GANPAT UNIVERSITY										
FACULTY OF PHARMACY										
Programme	Master of Pharmacy				Branch/Spec.	Regulatory Affairs				
Semester	I				Version	1.0				
Effective from Academic Year	2026-27				Effective for the Batch admitted in	July 2026				
Course Code	MRA104T	Course Name	REGULATIONS AND LEGISLATION FOR DRUGS & COSMETICS, MEDICAL DEVICES, BIOLOGICALS & HERBALS, AND FOOD & NUTRACEUTICALS IN INDIA AND INTELLECTUAL PROPERTY RIGHTS							
Teaching Scheme		Examination Scheme (Marks)								
Credit	4		CE	SE	ES	Total		SE	ES	
Hours	4	Marks	10	15	75	100	Duration	1 Hr	3 Hrs	

Pre-requisites
NIL

Course Outcomes	
On successful completion of the course, the students will be able to:	
CO1	Identify key Indian Acts, rules, regulatory authorities, standards, ethical guidelines, and IPR concepts governing pharmaceuticals, biologicals, medical devices, and nutraceuticals.
CO2	Explain regulatory requirements, approval procedures, pharmacopoeial standards, BA/BE concepts, ethical frameworks, and intellectual property systems relevant to drug development.
CO3	Apply Indian regulatory provisions, standards, BA/BE requirements, and ethical guidelines in regulatory filings, compliance activities, and product approval processes.
CO4	Analyze regulatory data, BA/BE and stability requirements, preclinical and clinical compliance issues, and IPR–regulatory linkages for informed decision-making.
CO5	Evaluate regulatory strategies, ethical acceptability, compliance with standards, and intellectual property protections across the product development lifecycle.
CO6	Develop regulatory dossiers, compliance plans, and IP-aware regulatory strategies in accordance with Indian laws and global guidelines.

Theory Syllabus		
Unit	Content	Hrs.
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 Psychotropic Substances Act; Medicinal and Toilet Preparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955; Prevention of Cruelty to Animals Act.	12

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2	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 Pharmacopoeial Standards, BIS standards and ISO and other relevant standards	12
4	Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs, Regulatory Requirements for Bioequivalence study. Stability requirements: ICH and WHO Guidelines for Drug testing in animals/Preclinical Studies Animal testing: Rationale for conducting studies, CPCSEA Guidelines 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 Patent Scenario. IPR vs Regulatory Affairs	12

Practical Content
Practical, assignments and tutorials are based on above syllabus.

Reference Books	
1	Manual of Patent Practice & Procedure, 3rd Edition, by The Patent Office of India
2	Patent Failure How Judges, Bureaucrats, and Lawyers put innovators at risk by James Bessen and Michael J. Meurer
3	Principles and Practice of Clinical Trial Medicine by Richard Chin and Bruce Y. Lee
4	Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research New delhi 2006.
5	CPCSEA Guidelines for Laboratory Animal Facility by Committee for the purpose of control and supervision on experiments on animals (CPCSEA)
6	ICH E6 Guideline — Good Clinical Practice‖ by ICH Harmonised Tripartite
7	Guidance for Industry on Submission of Clinical Trial Application for Evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organisation)
8	Guidance for Industry on Requirement of Chemical & Pharmaceutical Information including Stability Study Data before approval of clinical trials / BE studies by CDSCO.
9	Guidelines for Import and Manufacture of Medical Devices by CDSCO.
10	Guidelines from official website of CDSCO