRE-554	Lab Course in Epidemiological Principles in Clinical Research **OR** Lab Course in Reporting and Medical Writing	--	01	01	--	02
		Total Credits	**13**	**09**	**22**	**13**	**18**

M. Sc. Second Year Semester IV (Level 7.0)

Examination Scheme

[20% Continuous Assessment (**CA**) and 80% End Semester Assessment (**ESA**)]

Subject	Course Code	Course Name	Theory				Practical		Total
			Continuous Assessment (CA)			ESA			
			Test I	Test II	Avg of (T1+T2)/2	Total	CA	ESA	
Major (DSC)	SCLRC-551	Project Management and Business Development	20	20	20	80	--	--	100
	SCLRC-552	Audit & Inspection	20	20	20	80	--	--	100
Elective (DSE)	SCLRE-551 **OR** SCLRE-553	Epidemiological Principles in Clinical Research **OR** Reporting and Medical Writing	15	15	15	60	--	--	75
Value Education Course (VEC)	SVECP-551	Publication Ethics	10	10	10	40	-	--	50
Research Project	SCLRR-551	Research Project	-	-	-		30	120	150
DSE Practical	SCLRP-551	Lab Course in Project Management and Business Development	--	--	--	--	05	20	25
	SCLRP-552	Lab Course in Audit & Inspection	--	--	--	--	05	20	25
DSE Practical	SCLRE-552 **OR** SCLRE-554	Lab Course in Epidemiological Principles in Clinical Research **OR** Lab Course in Reporting and Medical Writing	--	--	--	--	05	20	25

SCLRC-501 REGULATORY AFFAIRS

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs.)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-501	Regulatory Affairs	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC-501	Regulatory Affairs	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic understanding of healthcare and legal systems.
2. Familiarity with medical terminology and concepts.

Course Objectives:

1. To introduce students to regulatory affairs in healthcare.
2. To provide students an overview of the Indian judicial system.
3. To explore legal compliance, including medical malpractice and ethics.
4. To understand FDA enforcement and global regulatory landscape.

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate knowledge of medical evidence, legitimacy, and paternity issues.
2. Analyze rights and obligations of medical professionals.
3. Understand Drugs and Cosmetics Act, Schedule Y, and related penalties.
4. Gain insights into FDA functions, food standards, and post-drug approval activities.
5. Acquire knowledge of Indian regulatory authorities and international guidelines.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Foundations of Regulatory Affairs**	15
	1.1	Introduction to the role of regulatory affairs in healthcare.	
	1.2	Overview of the Indian judicial system.	
	1.3	Topics include Medical Evidence, Legitimacy, and Paternity.	
	1.4	Examination of Privileged Communication and Professional Secrets.	
2.0	**II**	**Legal Compliance in Healthcare**	15
	2.1	Exploration of the rights and obligations of medical professionals.	
	2.2	In-depth analysis of Medical Malpractice and the Code of Medical Ethics.	
	2.3	Comprehensive study of the Drugs and Cosmetics Act & Schedule Y.	
	2.4	Focus on administrative bodies, drug rules, and penalties for offenses.	
3.0	**III**	**FDA and Regulatory Compliance**	15
	3.1	Introduction to the FDA and its enforcement of laws.	
	3.2.	Historical development of food standards.	
	3.3	Functions of the Center for Drug Evaluation & Research (CDER) and Center for Food Safety & Applied Nutrition (CFSAN).	
	3.4	Exploration of post-drug approval activities and FDA nutrition policy.	
4.0	**IV**	**Global Regulatory Landscape**	15
	4.1	Overview of Indian regulatory authorities and approval processes.	
	4.2	Examination of International Council for Harmonisation (ICH) guidelines.	
	4.3	Understanding the harmonization process and different guideline categories.	

	4.4	In-depth exploration of Quality, Safety, and Efficacy guidelines.	
		Total	**60**

References:

1. Weinberg, S. "A guide book for regulatory submission." Wiley publication, 2008.
2. Cohen, A., & Posner, J. "A guide to clinical drug research." Springer, 2000.
3. Dougles, J. Posano., & Mantus, David. "FDA Regulatory affairs." [3rd ed.] CRC Press, 2014.
4. Vedjignesh. "Introduction to regulatory affairs."
5. Fegodets. "Regulatory affairs".

SCLRP-501 LAB COURSE IN REGULATORY AFFAIRS
PART A

1. Simulate healthcare scenarios to understand the role of regulatory affairs.
2. Analyze real-life cases related to the Drugs and Cosmetics Act & Schedule Y.
3. Simulate scenarios highlighting FDA's enforcement of laws and historical development.
4. Conduct case studies on Quality, Safety, and Efficacy guidelines in regulatory affairs.

SCLRC-502 DRUG DESIGN AND DISCOVERY

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-502	Drug Design and Discovery	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC-502	Drug Design and Discovery	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic knowledge of pharmaceutical terminology.
2. Familiarity with healthcare and regulatory concepts.

Course Objectives:

1. To explore pharmacy history and the Indian pharmaceutical industry.
2. To introduce students to understand diverse pharmacy branches and their roles.
3. To examine drug discovery processes and regulatory environments.
4. To gain insights into manufacturing and packaging essentials.

Course Outcomes: After completion of this course, students will be able to

1. Acquire knowledge of drug sources, nomenclature, and classifications.
2. Demonstrate understanding of pharmaceutical manufacturing and quality assurance.
3. Comprehend drug discovery approaches and regulatory considerations.
4. Apply manufacturing and packaging principles to various drug products.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Pharmacy Fundamentals**	15
	1.1	History of Pharmacy and the Indian Pharmaceutical industry.	
	1.2	Drug sources, nomenclature, and classification.	
	1.3	Introduction to Pharmacopoeias.	
	1.4	Formulary, and Codex.	
2.0	**II**	**Diverse Pharmacy Branches**	15
	2.1	Overview of pharmacy branches: Pharmacognosy, Pharmaceutical Chemistry.	
	2.2	Quality Assurance, Pharmaceutics and Pharmacology.	
	2.3	Pharmacy Management and Pharmacy Practice.	
	2.4	Emphasis on Pharmaceutical Manufacturing with a focus on Quality Assurance and Quality Control.	
3.0	**III**	**Drug Discovery and Regulation**	15
	3.1	Evolution of drug development.	
	3.2.	Exploration of Drug Discovery Pipeline and Process.	
	3.3	Approaches to drug discovery: Synthetic/Medicinal Chemistry, Combinatorial Synthesis, Natural Product, In Silico methods, and Discovery Genomics.	
	3.4	Understanding the Drug Regulatory Environment, including legislation in India, regulatory authorities, and the International Conference on Harmonization (ICH).	
4.0	**IV**	**Manufacturing and Packaging Essentials**	15
	4.1	Manufacturing processes, highlighting multitasking machines.	
	4.2	Packaging regulations under cGMP, and USP requirements on containers and closures.	
	4.3	Quality Control considerations.	
	4.4	Specifics of Inhalation Drug Products, Drug Products for Injection, Ophthalmic Drug Products, Liquid-based Oral and Topical Drug Products, and Post-approval Packaging Changes.	
		Total	**60**

References:

1. Hill, Raymond G. "Drug Discovery and Development." [2nd ed.] 2012.
2. Rick, Ng. "Drugs: From Discovery to Approval." [3rd ed.]. Wiley-Blackwell, 2015.

SCLRP-501 LAB COURSE IN DRUG DESIGN AND DISCOVERY
PART B

1. Set up an exhibition showcasing the history of pharmacy and the Indian pharmaceutical industry.
2. Conduct practical sessions exploring Pharmacopoeias, Formulary, and Codex.
3. Simulate a drug discovery pipeline process, incorporating different approaches.
4. Analyze and discuss packaging regulations under cGMP, highlighting USP requirements.

SCLRC-503 PHARMACOGENOMICS

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-503	Pharmacogenomics	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA			
		Test I	Test II	Avg of (T1+T2)/ 2		CA	ESA	
SCLRC-503	Pharmacogenomics	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic understanding of genetics and molecular biology.
2. Familiarity with pharmaceutical terminology.

Course Objectives:

1. To understand pharmacogenomics, its history, and distinctions from pharmacogenetics.
2. To introduce students to explore practical applications and benefits of pharmacogenetics in clinical practice.
3. To examine the landscape of pharmacogenomics, including current drugs and future trends.
4. To understand drug properties, bioinformatics, and their relevance in pharmacogenomics.

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate knowledge of pharmacogenomics history and distinctions.
2. Apply pharmacogenetics concepts to clinical scenarios.

3. Evaluate the current pharmacogenomic drug landscape and its limitations.
4. Analyze drug properties, bioinformatics tools, and their impact on drug response.
5. Explore advanced topics such as pharmacogenetics of enzymes, xenobiotic reactions, and drug transporter variations.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Foundations of Pharmacogenomics**	15
	1.1	Introduction to Pharmacogenomics	
	1.2	Distinction Between Pharmacogenetics and Pharmacogenomics	
	1.3	Benefits of Pharmacogenetics in Clinical Practice	
	1.4	Practical Applications of Pharmacogenetics	
2.0	**II**	**Pharmacogenomics Landscape**	15
	2.1	Examining the promise and limitations of pharmacogenomics.	
	2.2	Surveying pharmacogenomic drugs currently in the market.	
	2.3	Discussing the future trajectory of pharmacogenomics.	
	2.4	Investigating determinants of drug response and the utilization of bioinformatics tools.	
3.0	**III**	**Drug Properties and Bioinformatics**	15
	3.1	Understanding the pharmacokinetics and pharmacodynamics of drugs.	
	3.2.	Exploring factors influencing drug properties.	
	3.3	Introduction to bioinformatics, its divisions, and application across various fields.	
	3.4	Highlighting major categories of bioinformatics tools with examples.	
4.0	**IV**	**Advanced Topics in Pharmacogenomics**	15
	4.1	Delving into pharmacogenetics of enzymes and transporters.	
	4.2	Understanding xenobiotic phase I and II reactions.	
	4.3	Examining drug transporters' structure, models, and mechanisms.	

	4.4	Discussing genetic variations in membrane transporters and their impact on drug response.	
		Total	**60**

Reference:

1. Katzung, Bertram G. "Basic and Clinical Pharmacology." [15th ed.]. McGraw-Hill, 2012.
2. Tripathi, K. D. "Essentials of Medical Pharmacology." [8th ed.]. Jaypee Brothers, 2018.
3. Satoskar, R. S. "Pharmacology and Pharmacotherapeutics." [18th ed.]. Popular Prakashan, Mumbai, 2003.
4. Rang, Dale, and Ritter, James M. "Pharmacology." [9th ed.]. Elsevier, 2023.

SCLRP-502 LAB COURSE IN PHARMACOGENOMICS

1. Research and create a timeline presentation on the history and chronology of pharmacogenomics.
2. Facilitate a debate comparing the benefits and limitations of pharmacogenetics.
3. Survey and analyze pharmacogenomic drugs currently in the market, discussing their promise and limitations.
4. Conduct a workshop on the utilization of bioinformatics tools in pharmacogenomics.
5. Organize experiments illustrating the pharmacokinetics and pharmacodynamics of drugs.
6. Discuss genetic variations in membrane transporters and their impact on drug response.
7. Delve into xenobiotic phase I and II reactions, discussing their implications.
8. Explore the structure, models, and mechanisms of drug transporters in the context of pharmacogenomics.

SCLRE-501 CLINICAL TRIAL OPERATIONS

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-501	Clinical Trial Operations	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE -501	Clinical Trial Operations	15	15	15	60	--	--	75

Course Prerequisite:

1. Basic knowledge of clinical research terminology.
2. Understanding of ethical considerations in research.

Course Objectives:

1. To learn the process of selecting clinical trial sites and investigators.
2. To understand budgeting and roles of sponsors and institutions in clinical trials.
3. To introduce students to gain proficiency in documentation for site initiation and related activities.
4. To explore site conduct processes, including recruitment, file management, and monitoring.
5. To familiarize students with procedures for site close-out, data handling, and report preparation

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate the ability to select suitable clinical trial sites and investigators.

2. Apply budgeting skills and understand sponsor and institution roles.
3. Prepare documentation for site initiation and conduct activities.
4. Manage recruitment processes, databases, and data monitoring effectively.
5. Execute procedures for site close-out, database lock, and report preparation.
6. Understand ethical considerations in result publication and submission to regulatory agencies.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Clinical Trial Setup**	12.
	1.1	Selection of clinical trial sites.	
	1.2	Choosing clinical investigators and budgeting.	
	1.3.	Roles and responsibilities of the Sponsor	
	1.4	Roles and responsibilities of the institution in clinical trials.	
2.0	**II**	**Site Initiation**	11.
	2.1	Documentation required for site initiation.	
	2.2	Conduct activities, including protocol, CRF, ICD, Investigator brochure, clinical trial agreement, and regulatory approvals.	
	2.3	Roles and responsibilities of Clinical Trial Coordinators and Clinical Investigators.	
	2.4	Site initiation visits.	
3.0	**III**	**Site Conduct**	11
	3.1	Recruitment processes and IP/IMP/Pharmacy file management.	
	3.2	Maintenance of the CT site master file and databases.	
	3.3	Roles of Monitors and Auditors/Inspectors.	
	3.4	Independent data monitoring activities and SOPs., Contingency planning for unexpected situations.,	

4.0	**IV**	**Site Close-Out**	11
	4.1	Procedures for suspending and prematurely terminating a trial.	
	4.2	Handling missing data and query resolution., Database lock and site close-out report.	
	4.3	Preparation of the clinical study report.	
	4.4	Submission to ethics committees and regulatory agencies., Publication of results.	
		Total	**45**

References:

1. Gallin, J., I. "Principles and Practice of Clinical Research." [3rd ed.]. Academic Press, 2012.
2. Richard, C., and Bruce Y. Lee. "Principles and Practice of Clinical Trial Medicine." [1st ed.]. Academic Press, 2008.
3. Guidelines like GCP, USFDA, EMEA, Indian GCP, etc.

SCLRE-502 LAB COURSE IN CLINICAL TRIAL OPERATIONS

1. Role-play the process of selecting clinical trial sites, considering different criteria.
2. Conduct a workshop on the roles and responsibilities of clinical investigators, emphasizing budgeting.
3. Engage in hands-on activities, preparing documentation required for site initiation.
4. Facilitate discussions on the roles and responsibilities of Clinical Trial Coordinators and Clinical Investigators during site initiation visits.
5. Develop a recruitment strategy for a clinical trial, considering ethical considerations.
6. Role-play scenarios depicting the roles of Monitors and Auditors in clinical trial conduct.
7. Conduct a workshop on independent data monitoring activities and SOPs.
8. Simulate procedures for suspending and prematurely terminating a trial, handling missing data, and preparing the clinical study report.

SCLRE-503 SPECIAL REGULATORY PROCESS

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-503	Special Regulatory Process	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE -503	Special Regulatory Process	15	15	15	60	--	--	75

Course Prerequisite:

1. Basic pharmaceutical terminology understanding.
2. Familiarity with drug development concepts.

Course Objectives:

1. To understand requirements for New Drugs, Biologics, Botanical Drug Products, and Dietary Supplements.
2. To comprehend components of IND applications, FDA's role, and IND types/categories.
3. To expose students to learn about resources for IND applications, including guidance documents and emergency use.
4. To gain insight into the FDA's drug review process, emphasizing safety, effectiveness, and clinical data quality.
5. To explore CMC information introduction, requirements for different IND phases, and regulatory processes.

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate knowledge of IND requirements for diverse drug categories.
2. Prepare components of an IND application, understanding FDA's role and IND types.
3. Effectively access resources for IND applications and understand emergency use and DSOB.
4. Evaluate clinical data quality and understand the FDA's drug review process.
5. Apply CMC information requirements to various phases of IND studies.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**IND Requirements and FDA's Role**	12
	1.1	Overview of IND requirements for New Drugs, Biologics, Botanical Drug Products, and Dietary Supplements.	
	1.2	Components of IND applications, FDA's role in drug development, and types/categories of INDs.	
	1.3	Resources for IND applications, including guidance documents, MaPPs, laws, regulations, and forms.	
	1.4	Emergency use of investigational drugs and the Drug Safety Oversight Board (DSOB).	
2.0	**II**	**FDA's Drug Review Process**	11
	2.1	Ensuring drug safety in drug review process.	
	2.2	Effectiveness in the FDA's drug review process.	
	2.3	Stages of drug development and review.	
	2.4	Importance of high-quality clinical data in the review process.	
3.0	**III**	**Compliance of CMC Information**	11
	3.1	Introduction to Chemistry, Manufacturing, Control (CMC) information.	
	3.2.	CMC information requirements for IND applications in Exploratory Phase I, Phase II, and Phase III studies.	
	3.3	Regulatory processes for cosmetics, medical devices,	
	3.4	Regulatory processes for veterinary products.	
4.0	**IV**	**Biosimilars & Biopharmaceuticals**	11

	4.1	Overview of Biosimilars and Biopharmaceuticals.	
	4.2	Global regulatory standards, including EMEA guidelines.	
	4.3	Indian regulations and guidance for biopharmaceuticals.	
	4.4	Regulatory bodies and guidelines for generating preclinical and clinical data for r-DNA based vaccines, diagnostics, and other biological products.	
		Total	**45**

References:

1. Dougles, J. P., & Mantus, D. "FDA Regulatory Affairs." [3rd ed.]. CRC Press, 2014.
2. Cohen, A., & Posner, J. "A Guide to Clinical Drug Research." [2nd ed.]. Springer, 2020.
3. Weinberg, S. "A Guide Book for Regulatory Submission." Wiley, 2008.
4. Vedjignesh. "Introduction to Regulatory Affairs."

SCLRE-504 LAB COURSE IN SPECIAL REGULATORY PROCESS

1. Provide an overview of IND requirements for New Drugs, Biologics, Botanical Drug Products, and Dietary Supplements.
2. Engage in exercises exploring FDA's role in drug development, emphasizing emergency use scenarios.
3. Discuss the importance of high-quality clinical data in the FDA's drug review process.
4. Create a presentation on Chemistry, Manufacturing, Control (CMC) information requirements for different phases of clinical studies.
5. Analyze regulatory processes for cosmetics, medical devices, and veterinary products.
6. Provide an overview of Biosimilars and Biopharmaceuticals, including global regulatory standards and Indian regulations.
7. Conduct a workshop on generating preclinical and clinical data for r-DNA based vaccines, diagnostics, and other biological products.
8. Facilitate discussions on regulatory bodies and guidelines related to biosimilars and biopharmaceuticals.

SEMESTER- IV

SCLRC-551 PROJECT MANAGEMENT AND BUSINESS DEVELOPMENT

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-551	Project Management and Business Development	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC-551	Project Management and Business Development	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic understanding of project management concepts.
2. Familiarity with clinical research terminology.
3. Entry-level knowledge of Clinical Research Organizations (CROs).

Course Objectives:

1. To introduce students to project management basics, emphasizing the triple constraints.
2. To explore project management processes, activities, and associated documentation.
3. To understand project control variables and their relevance in clinical trials.
4. To recognize the crucial role of project management in ensuring success, especially in CROs.

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate proficiency in key project management processes: Initiating, Planning, Executing, Monitoring & Controlling, Closing.
2. Develop effective Clinical Project Development Plans (CPDP) and navigate approval procedures in clinical research.
3. Gain insights into business development stages within the clinical research industry.
4. Understand outsourcing dynamics, including reasons for outsourcing, the India Advantage, and the role of a business development manager.
5. Evaluate the benefits and procedures of outsourcing Phase I to Phase IV studies.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Foundations of Project Management**	15
	1.1	Introduction to project management and its triple constraints.	
	1.2	Project management activities, objectives, and associated documents.	
	1.3	Exploring project control variables and the significance of project management in clinical trials.	
	1.4	Understanding the role of project management in ensuring success, particularly in Clinical Research Organizations (CROs).	
2.0	**II**	**Project Management Process & Development Plan**	15
	2.1	Overview of project management processes: Initiating, Planning, Executing.	
	2.2	Overview of project management processes: Monitoring & Controlling, Closing.	
	2.3	Preparation and content of Clinical Project Development Plans (CPDP).	
	2.4	Review and approval procedures for CPDP in clinical research.	

3.0	**III**	**Business Development in Clinical Research**	15
	3.1	Introduction to business development in the clinical research industry.	
	3.2.	Stages of business development: Start-up Phase, Growth Phase, Maturity Phase, Decline Phase.	
	3.3	Outsourcing in clinical research, reasons for outsourcing to contract research organizations, and the India Advantage.	
	3.4	Scope and future of CROs, with a list of clinical research organizations and IT companies in India., The role of a business development manager.	
4.0	**IV**	**Clinical Research Outsourcing & Services**	15
	4.1	Benefits of outsourcing and the process of outsourcing Phase I to Phase IV studies.	
	4.2	Overview of services offered by CROs, including acute, sub-acute, and chronic animal studies, bioequivalence, bioavailability, clinical trial management, monitoring, pharmacovigilance,	
	4.3	Data management, regulatory affairs, protocol development, site management, clinical trial supplies, centralized lab management,	
	4.4	Centralized ECG reading services, and centralized imaging services.	
		Total	**60**

References:

1. Clifford F, Gray, & Erik W. Larson, "Project Management - The Managerial Approach." [8th ed.]. McGraw Hill, 2008.
2. Dale Copper, Stephen Grey, Geoffrey Raymond Guideline "Project Risk Management." [1st ed.]. John Wiley & Sons, 2005.
3. Cleland, D. L., & Ireland, Lewis R. "Business Development: The Expanding Role of Project Management." McGraw-Hill, 2002.
4. Oliver F Lehmann, "Principles Business Management." CRC Press, 2018.

SCLRP-551 LAB COURSE IN PROJECT MANAGEMENT AND BUSINESS DEVELOPMENT

1. Simulate a project management scenario to explore triple constraints and their impact.
2. Develop a project management plan, including activities, objectives, and associated documents.
3. Analyze project control variables and their significance in clinical trials.
4. Explore the role of project management in ensuring success, focusing on Clinical Research Organizations (CROs).
5. Conduct a workshop on project management processes: Initiating, Planning, Executing, Monitoring & Controlling, Closing.
6. Create Clinical Project Development Plans (CPDP) and discuss review and approval procedures.
7. Explore stages of business development in the clinical research industry.
8. Analyze outsourcing processes in clinical research, emphasizing reasons and advantages.

SCLRC-552 AUDIT AND INSPECTION

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-552	Audit and Inspection	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC-552	Audit and Inspection	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic understanding of Quality Assurance (QA) and clinical research terminology.
2. Familiarity with the Quality Plan, Quality System, and the differentiation between Quality Control (QC) and QA.
3. Entry-level knowledge of organizing and structuring the QA function.

Course Objectives:

1. To introduce QA fundamentals, including its definition and overview of activities in clinical research.
2. To explore the definition and purpose of audits, emphasizing Quality Assurance Audits and motives for process audits.
3. To understand objectives and roles in process audits, with a focus on addressing audit findings related to fraud, misconduct, site audits, FDA inspections, and PL 483 warning letters.
4. To define audits as per ICH GCP, outlining goals and criteria for study site audits, and addressing common findings in the context of fraud and misconduct.

5. To differentiate inspections from audits, understand their types and purposes, and address warning letters. Explore various types of audits in Clinical Data Management (CDM), including protocol audits, CRF audits, database build audits, DMP reviews, and study-specific audits.

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate a solid understanding of QA fundamentals and their application in clinical research.
2. Execute Quality Assurance Audits in clinical research and analyze process audit findings.
3. Address fraud, misconduct, and common audit findings effectively.
4. Develop proficiency in differentiating inspections from audits and apply audit principles to Clinical Data Management (CDM) functions.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Fundamentals of Audits and Quality Assurance**	15
	1.1	Introduction to Quality Assurance (QA) and its definition.	
	1.2	Understanding the Quality Plan, Quality System, and the differentiation between Quality Control (QC) and QA.	
	1.3	Structuring the QA function and addressing critical issues in organizing it.	
	1.4	Overview of QA activities, including audits, in clinical research.	
2.0	**II**	**Audits in Clinical Research**	15
	2.1	Definition and purpose of audits.	
	2.2	Quality Assurance Audits in Clinical Research and motives for process audits.	
	2.3	Objectives of process audits, roles of auditors, and conducting a clinical research department process audit.	
	2.4	Addressing audit findings, focusing on research fraud, misconduct, site audits, FDA inspections, and PL 483 warning letters.	

3.0	**III**	**Site Audits, Fraud, and Misconduct**	15
	3.1	Definition of audits as per ICH GCP.	
	3.2.	Goals and objectives of study site audits and types of clinical trial site audits.	
	3.3	Criteria for onsite audits, the audit process, and preparation activities.	
	3.4	Common audit findings in the context of fraud and misconduct.	
4.0	**IV**	**FDA Inspections, PL 483, and Auditing CDM Function**	15
	4.1	Differentiating inspections from audits and understanding their definitions.	
	4.2	Types and purposes of inspections, the process of regulatory inspections, and forms.	
	4.3	Addressing warning letters and the selection of study sites for inspection.	
	4.4	Types of audits in Clinical Data Management (CDM), including protocol audits, CRF audits, database build audits, DMP reviews, and study-specific audits.	
		Total	**60**

References:

1. Machin, David. "Textbook of Clinical Trials." John Wiley & Sons Ltd. 2004.
2. Mihajlovic-Madzarevic, Vera. "Clinical Trials Audit Preparation: A Guide for Good Clinical Practice (GCP) Inspections." John Wiley & Sons, 2010.
3. Johnstone , Gramling , Rittenberg ,"Auditing: A Risk based Approach to conducting a quality" [9th ed.].2013.

SCLRP-552 LAB COURSE IN AUDIT AND INSPECTION

1. Introduce Quality Assurance (QA) and its role in clinical research.
2. Explore the Quality Plan, System, and differentiate between Quality Control (QC) and QA.
3. Structure the QA function and address critical issues through case studies.
4. Discuss audits in clinical research, their definition, and purpose.
5. Conduct Quality Assurance Audits, focusing on motives for process audits.
6. Role-play a clinical research department process audit and address audit findings.
7. Explore goals and objectives of study site audits, emphasizing types of clinical trial site audits.
8. Differentiate inspections from audits, addressing warning letters, and conducting audits in Clinical Data Management (CDM).

SCLRE-551 EPIDEMIOLOGICAL PRINCIPLES IN CLINICAL RESEARCH

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-551	Epidemiological Principles In Clinical Research	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE -551	Epidemiological Principles In Clinical Research	15	15	15	60	--	--	75

Course Prerequisite:

1. Basic understanding of medical terminology.
2. Familiarity with general concepts in healthcare and research.

Course Objectives:

1. To explore historical aspects and evolution of epidemiology.
2. To define key epidemiological concepts, including descriptive and analytical approaches.
3. To understand disease burden, natural history, and measures of risk and death.
4. To learn tools of epidemiology, including measuring disease frequency and various indicators.
5. To discuss mechanisms of bias in clinical research and conceptual approaches to multivariable analysis.

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate understanding of historical aspects and key concepts in epidemiology.
2. Apply tools of epidemiology to measure disease frequency and interpret various indicators.
3. Evaluate bias mechanisms in clinical research and apply conceptual approaches to multivariable analysis.
4. Analyze research implications of evidence-based clinical medicine, including diagnostic, screening, and prognostic tests.
5. Utilize principles of pharmacoepidemiology and molecular/genetic methods in the context of clinical research.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Epidemiology**	12.
	1.1	Historical aspects and evolution of epidemiology.	
	1.2	Key definitions and concepts in epidemiology.	
	1.3.	Descriptive and analytical approaches in epidemiology.	
	1.4	Understanding disease burden, natural history of diseases, and measures of risk and death.	
2.0	**II**	**Fundamentals of Epidemiology**	11.
	2.1	Tools of epidemiology: measuring disease frequency (prevalence, incidence, morbidity rates, attack rates, etc.).	
	2.2	Measures of disease occurrence and association, mortality indicators, and morbidity indicators.	
	2.3	Mechanisms of bias in clinical research and a conceptual approach to multivariable analysis.	
	2.4	Research implications of evidence-based clinical medicine, including diagnostic, screening, and prognostic tests.	
3.0	**III**	**Pharmacoepidemiological Studies**	11
	3.1	Introduction to pharmacoepidemiology.	

	3.2	Concepts, principles, and use of molecular and genetic methods in epidemiology and clinical research.	
	3.3	Overview of the Human Genome Project.	
	3.4	Framework for interpreting, assessing, and incorporating molecular and genetic measures in research.	
4.0	**IV**	**Social Aspects in Clinical Research**	11
	4.1	Meaning of race, ethnicity, social class, and culture, and their impact on clinical research.	
	4.2	Application of pharmacogenomics in clinical research, including GWAS.	
	4.3	Exploring social aspects	
	4.4	Effects on the conduct and interpretation of clinical research	
		Total	**45**

References:

1. Duncan, David. "Epidemiology: Basis for Disease Prevention and Health Promotion." [5th ed.]. Macmillan Publishing Company, 2004.
2. Fletcher, Robert H., & Fletcher, Suzanne W. "Clinical Epidemiology: The Essentials." [5th ed.]. Wolters Kluwer Health,
3. MacMahon, Brian, and Thomas F. Pugh. "Methods in Epidemiologic Research." [5th ed.] Lippincott Williams & Wilkins
4. Rothman, Kenneth J. "Epidemiology: An Introduction." [2nd ed.]. Oxford University Press, 2012.
5. Celentano, David D., & Szklo, Moyses. "Gordis Epidemiology." [6th ed.]. Elsevier Health Sciences, 2018.
6. Barnes, Ethen. "Diseases and Human Evolution." University of New Mexico Press, 2007.

SCLRE-552 LAB COURSE IN EPIDEMIOLOGICAL PRINCIPLES IN CLINICAL RESEARCH

1. Investigate historical aspects and evolution of epidemiology.
2. Explore key definitions and concepts in epidemiology.
3. Analyze descriptive and analytical approaches in epidemiology.
4. Discuss disease burden, natural history, and measures of risk and death.
5. Measure disease frequency, incidence, and morbidity rates using epidemiological tools.
6. Explore mechanisms of bias in clinical research and apply multivariable analysis conceptually.
7. Introduce pharmacoepidemiology, molecular, and genetic methods in research.
8. Examine the impact of race, ethnicity, and social aspects on clinical research, including GWAS.

SCLRE-553 REPORTING AND MEDICAL WRITING

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-503	Reporting and Medical Writing	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE -503	Reporting and Medical Writing	15	15	15	60	--	--	75

Course Prerequisite:

1. Basic understanding of medical terminology.
2. Familiarity with data presentation tools.
3. Entry-level knowledge of clinical study report structure

Course Objectives:

1. To introduce the scope of medical writing and qualities of effective medical writers.
2. To explore types of data and tools for presentation, including graphical methods.
3. To provide insights into the structure of Clinical Study Reports (CSRs) and laboratory tests reporting.
4. To cover contents of the Investigator's Brochure, Common Technical Document (CTD), and global submission dossiers.
5. To develop language and technical skills for medical writers, including referencing, software proficiency, language orientation, punctuation, and writing techniques.

Course Outcomes: After completion of this course, students will be able to

1. Demonstrate effective medical writing skills.

2. Apply data presentation tools, including graphical methods, for qualitative and quantitative data.
3. Create structured Clinical Study Reports (CSRs) and accurately report clinical laboratory tests.
4. Prepare comprehensive Investigator's Brochures and understand the components of global submission dossiers.
5. Develop language and technical proficiency for medical writing, including referencing, software skills, language orientation, and punctuation.

.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Fundamentals of Medical Writing & Data Presentation**	12
	1.1	The scope of medical writing and qualities of an effective medical writer.	
	1.2	Types of data and tools for data presentation.	
	1.3	Graphical methods for qualitative data: Frequency Tables, Pie Charts, Bar Charts, and comparing distributions.	
	1.4	Graphical methods for quantitative data: Stem and Leaf Plots, Histograms, Line Graphs, Dot Plots, Box Plots, and Scatter Plots.	
2.0	**II**	**The Clinical Study Report & Laboratory Tests Reporting**	11
	2.1	Structure of the Clinical Study Report (CSR) and possible modifications.	
	2.2	CSR components: Study patients, efficacy and safety evaluation, discussion, overall conclusions, tables, figures, graphs, reference list, and appendices.	
	2.3	Reporting clinical laboratory tests: Reference ranges, interpretation of normal values	
	2.4	Units of measurement, and factors affecting test interpretation.	
3.0	**III**	**Investigator's Brochure and Global Submission Dossiers**	11

	3.1	Contents of the Investigator's Brochure: Table of Contents, Summary, Introduction, Physical, Chemical, and Pharmaceutical Properties, Non-clinical Studies.	
	3.2.	Effects in Humans, and Guidance for the Investigator.	
	3.3	Components of the Common Technical Document (CTD) and global submission.	
	3.4	Bibliography preparation and computer skills for medical writers.	
4.0	**IV**	**Language and Technical Skills for Medical Writers**	11
	4.1	Types of referencing: Primary and secondary, focusing on Vancouver style.	
	4.2	MS Word, MS Excel, and MS PowerPoint skills for typing, tabulation, and presentation., Basic language orientation: Sentence structure, active/passive voice, proper use of tenses.	
	4.3	Punctuation for clarity and style: Types of punctuation, capitalization, hyphens, quotation marks, apostrophes, commas, and differences between British and American English.	
	4.4	Techniques to improve simplicity and clarity of style: Linking passages, constructing paragraphs, and building strong sentences.	
		Total	**45**

References:

1. Taylor, Robert B. "Clinician's Guide to Medical Writing." [1st ed]. Springer New York, 2005.
2. Iles, Robert L., & Volkland, Debra. "Guidebook to Better Medical Writing." [2nd ed], Robert L. Iles, illustrated, revised 2003.
3. Neville W. Goodman , Martin B. Edwards " Medical Writing." [3rd ed], Cambridge University press, 2006.

SCLRE-554 LAB COURSE IN REPORTING AND MEDICAL WRITING

1. Discuss the scope of medical writing and qualities of effective medical writers.
2. Explore types of data and tools for qualitative and quantitative data presentation.
3. Conduct hands-on exercises on graphical methods for data presentation.
4. Structure a Clinical Study Report (CSR) and discuss modifications.
5. Address reporting of clinical laboratory tests, including interpretation and reference ranges.
6. Create an Investigator's Brochure, understand CTD components, and prepare global submission dossiers.
7. Develop referencing skills focusing on Vancouver style.
8. Enhance language and technical skills for medical writers, covering MS Word, MS Excel, and MS PowerPoint.

SVECP-551: Publication Ethics

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs.)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SVECP-551	Publication Ethics	02	--	02	--	02

Assessment Scheme

Course Code	Course Name	Theory				Practical		Total
		CA			ESA			
		Test I	Test II	Avg of (T1+T2)/2		CA	ESA	
SVECP-551	Publication Ethics	10	10	10	40	--	--	50

Course pre-requisite: General awareness regarding publication basics

Course objectives:

- To know rules, issues, options, and resources for research ethics.
- To familiarize with various institutional ethics review boards/academic integrity guidelines.
- To understand the purpose and value of ethical decision-making.
- To have a positive disposition towards continued learning about research ethics

Course outcomes:

- To have a positive disposition towards continued learning about research philosophy & ethics.
- To know Rules, Regulations, Issues, Options, and Scientific Resources of Research Ethics.
- To learn the culture of fairness, honesty and integrity in academic communications and to understand the purpose and value of ethical decision-making.
- Avoid wasteful and duplicate publications & encourage original contributions to advance Academic Research and Scholarship.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.

1.0	**I**	**Publication ethics**	**08**
	1.1	Publication ethics: definition, introduction and importance, Best practices/standards setting initiatives and guidelines: COPE, WAME, etc. Conflicts of interest	
	1.2	Publication misconduct: definition, concept, problems that lead to unethical behavior and vice verse, types	
	1.3	Violation of publication ethics, authorship and contributor ship	
	1.4	Identification of publication misconduct, complaints and appeals. Predatory publishers and journals	
2.0	**II**	**Open access publishing**	**07**
	2.1	Open access publications and initiatives.	
	2.2	SHERPA/RoMEO online resource to check publisher copyright and self- archiving policies	
	2.3	Software tool to identify predatory publications developed by SPPU	
	2.4	Journal finder/ journal suggestion tools viz. JANE	
3.0	**III**	**Publication misconduct**	**07**
	3.1	Subject specific ethical issues, FFP, authorship	
	3.2	Conflicts of interest	
	3.3	Complaints and appeals: examples and fraud from India and abroad	
	3.4	Use of plagiarism software like Turnitin, Urkund and other open source software tools.	
4.0	**IV**	**Databases and research metrics**	**08**
	4.1	Databases: Indexing databases	
	4.2	Citation databases: Web of Science, Scopus, etc.	
	4.3	Research Metrics: Impact Factor of journal as per journal citation report, SNIP, SJR, IPP, Cite Score.	
	4.4	Metrics: h-index, g index, i10 index, altmetrics	
		Total	**30**

References:

1. Donna M. Mertens, Pauline E. Ginsberg The Handbook of Social Research Ethics, SAGE (2009).
2. Rose Wiles, Bloomsbury What are Qualitative Research Ethics? (2013).
3. Robin Levin Penslar, eds, Research Ethics: Cases and Materials, Indiana University Press (1995).
4. Gary Comstock, Research Ethics: A Philosophical Guide to the Responsible Conduct of Research, Cambridge University Press (2013)
5. Bird, A. Philosophy of Science. Routledge, 2006.

6. MacIntyre, Alasdair A Short History of Ethics London, 1967
7. P. Chaddah Ethics in Competitive Research: Do not get scooped; do not get plagiarized, 2018
8. National Academy of Sciences, National Academy of Engineering and Institute of Medicine,2009.
9. On being a Scientist: A Guide to Responsible Conduct in Research. Third Edition. National Academies Press.
10. Resnik, D. B. What is ethics in research & why is it important. National Institute of Environmental Health Sciences, 2018. Retrieved from https www.nichs.nih.gov/research/resources/bioethics/whatis/index.cfm
11. Beall, J. Predatory publishers are corrupting open access. Nature, 2012. https://doi.org/10.1038/489179a
12. Indian National Science Academy (INSA), Ethics in Science Education, Research and Governance,2019. http://www.insaindia.res.in/pdf/Ethics Book.pdf

**********02.06.2024**********