INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (REGULATORY AFFAIRS)**
SEMESTER	**1**
COURSE TITLE	**REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS**
COURSE CODE	**13MR0104**
COURSE CREDITS	**4**

Objective:

1 This course is designed to impart fundamental knowledge on the clinical development process of drugs, pharmaceuticals, and Medical Devices, phases and conduct of clinical trials and research, regulations, and guidance governing the conduct of clinical research in India, the USA, and the EU. It prepares the students to learn in detail about various laws, legislations, and guidance related to safety, efficacy, ethical conduct, and regulatory approval of clinical research.

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

1 Know different Acts and guidelines that regulate Drugs & Cosmetics,Medical Devices, Biologicals & Herbals, and Food & Nutraceuticalsindustry in India.

2 Understand the approval process and regulatory requirements forDrugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food& Nutraceuticals.

Pre-requisite of course:B. Pharm. Qualified

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	**Biologicals & Herbals, and Food & Nutraceuticals Acts and Rules (with latest amendments):** 1. Drugs and Cosmetics Act 1940 and Rules 1945: DPCO and NPPA. 2. Other relevant provisions (rules schedules and guidelines for approval of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals in India. Other relevant Acts: Narcotics Drugs and PsychotropicSubstances Act; Medicinal and ToiletPreparations (ExciseDuties) Act, 1955; Pharmacy Act, 1948; Drugs and MagicRemedies (Objectionable Advertisements) Act, 1955; Preventionof Cruelty to Animals Act.	12

DR. MAUSAMI CHANDRAKANTBHAI VAGHELA
Digitally signed by (Name of HOD)

DR. LALJI HAKUBHAI BALDANIYA
Digitally signed by (Name of Dean/ Principal)

Contents : Unit	Topics	Contact Hours
2	**Regulatory requirements** Regulatory requirements and approval procedures for Drugs & Cosmetics Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (Central Drug Standard Control Organization) and State Licensing Authority: Organization, Responsibilities. • Rules, regulations, guidelines, and standards for regulatory filing of Drugs & Cosmetics, Medical Devices, Biologicals & Herbals, and Food & Nutraceuticals. • Format and contents of Regulatory dossier filing Clinical trial/ investigations.	12
3	**Indian Pharmacopoeia Standards** Indian Pharmacopoeia Standards, BIS standards and ISO, and other relevant standards.	12
4	**Bioavailability and Bioequivalence data (BA &BE),** BCSClassification of Drugs, Regulatory Requirements forBioequivalence study.Stability requirements: ICH and WHO. Guidelines for Drug Testing in Animals/Preclinical Studies.Animal testing: Rationale for conducting studies, CPCSEAGuidelines.Ethical guidelines for human participants.ICMR-DBT Guidelines for Stem Cell Research.	12
5	**Intellectual Property Rights** Patent, Trademark, Copyright,Industrial Designs and Geographical Indications, Indian PatentScenario. IPR vs Regulatory Affairs.	12
Total Hours		**60**

Textbook :

1 Manual of Patent Practice & Procedure,, 3rd Edition, by The Patent Office of India., 2021

References:

1 Manual of Patent Practice & Procedure, , Manual of Patent Practice & Procedure, , 3rd Edition, by The Patent Office of India., 2021

2 Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at Risk , Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at Risk , by James Bessen and Michael J. Meurer, GianCarlo Moschini, , 2010

3 Principles and Practice of Clinical Trial Medicine , Principles and Practice of Clinical Trial Medicine , by Richard Chin and Bruce Y. Lee, Elsevier,, 2008

4 Ethical Guidelines for Biomedical Research on Human Participants , Ethical Guidelines for Biomedical Research on Human Participants , by Indian Council of Medical Research, New Delhi , 2006

5 CPCSEA Guidelines for Laboratory Animal Facility, CPCSEA Guidelines for Laboratory Animal Facility, by Committee for the Purpose of Control and Supervision on Experiments on Animals , (CPCSEA)., 1960

6 ICH E6 , ICH E6 , Guideline, Good Clinical Practice? by ICH Harmonised Tripartite., 2015

References:

7 Guidance for Industry on Submission of Clinical Trial Applications for Evaluating Safety and Efficacy, Guidance for Industry on Submission of Clinical Trial Applications for Evaluating Safety and Efficacy, by CDSCO , (Central Drug Standard Control Organisation)., 1940

8 Guidance for Industry on the Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials/ BE studies , Guidance for Industry on the Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials/ BE studies , by CDSCO, (Central Drug Standard Control Organisation)., 1940

9 Guidelines for Import and Manufacture of Medical Devices , Guidelines for Import and Manufacture of Medical Devices , by CDSCO, (Central Drug Standard Control Organisation)., 1940

10 Guidelines from official website of , Guidelines from official website of , by CDSCO, (Central Drug Standard Control Organisation)., 1940

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	**Understand**	**Apply**	**Analyze**	**Evaluate**	**Higher order Thinking / Creative**
10.00	20.00	25.00	25.00	10.00	10.00