Dr. Rafiq Zakaria Campus
Maulana Azad Educational Trust
Y.B. Chavan College of Pharmacy
An ISO 9001:2008 Certified Institute
(B. Pharm., M. Pharm & Research Center)

COURSE MODULE

Program Title	M. Pharmacy
Department	Pharmaceutics
Course Title	Regulatory Affairs

NAME OF INSTITUTION : Y. B. CHAVAN COLLEGE OF PHARMACY, AURANGABAD

1. AFFILIATED UNIVERSITY : DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD

2. DEPARTMENT : Pharmaceutics

4. PROGRAM TITLE : M. PHARM

4.1. Program Outcomes (PO):

PO 01: Ability to independently carry out research/ investigation and development work to solve practical problems.

PO 02: Ability to write and present a substantial technical report/ documents.

PO 03: Ability to demonstrate a degree of mastery over the area as per the specialization of the program.

PSO1: Ability to independently develop the business proposal in the specialized area.

PSO2: Ability to use software and technology in research analysis and product/ process design.

5. COURSE SPECIFICATION :

5.1.Course Identification and General Information

a. Course Title:	Regulatory Affairs		
b. Course Number/ Code	**MPH 104T**		
c. Credit Hours	Theory	Practical	Total
	4	------	4
d. Study level/ semester at which this course is offered	Semester III		
e. Pre-requisite	Pharmaceutical Jurisprudence (B.Pharm)		
f. Co-requisite	--------		
g. Language of teaching the course	English		
h. Prepared by	Dr. M. H. Dehghan		
i. Approved by	Head of Department Pharmaceutics		

5.2.Course Description/Scope:

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.

5.3. Course Objectives

Upon completion of the course, student shall be able to understand

- The Concepts of innovator and generic drugs, drug development process
- The Regulatory guidance's and guidelines for filing and approval process
- Preparation of Dossiers and their submission to regulatory agencies in different countries
- Post approval regulatory requirements for actives and drug products
- Submission of global documents in CTD/ eCTD formats
- Clinical trials requirements for approvals for conducting clinical trials
- Pharmacovigilence and process of monitoring in clinical trials.

5.4. Course Outcomes (CO):

Code	Course outcome
CO S1-MPT104.01	Ability to prepare documentation as per regulatory requirement of various regulatory bodies.
CO S1-MPT104.02	Application of various regulations and guidelines prescribed by various agencies in research, quality assurance and marketing approval process of pharmaceutical products.
CO S1-MPT104.03	Knowledge about ICH guidelines, NDA, ANDA, CTD and e.CTD filing.
CO S1-MPT104.04	Ability to Understand and draft clinical trial protocols.

5.4.1 CO-PO Matrix: (PO: Program Outcome; CO: Course Outcome)

Course code (CO)	Program Outcome (PO)				
	PO1	PO2	PO3	PSO 1	PSO2
CO S1-MPT104.01	H	M	M	M	H
CO S1-MPT104.02	M	S	M	-	M
CO S1-MPT104.03	H	S	H	S	S
CO S1-MPT104.04	H	M	H	S	M

Correlation levels 1, 2 or 3 as defined below:
S: Slight (Low); M: Moderate (Medium); H: Substantial (High); If there is no correlation, put '-'

6. Teaching and Assessment Methods for achieving learning outcome:

Teaching Strategies /methods used	Methods of Assessment
Lectures Group Discussions Demonstrations Problem Solving Sessions	Assignments Oral Presentations Written Examinations Laboratory Experimental Reports (daily assessment).

6. COURSE CONTENTS:

6.1. Theoretical Aspect:

Order	Topic list/units	Subtopics list	Number of Weeks	Contact Hours
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.	4	12
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	4	12
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	4	12
4	Non clinical drug development	Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).	4	12
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,	4	12

		pharmacovigilance safety monitoring in clinical trials.		

6.2. Practical Aspect (If Any):-------

6.3. Assignments/Tutorials:

Assignments are given as questions on the respective chapters.

7. LEARNING RESOURCES:

Sr. No.	Title of Learning Material	Details
1	Text books	**1.** Forensic Pharmacy by Kuchikar and Itkar, Drug Regulatory Affairs by Vaywahare, Itkar and Kuchikar.
2	Essential references (as per syllabus)	1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargeland 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 AGuarino, 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, andbiologics/edited By Douglas J. Pisano, David Mantus. 6. Clinical Trials and Human Research: A Practical Guide to RegulatoryCompliance By Fay A.Rozovsky and Rodney K. Adams
3	Reference material	CDSO publications and updates of Drug and Cosmetics Act 1940 and Drug and Cosmetics Rules 1945, Amendments to the Drug and Cosmetics Act and Rules. CDER publications and Guidance

		EMEA publications and guidance Orange Book, ICH guidelines, Indian Patent Act. Country Specific Regulatory Guidelines (available from internet) Government Publications on issues affecting sale, distribution, manufacturing, excise.
4	E-materials and websites	www.ich.org/ www.fda.gov/ europa.eu/index_en.htm https://www.tga.gov.au/tga-basics Ppt. and reviews available on LMS.
5	Other learning material	---

8. STUDENT SUPPORT:

Office Hours/Week	Other Procedures
Two hours minimum	WhatsApp, e-mail.

9. SCHEDULE OF ASSESSMENT TASKS DURING THE SEMESTER:

Sr. No.	Assessment Method	Week due	Marks	Proportion of Final Assessment
01	Assignments, Exercises & tutorials/Attendance		10	10%
02	Sessional (Internal Theory exam)		15	15%
04	Final exam (theory)	As per University at end of course	75	75%
Total			100	100%

10. FACILITIES REQUIRED:

Sr. No.	Particular of Facility Required
01	Lecture/ Tutorial Rooms (capacity for 60 students)
02	Laboratory (capacity for 20 students)
03	Computing resources: P-IV-PCs with recent hardware/ utilization of open source and licensed application software
04	Other resources: Appropriate laboratory tools, Chemicals, Glass ware, Apparatus, Instrumentation

11. COURSE IMPROVEMENT PROCESSES:

11.1. Strategies for obtaining student feedback on effectiveness of teaching:

Course delivery evaluation by students using: Questionnaire forms and online questionnaires

11.2. Other strategies for evaluation of teaching by the instructor or by the department:

Periodic review by Academic Planning & Monitoring Committee and departmental review committee, Observations and assistance of colleagues, External assessments by advisors/ examiners and auditors.

11.3. Process for improvement of teaching:

Use of ICT tools, teaching aids, Simultaneous practical orientation and theory classes (SPOT), Adoption of reflective teaching.

11.4. Describe the planning procedures for periodically reviewing of course effectiveness and planning for improvement:

Procedure for periodic planning and reviewing includes: periodic review by departmental review committee, review of course delivery and outcome through assessment and feedback from all stake holders.

11.5. Course development plans:

Provide inputs for course improvement and update to University Course development Committees (Board of Studies)

12. INFORMATION ABOUT FACULTY MEMBER RESPONSIBLE FOR THE COURSE:

Name	Dr Dehghan M H
Location	Dept of Pharmaceutics- M.Pharm,
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Office Hours	10:00 AM to 5:00 PM