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	MRA105P	Course Name	**Regulatory Affairs Practical - I**							
Teaching Scheme		Examination Scheme (Marks)								
Credit	6		CE	SE	ES	Total		SE	ES	
Hours	12	Marks	20	30	100	150	Duration	1 Hr	3 Hrs	

Pre-requisites
NIL

Course Outcomes	
On successful completion of the course, the students will be able to:	
CO1	List regulatory procedures, documentation types, submission formats, and compliance requirements related to pharmaceutical practices and regulatory submissions.
CO2	Explain the purpose and regulatory significance of SOPs, quality control tests, dossiers, audits, clinical trial applications, and intellectual property filings.
CO3	Prepare SOPs, protocols, analytical reports, regulatory dossiers, checklists, and submissions for drugs, clinical trials, BA/BE studies, and IP registration.
CO4	Analyze case studies, audit findings, warning letters, labeling differences, and regulatory requirements across India, US, EU, and Japan.
CO5	Evaluate regulatory pathways, submission strategies, compliance status, and marketing authorization procedures across global regulatory systems.
CO6	Develop complete regulatory submissions, eCTD files, CTAs, checklists, and scientifically justified regulatory responses in line with international guidelines.

Theory Syllabus			
Unit	Content	Hrs.	
1	Case studies (4 Nos.) of each of Good Pharmaceutical Practices.		
2	Documentation for in process and finished products Quality control tests for Solid, liquid, Semisolid and Sterile preparations.		
3	Preparation of SOPs, Analytical reports (Stability and validation)		
4	Protocol preparation for documentation of various types of records (BMR, MFR, DR)		
5	Labeling comparison between brand & generics.		

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6	Preparation of clinical trial protocol for registering trial in India		
7	Registration for conducting BA/ BE studies in India		
8	Import of drugs for research and developmental activities		
9	Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM		
10	Registering for different Intellectual Property Rights in India		
11	GMP Audit Requirements as per CDSCO.		
12	Preparation and documentation for Indian Patent application		
13	Preparation of checklist for registration of IND as per ICH CTD format.		
14	Preparation of checklist for registration of NDA as per ICH CTD format.		
15	Preparation of checklist for registration of ANDA as per ICH CTD format.		
16	Case studies on response with scientific rationale to USFDA Warning Letter		
17	Preparation of submission checklist of IMPD for EU submission.		
18	Comparison study of marketing authorization procedures in EU		
19	Comparative study of DMF system in US, EU and Japan		
20	Preparation of regulatory submission using eCTD software		
21	Preparation of Clinical Trial Application (CTA) for US submission		
22	Preparation of Clinical Trial Application (CTA) for EU submission		
23	Comparison of Clinical Trial Application requirements of US, EU and Japan of a dosage form.		
24	Regulatory requirements checklist for conducting clinical trials in India.		
25	Regulatory requirements checklist for conducting clinical trials in Europe.		
26	Regulatory requirements checklist for conducting clinical trials in USA		

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