Course Syllabus
Gyanmanjari Pharmacy College
Semester-1(M. Pharm.)

Subject: Regulatory Affair (MPHPC11504)

Type of course: Major

Prerequisite: B.Pharmacy

Rationale: Course 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: filing process of IND, NDA and ANDA.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks					Total Marks
				Theory Marks		Practical Marks		CA	
Cl	T	P	C	ESE	MSE	V	P	ALA	
4	-	-	4	75	25	--	--	50	150

Legends: Cl-Class Room Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.

Course Content:

Chapter No.	Course content	Hrs	% Weightage
1.	**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.	12	20
2.	**Regulatory requirement for product approval:** API, biologics, novel, therapies obtaining NDA, ANDA for generic drugs ways and means of US registration for foreign drugs	12	20
3.	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.	12	20
4.	**Non clinical drug development:** Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	12	20
5.	**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.	12	20

Continuous Assessment:

Sr. No	Active Learning Activities	Marks
1.	**Research and Present Regulations by Region:** Assign students to research regulatory requirements in different regions (e.g., FDA in the U.S., EMA in Europe, PMDA in Japan) and present their findings and upload GMIU web portal.	25
2.	**Regulatory Document Review & Creating a Regulatory compliance checklist:** Provide students with examples of regulatory documents (e.g. IND applications, NDA submissions) for review within given period of time and Task give to the students with creating a compliance checklist for a specific drug development phase (e.g., preclinical, clinical, post-marketing) also, can upload GMIU web portal.	25
Total		50

Suggested Specification table with Marks (Theory):75

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	20%	45 %	20%	10%	05 %	-

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Course Outcome:

After learning,the course the students should be able to:	
CO1	The Concepts of innovator and generic drugs, drug development process. The Regulatory guidance's and guidelines for filing and approval Process
CO2	Preparation of Dossiers and their submission to regulatory agencies in different countries and Post approval regulatory requirements for actives and drug products
CO3	Submission of global documents in CTD/ e CTD formats
CO4	Clinical trials requirements for approvals for conducting clinical trials Pharmacovigilance And process of monitoring in clinical trials.

Instructional Method:

The course delivery method will depend upon the requirement of content and need of students. The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, MOOCs etc.
From the content 10% topics are suggested for flipped mode instruction.
Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory
The internal evaluation will be done on the basis of Active Learning Assignment
Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.

Reference 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] europa.eu/index_en.htm

[10] https://www.tga.gov.au/tga-basicsSpectroscopy by Donald L Pavia, Gary M Lampman, George S Kriz, James A Vyvyan