INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (REGULATORY AFFAIRS)**
SEMESTER	**1**
COURSE TITLE	**CLINICAL RESEARCH REGULATIONS**
COURSE CODE	**13MR0103**
COURSE CREDITS	**4**

Objective:

1 This course is designed to impart fundamental knowledge on the clinical development process of drugs, pharmaceuticals, and Medical Devices, phases and conduct of clinical trials and research, regulations, and guidance governing the conduct of clinical research in India, the USA, and the EU. It prepares the students to learn in detail about various laws, legislations, and guidance related to safety, efficacy, ethical conduct, and regulatory approval of clinical research.

Course Outcomes: After completion of this course, student will be able to:

1 History, origin, and ethics of clinical and biomedical research and evaluation.

2 Clinical drug, medical device development process, and different types and phases of clinical trials.

3 Regulatory requirements and guidance for the conduct of clinical trials and research.

Pre-requisite of course:B. Pharm. Qualified

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
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, multipleascending, dose escalation, methods, food effect studies, drug–drug interaction, PK endpoints. ? Phase II studies (proof of concept or principal studies toestablish 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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Contents : Unit	Topics	Contact Hours
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 – GoodClinical Practice (ICH-GCP) guidelines. ? The ethics of randomized clinical trials. ? The role of placebo in clinical trials. ? Ethics of clinical research in special populations. ? Institutional Review Board/Independent EthicsCommittee/Ethics Committee – composition, roles,responsibilities, review and approval process, and ongoingmonitoring of safety data. ? Data safety monitoring boards. ? Responsibilities of a sponsor, CRO, and investigator in the ethicalconduct of clinical research. ? Ethical principles governing the 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 the USA (FDA). ? NDA 505(b)(1) of the FD&C Act (Application for approval of anew drug). ? NDA 505(b)(2) of the FD&C Act (Application for approval of anew drug that relies, at least in part, on data not developedby the applicant). ? ANDA 505(j) of the FD&C Act (Application for approval of ageneric drug product). ? FDA Guidance for Industry - Acceptance of Foreign ClinicalStudies. ? FDA Clinical Trials Guidance Document: Good ClinicalPractice. EU: Clinical Research regulations in European Union (EMA).	12
4	**Clinical Research-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 DrugRegistration. ? E7 – Studies in support of General Population: Geriatrics. ? E8 – General Considerations of Clinical Trials. ? E10 – Choice of Control Groups and Related Issues inClinical Trials. ? E 11 – Clinical Investigation of Medicinal Products in thePediatric Population. ? General biostatics principle applied in clinical research.	12

Contents : Unit	Topics	Contact Hours
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
Total Hours		**60**

Textbook :

1 Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance, by Fay A. Rozovsky and Rodney K. Adams., Fay A. Rozosky, Rodney K. Adams, 2003

References:

1 Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance , Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance , by Fay A. Rozovsky and Rodney K. Adams., Fay A. Rozosky, Rodney K. Adams, 2003

2 HIPAA and Human Subjects Research: A Question-and-Answer Reference Guide , HIPAA and Human Subjects Research: A Question-and-Answer Reference Guide , by Mark Barnes, JD, LLM, and, Jennifer Kulynych, JD, Ph.D., 2003

3 Principles and Practices of Clinical Research, Second Edition, Principles and Practices of Clinical Research, Second Edition, John I. Gallin and Frederick P. Ognibene,, Elsevier, 2011

4 Reviewing Clinical Trials: A Guide for the Ethics Committee, Reviewing Clinical Trials: A Guide for the Ethics Committee, Johan PE Karlberg and Marjorie A Speers; Karlberg, Johan Petter Einar, Hong Kong., 2003

5 International Pharmaceutical Product Registration: Aspects of Quality, Safety, and Efficacy; , International Pharmaceutical Product Registration: Aspects of Quality, Safety, and Efficacy; , Anthony C. Cartwright;, Taylor & Francis Inc., USA., 2000

6 New Drug Approval Process: The Global Challenge;, New Drug Approval Process: The Global Challenge;, Guarino, Richard A; Marcel Dekker Inc., NY.th Edition Edited , by Richard A. Guarino. Marcel Dekker, 2005

7 FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics, FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics, Douglas J. Pisano, David Mantus;, CRC Press, USA., 2008

8 Country Specific Guidelines , Country Specific Guidelines , from official , websites, .

References:

9 Drugs & Cosmetics, Drugs & Cosmetics, Act & Rules, and Amendments., 1940

Suggested Theory Distribution:

The suggested theory distribution as per Bloom's taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery					
Remember / Knowledge	**Understand**	**Apply**	**Analyze**	**Evaluate**	**Higher order Thinking / Creative**
10.00	20.00	25.00	25.00	10.00	10.00

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