INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (PHARMACEUTICS)**
SEMESTER	**1**
COURSE TITLE	**REGULATORY AFFAIRS**
COURSE CODE	**13MC0104**
COURSE CREDITS	**4**

Objective:

1 The course is designed to impart advanced knowledge and skills required to learn the concept of generic drugs and their development, various regulatory filings in different countries, different phases of clinical trials, and submitting regulatory documents: IND, NDA filing process, and ANDA.
1. To know the approval process of;

2 The course is designed to impart advanced knowledge and skills required to learn the concept of generic drugs and their development, various regulatory filings in different countries, different phases of clinical trials, and submitting regulatory documents: IND, NDA filing process, and ANDA.
2. To know the chemistry, manufacturing controls, and their regulatory importance;

3 The course is designed to impart advanced knowledge and skills required to learn the concept of generic drugs and their development, various regulatory filings in different countries, different phases of clinical trials, and submitting regulatory documents: IND, NDA filing process, and ANDA.
3. To learn the documentation requirements for;

4 The course is designed to impart advanced knowledge and skills required to learn the concept of generic drugs and their development, various regulatory filings in different countries, different phases of clinical trials, and submitting regulatory documents: IND, NDA filing process, and ANDA.
4. To learn the importance.

5 The course is designed to impart advanced knowledge and skills required to learn the concept of generic drugs and their development, various regulatory filings in different countries, different phases of clinical trials, and submitting regulatory documents: IND, NDA filing process, and ANDA. 1. To know the approval process of; 2. To know the chemistry, manufacturing controls, and their regulatory importance; 3. To learn the documentation requirements for; 4. To learn the importance.

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

1 1. The Concepts of innovator and generic drugs, drug development process.

2 2. The Regulatory guidance and guidelines for the filing and approval process.

3 3. Preparation of Dossiers and their submission to regulatory agencies in different countries.

4 4. Post-approval regulatory requirements for actives and drug products.

5 5. Submission of global documents in CTD/ eCTD formats.

6 6. Clinical trial requirements for approvals for conducting clinical trials.
7. Pharmacovigilance and process of monitoring in clinical trials.

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DR. LALJI HAKUBHAI BALDANIYA
Digitally signed by (Name of Dean/ Principal)

Pre-requisite of course:B.Pharm. Degree holder from an Indian university established by law in India from an institution approved by the Pharmacy Council of India and has scored not less than 55 percent of the maximum marks (aggregate of 4 years of B.Pharm.).

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	**Unit1** a. Documentation in the Pharmaceutical Industry: Master formula record, DMF (Drug Master File), distribution records. Generic drugs product development; Introduction, Hatch- Waxman act and amendments, CFR (CODE OF FEDERAL REGULATION), drug product performance, in-vitro, ANDA regulatory approval process, NDA approval process, BE and drug product assessment, in –vivo, scale-up process approval changes, post-marketing surveillance, outsourcing BA and BE to CRO., b. The regulatory requirement for product approval: API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs.	15
2	**Unit-2** CMC, post-approval regulatory affairs. Regulation for combination products and medical devices. CTD and e-CTD format, industry, and FDA liaison. ICH - Guidelines of ICH-Q, S, E, M. Regulatory requirements of EU, MHRA, TGA, and ROW countries.	15
3	**Unit-3** Non-clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD), and investigator brochure (IB).	15
4	**Unit-4** Clinical trials: Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- a new, requirement for clinical study process, pharmacovigilance safety monitoring in clinical trials.	15
Total Hours		**60**

Textbook :

1 Generic Drug Product Development, Solid Oral Dosage forms, , Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol. 143., 2018

2 The Pharmaceutical Regulatory Process, Second Edition , Ira R. Berry and Robert P. Martin, , Informa Health care Publishers., 2016

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Textbook :

3 New Drug Approval Process: Accelerating Global Registrations , Richard A Guarino, MD, Drugs and the Pharmaceutical Sciences, Vol.190., 2005

4 FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics, Douglas J. Pisano, David Mantus., Douglas J. Pisano, David Mantus., 2008

5 Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance , Fay A. Rozovsky and Rodney K. Adams., Fay A. Rozovsky and Rodney K. Adams., 2010

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**
20.00	25.00	25.00	15.00	10.00	5.00

Instructional Method:

1 The course delivery method will depend upon the requirement of content and the need of students. The teacher in addition to the conventional teaching method by the blackboard may also use any tools such as demonstration, role play, quiz, brainstorming, MOOCs etc.

2 The internal evaluation will be done based on continuous evaluation of students in the laboratory and classroom.

3 Students will use supplementary resources such as online videos, NPTEL videos, MOOCs/ e-courses, virtual laboratories.

Supplementary Resources:

1 www.ich.org/

2 www.fda.gov/

3 europa.eu/index_en.htm

4 https://www.tga.gov.au/tga-basics

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