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	MRA101T	Course Name	GOOD REGULATORY PRACTICES							
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	Recall national and international regulatory guidelines and harmonization standards applicable to pharmaceuticals and medical devices.
CO2	Explain the principles, regulatory frameworks, and documentation requirements of cGMP, GLP, GALP, GDP, quality management systems, and validation practices.
CO3	Apply regulatory guidelines and quality system principles to ensure compliance in manufacturing, laboratory operations, computerized systems, distribution, and validation activities.
CO4	Analyze regulatory compliance data, audit findings, deviations, OOS results, and inspection observations to identify gaps and risks within pharmaceutical quality systems.
CO5	Evaluate the effectiveness of quality management systems, validation strategies, computerized systems, and supply chain controls against global regulatory and harmonization standards.
CO6	Design regulatory-compliant SOPs, validation master plans, audit programs, quality documentation, and compliance strategies in line with global regulatory requirements.

Theory Syllabus		
Unit	Content	Hrs.
1	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.	12
2	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	12
3	Good Automated Laboratory Practices: Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation,21 CFR Part 11, General check list of 21CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.	12

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

4	Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance and ISO standards	12
5	Quality management systems: Concept of Quality, Total Quality Management, Quality by design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)]and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety and efficacy of drug substances and products, ISO 13485, Sch MIII and other relevant CDSCO regulatory guidance documents.	12

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

Reference Books	
1	Good Laboratory Practice Regulations, by Sandy Weinberg, Fourth Edition Drugs and the Pharmaceutical Sciences, Vol.168
2	Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3	Establishing a cGMP Laboratory Audit System, A practical Guide by David M.Bleisner, Wiley Publication.
4	How to practice GLP by PP Sharma, Vandana Publications
5	Laboratory Auditing for Quality and Regulatory compliance bu Donald C.Singer, Drugs and the Pharmaceutical Sciences, Vol.150.
6	Drugs & Cosmetics Act, Rules & Amendments