LJ UNIVERSITY

LJ INSTITUTE OF PHARMACY
Department of Pharmaceutical Technology

SEMESTER: I

Subject Name: REGULATORY AFFAIRS
Subject Code: MPH104T

Scope: The course is designed to impart advanced knowledge and skills required to learn the concept of generic drug and their development, various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents.

Objectives: Upon completion of the course, it is expected that the students will be able to understand:

- Understand the concepts of innovator and generic drugs, the drug development process, and the relevant documents.
- Understand the Regulatory requirement for product approval.
- Explain post-approval regulatory requirements for actives and drug products. Explain the submission of global documents in CTD/ eCTD formats of dosage forms including storage, packaging, and quality control. Explain the Preparation of Dossiers and their submission to regulatory agencies in different countries.
- Understand the global submission of IND, NDA, ANDA.
- Understand clinical trials requirements for approvals for conducting clinical trials. Explain the Pharmacovigilance and process of monitoring in clinical trials.

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme	
				Theory	
Theory	Tutorial	Practical	Total	External	Internal
4	0	0	4	75	25

Sr. No.	Course Contents	Hours
1	A.)**Documentation in 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.) 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	**CMC, post approval regulatory affairs.** Regulation for combination products and medical devices. CTD and ECTD format, industry and FDA liaison. ICH - Guidelines of ICH-Q, S E, M. Regulatory requirements of EU, MHRA, TGA and ROW countries.	**15**
3	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	**15**
4	**Clinical trials:** Developing clinical trial protocols. Institutional review board/ independent ethics committee Formulation and working procedures informed Consent process and procedures. HIPAA- new, requirement to clinical study process, pharmacovigilance safety monitoring in clinical trials.	**15**
Total Hours		60

Recommended Books:

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

2. The Pharmaceutical Regulatory Process, Second Edition Edited by Ira R. Berry and Robert P.Martin, Drugs and the Pharmaceutical Sciences,Vol.185, Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD,5th edition, Drugs and the Pharmaceutical Sciences,Vol.190.

4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons Inc.

5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.

6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A.Rozovsky and Rodney K. Adams

7. www.ich.org/

8. www.fda.gov/

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