

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	MASTER OF PHARMACY (REGULATORY AFFAIRS)
SEMESTER	1
COURSE TITLE	REGULATORY AFFAIRS PRACTICAL-1
COURSE CODE	13MR0105
COURSE CREDITS	6

Objective:

- 1 This course is designed to acquire the practical skills and knowledge needed to navigate the regulatory landscape, ensuring compliance and facilitating the development, registration, and post-approval activities of pharmaceutical products and medical devices.

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

- 1 Demonstrate an understanding of regulatory affairs principles through apply regulatory requirements to pharmaceutical products.
- 2 Interpret and navigate regulatory documents. Prepare regulatory submissions.
- 3 Conduct regulatory assessments. Develop regulatory strategies. Implement quality and compliance measures.
- 4 Demonstrate professional ethics and responsibility.

Pre-requisite of course:B. Pharm. Qualified

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
0	0	12	0	0	20	100	30
Contents : Unit	Topics						Contact Hours
Total Hours							

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	Practical-1 Case studies (4 Nos.) of each of Good Pharmaceutical Practices.	12
2	Practical-2 Documentation for in-process and finished products Quality control tests for Solid, liquid, Semisolid, and Sterile preparations.	12
3	Practical-3 Preparation of SOPs, Analytical reports (Stability and validation).	12

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
4	Practical-4 Protocol preparation for documentation of various types of records (BMR, MFR, DR).	12
5	Practical-5 Labeling comparison between brand & generics.	12
6	Practical-6 Preparation of clinical trial protocol for registering trials in India.	12
7	Practical-7 Registration for conducting BA/ BE studies in India.	12
8	Practical-8 Import of drugs for research and developmental activities.	12
9	Practical-9 Preparation of regulatory dossier as per Indian CTD format and submission in SUGAM.	12
10	Practical-10 Registering for different Intellectual Property Rights in India.	12
11	Practical-11 GMP Audit Requirements as per CDSCO.	12
12	Practical-12 Preparation and documentation for Indian Patent application.	12
13	Practical-13 Preparation of checklist for registration of IND as per ICH CTD format.	12
14	Practical-14 Preparation of checklist for registration of NDA as per ICH CTD format.	12
15	Practical-15 Preparation of checklist for registration of ANDA as per ICH CTD format.	12
16	Practical-16 Case studies on response with a scientific rationale to USFDA Warning Letter.	12
17	Practical-17 Preparation of submission checklist of IMPD for EU submission.	12
18	Practical-18 Comparison study of marketing authorization procedures in the EU.	12
19	Practical-19 Comparative study of DMF system in the US, EU, and Japan.	12
20	Practical-20 Preparation of regulatory submissions using eCTD software.	12
21	Practical-21 Preparation of Clinical Trial Application (CTA) for US submission.	12

Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
22	Practical-22 Preparation of Clinical Trial Application (CTA) for EU submission.	12
23	Practical-23 Comparison of Clinical Trial Application Requirements of the US, EU, and Japan of a dosage form.	12
24	Practical-24 Regulatory requirements checklist for conducting clinical trials in India.	12
25	Practical-25 Regulatory requirements checklist for conducting clinical trials in Europe.	12
26	Practical-26 Regulatory requirements checklist for conducting clinical trials in USA.	12
Total Hours		312

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
10.00	20.00	25.00	25.00	10.00	10.00