GANPAT UNIVERSITY									
FACULTY OF PHARMACY									
Programme	Maser 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	MRA103T		Course Name		CLINICAL RESEARCH REGULATIONS				
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 clinical trial phases, ethical principles, regulatory pathways, and key national and international clinical research guidelines.
CO2	Explain the clinical drug development process, ethical conduct of clinical research, and regulatory requirements governing drugs, medical devices, and IVDs.
CO3	Apply GCP principles, ethical guidelines, and regulatory requirements to protocol development, informed consent, safety reporting, and clinical trial conduct.
CO4	Analyze clinical trial designs, regulatory submissions, safety data, and inspection findings to identify compliance and risk issues.
CO5	Evaluate clinical evidence, ethical safeguards, and regulatory strategies for approval, post-marketing surveillance, and pharmacovigilance.
CO6	Develop clinical trial protocols, informed consent documents, regulatory submissions, and safety management plans in compliance with global regulations.

Theory Syllabus		
Unit	Content	Hrs.
1	Clinical Drug Development Process • Different types of Clinical Studies • Phases of clinical trials, Clinical Trial protocol • Phase 0 studies • Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points • Phase II studies (proof of concept or principle studies to establish efficacy) • Phase III studies (Multi ethnicity, global clinical trial, registration studies) • Phase IV studies (Post Marketing Studies; PSUR) Clinical Investigation and Evaluation of Medical Devices & IVDs Different Types of Studies Key Concepts of Medical Device Clinical Evaluation Key concepts of Clinical Investigation	12

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2	Ethics in Clinical Research: • Historical Perspectives: Nuremberg Code, Thalidomide study , Nazis Trials, Tuskegee Syphilis Study, The Belmont Report, The declaration of Helsinki • Origin of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines. • The ethics of randomized clinical trials • The role of placebo in clinical trials • Ethics of clinical research in special population • Institutional Review Board/Independent Ethics Committee/Ethics Committee – composition, roles, responsibilities, review and approval process and ongoing monitoring of safety data •Data safety monitoring boards. • Responsibilities of sponsor, CRO, and investigator in ethical conduct of clinical research • Ethical principles governing informed consent process • Patient Information Sheet and Informed Consent Form • The informed consent process and documentation				12
3	Regulations governing Clinical Trials India: Clinical Research regulations in India – Schedule Y & Medical Device Guidance USA: Regulations to conduct drug studies in USA (FDA) • NDA 505(b)(1) of the FD&C Act (Application for approval of a new drug) • NDA 505(b)(2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant) • ANDA 505(j) of the FD&C Act (Application for approval of a generic drug product) • FDA Guidance for Industry - Acceptance of Foreign Clinical Studies • FDA Clinical Trials Guidance Document: Good Clinical Practice EU: Clinical Research regulations in European Union (EMA)				12
4	ClinicalResearch Related Guidelines • Good Clinical Practice Guidelines (ICH GCP E6) • Indian GCP Guidelines • ICMR Ethical Guidelines for Biomedical Research • CDSCO guidelines GHTF study group 5 guidance documents Regulatory Guidance on Efficacy and Safety ICH Guidance's • E4 – Dose Response Information to support Drug Registration • E7 – Studies in support of General Population: Geriatrics • E8 – General Considerations of Clinical Trials • E10 – Choice of Control Groups and Related Issues in Clinical Trials, • E 11 – Clinical Investigation of Medicinal Products in the Pediatric Population • General biostatics principle applied in clinical research				12
5	USA & EU Guidance USA: FDA Guidance • CFR 21Part 50: Protection of Human Subjects • CFR 21Part 54: Financial Disclosure by Clinical Investigators • CFR 21Part 312: IND Application • CFR 21Part 314: Application for FDA Approval to Market a New Drug • CFR 21Part 320: Bioavailability and bioequivalence requirements • CFR 21Part 812: Investigational Device Exemptions • CFR 21Part 822: Post-market surveillance • FDA Safety Reporting Requirements for INDs and BA/BE Studies • FDA Med Watch • Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment European Union: EMA Guidance • EU Directives 2001 •EudraLex (EMEA) Volume 3 – Scientific guidelines for medicinal products for human use • EU Annual Safety Report (ASR) • Volume 9A – Pharmacovigilance for Medicinal Products for Human Use • EU MDD with respect to clinical research • ISO 14155				12
Practical Content					
Practical, assignments and tutorials are based on above syllabus.					
Reference Books					
1	Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams				

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2	HIPAA and Human Subjects Research: A Question and Answer Reference Guide By Mark Barnes, JD, LLM and Jennifer Kulynych, JD, PhD
3	Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene
4	International Pharmaceutical Product Registration: Aspects of Quality, Safety and Efficacy; Anthony C. Cartwright; Taylor & Francis Inc., USA.
5	New Drug Approval Process: The Global Challenge; Guarino, Richard A; Marcel Dekker Inc., NY.
6	FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics; Douglas J. Pisano, David Mantus; CRC Press, USA
7	Country Specific Guidelines from official websites.
8	Drugs & Cosmetics Act & Rules and Amendments.
9	EU Clinical Research Directive 2001: http://www.eortc.be/services/doc /clinical-eudirective-04-april-01.pdf
10	Code of Federal Regulations, FDA: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
11	Guidelines of International Conference on Harmonization: http://www. ich.org/products/guidelines.html
12	Eudralex Guidelines: http://www.gmpcompliance.info/euguide.htm
13	FDA New Drug Application: http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm
14	Medicines and Healthcare products Regulatory Agency: http://www.mhra.gov.uk
15	Central Drugs Standard Control Organization Guidance for Industry: http://cdsco.nic.in/CDSCO-GuidanceForIndustry.pdf
16	ICMR Ethical Guidelines for Biomedical Research: http://icmr.nic.in /ethical_guidelines.pdf