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	MRA102T	Course Name	DOCUMENTATION AND REGULATORY WRITING						
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	List key pharmaceutical documents, dossier components, audit types, inspection requirements, and post-approval regulatory pathways.								
CO2	Explain the structure, purpose, and regulatory significance of pharmaceutical documentation, CTD/eCTD submissions, audits, inspections, and product life-cycle processes.								
CO3	Prepare regulatory documents, compile and submit dossiers, and implement audit and inspection requirements in compliance with global and Indian regulatory systems.								
CO4	Analyze audit findings, inspection observations, submission deficiencies, and post-approval changes to identify compliance gaps and regulatory risks.								
CO5	Evaluate regulatory strategies, submission pathways, CAPA effectiveness, and lifecycle management decisions against applicable regulatory and risk-management standards.								
CO6	Design comprehensive regulatory dossiers, audit programs, CAPA plans, and lifecycle management strategies in accordance with national and international regulations.								
Theory Syllabus									
Unit	Content								Hrs.
1	Documentation in pharmaceutical industry: Exploratory Product Development Brief (EPDB) for Drug substance and Drug product, Product Development Plan (PDP), Product Development Report (PDR), Master Formula Record, Batch Manufacturing Record and its calculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications, Distribution records, Certificate of Analysis (CoA), Site Master File and Drug Master Files (DMF).								12
2	Dossier preparation and submission: Introduction and overview of dossiers, contents and organization of dossier, binders and sections, compilation and review of dossier. Paper submissions, overview and modules of CTD, electronic CTD submissions; Electronic submission: Planning electronic submission, requirements for submission, regulatory bindings and requirements, Tool and Technologies, electronic dossier submission process and validating the submission, Electronic Submission Gateway (ESG). Non								12

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	eCTD electronic submissions (NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation of submission. Submission in Sugam system of CDSCO.	
3	Audits: Introduction, Definition, Summary, Types of audits, GMP compliance audit, Audit policy, Internal and External Audits, Second Party Audits, External third party audits, Auditing strategies, Preparation and conducting audit, Auditing strategies, audit analysis, audit report, audit follow up. Auditing/inspection of manufacturing facilities by regulatory agencies. Timelines for audits/inspection. GHTF study group 4 guidance document. ISO 13485.	12
4	Inspections: Pre-approval inspections, Inspection of pharmaceutical manufacturers, Inspection of drug distribution channels, Quality systems requirements for national good manufacturing practice inspectorates, inspection report, model certificate of good manufacturing practices, Root cause analysis, Corrective and Preventive action (CAPA).	12
5	Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes [SUPAC], Changes Being Effected in 30 Days (CBE-30), Annual Report, Post marketing Reporting Requirements, Post approval Labeling Changes, Lifecycle Management, FDA Inspection and Enforcement, Establishment Inspection Report (EIR), Warning Letters, Recalls, Seizure and Injunctions. ISO Risk Management Standard	12

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

Reference Books	
1	Compliance auditing for Pharmaceutical Manufacturers. Karen Ginsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London NewYork, Washington D.C.
2	Pharmaceutical Manufacturing Handbook, Regulations and Quality by Shayne Cox Gad. Wiley-Interscience, A John Wiley and sons, Inc., Publications.
3	Handbook of microbiological Quality control. Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyar. CRC Press. 2000.
4	Laboratory auditing for quality and regulatory compliance. Donald C. Singer, Raluca-loana Stefan, Jacobus F. Van Staden. Taylor and Francis (2005).
5	Implementing Juran's Road Map for Quality Leadership: Benchmarks and Results, By Al Endres, Wiley, 2000
6	Understanding, Managing and Implementing Quality: Frameworks, Techniques and Cases, By Jiju Antony; David Preece, Routledge, 2002
7	Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report By Edward E. Lawler; Susan Albers Mohrman; George Benson, Jossey-Bass, 2001
8	Corporate Culture and the Quality Organization By James W. FairfieldSonn, Quorum Books, 2001

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9	The Quality Management Sourcebook: An International Guide to Materials and Resources By Christine Avery; Diane Zabel, Routledge, 1997
10	The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications
11	Juran's Quality Handbook, Sixth Edition, Joseph M. Juran and Joseph A. De Feo, ASQ Publications
12	Root Cause Analysis, The Core of Problem Solving and Corrective Action, Duke Okes, 2009, ASQ Publications
13	International Medical Device Regulators Forum (IMDRF) Medical Device Single Audit Program (MDSAP)