Faculty of Pharmacy
Master of Pharmacy (M. Pharm.)
(W. E. F.: 2023-24)
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Name of Faculty	:	Faculty of Pharmacy
Name of Program	:	Master of Pharmacy
Course Code	:	1MPH04
Course Title	:	Regulatory Affairs
Type of Course	:	Pharmaceutics
Year of Introduction	:	2023-24

Prerequisite	:	To have sufficient knowledge about basics of pharmaceutical dosage forms
Course Objective	:	To develop a comprehensive understanding of regulatory frameworks, processes, and guidelines governing pharmaceutical products and to acquire the skills necessary to ensure compliance with regulatory requirements and contribute to the successful development, approval, and post-marketing surveillance of pharmaceutical products. This objective encompasses the main goals of a regulatory affairs program, which include gaining knowledge about regulatory frameworks, understanding the processes involved in obtaining regulatory approvals for pharmaceutical products, and learning how to navigate post-marketing surveillance and compliance.
Course Outcomes	:	At the end of this course, students will be able to:
	CO1	To understand the concepts of innovator and generic drugs, drug development process.
	CO2	To apply the knowledge of the regulatory guidance's and guidelines for filing and approval process, preparation of dossiers and their submission to regulatory agencies in different countries
	CO3	To learn the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals and the submission of global documents in CTD/ eCTD, ASEAN formats.
	CO4	To evaluate the clinical trials requirements for approvals for conducting clinical trials, pharmacovigilance and process of monitoring in clinical trials
	CO5	To understand of basic terminology, regulatory guidance's, guidelines, laws and acts.

Teaching and Examination Scheme

Teaching Scheme (Contact Hours)			Credits	Examination Marks				
				Theory Marks		Practical Marks		Total Marks
L	T	P	C	SEE	CIA	SEE	CIA	
04	00	00	04	75	25	-	-	100

Legends: ***L****-Lecture;* ***T****–Tutorial/Teacher Guided Theory Practice;* ***P****– Practical,****C*** *– Credit,* ***SEE*** *– Semester End Examination,* ***CIA*** *- Continuous Internal Assessment (It consists of Assignments/Seminars/Presentations/MCQ Tests, etc.))*

Course Content

Unit No.	Topics	Teaching Hours	Weightage	Mapping with CO
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	25%	CO1 CO5
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	25%	CO2 CO3
3	Non clinical drug development: Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	15	25%	CO1 CO5
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	15	25%	CO4 CO5

	clinical study process, pharmacovigilance safety monitoring in clinical trials.			

Suggested Distribution of Theory Marks Using Bloom's Taxonomy						
Level	Remembrance	Understanding	Application	Analyse	Evaluate	Create
Weightage	**0**	**40**	**60**	**0**	**0**	**0**

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

Suggested Learning Websites

Sr. No.	Name of Website
1	https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application
2	https://www.fda.gov/drugs/types-applications/new-drug-application-nda
3	https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda
4	https://www.ich.org/page/ctd
5	https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd
6	https://www.pharmaguideline.com/2021/07/investigational-medicinal-product-dossier.html
7	https://ichgcp.net/7-investigators-brochure
8	https://www.ich.org/
9	https://www.pharmaguideline.net/regulatory-affairs/
10	https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines_en.pdf
11	https://pci.nic.in/pdf/Syllabus_B_Pharm.pdf
12	https://www.aicte-india.org/downloads/bpharma.pdf.
13	https://www.ipc.gov.in/
14	https://www.ayush.gov.in/
15	https://ayudmla.gujarat.gov.in/home.php
16	https://www.fda.gov/
17	https://www.pharmacopoeia.com/
18	https://ipapharma.org/
19	https://gpat.nta.nic.in/
20	https://drnaitiktrivedi.com/
21	https://gdc4gpat.com/course/gpat/
22	https://niscpr.res.in/
23	https://delnet.in/
24	https://ihubgujarat.in/
25	https://www.ssipgujarat.in/

Recommended Books (Latest Editions)

Sr. No.	Name of Book
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