

<b>INSTITUTE</b>	<b>FACULTY OF PHARMACY</b>
<b>PROGRAM</b>	<b>MASTER OF PHARMACY (REGULATORY AFFAIRS)</b>
<b>SEMESTER</b>	<b>2</b>
<b>COURSE TITLE</b>	<b>REGULATORY AFFAIRS PRACTICAL-2</b>
<b>COURSE CODE</b>	<b>13MR0205</b>
<b>COURSE CREDITS</b>	<b>6</b>

**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 drugs, cosmetics, medical devices, herbals, biologicals, food, and nutraceuticals.

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

- 1 Demonstrate an understanding of regulatory affairs principles through applying 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:--**

**Teaching and Examination Scheme**

<b>Theory Hours</b>	<b>Tutorial Hours</b>	<b>Practical Hours</b>	<b>ESE</b>	<b>IA</b>	<b>CSE</b>	<b>Viva</b>	<b>Term Work</b>
0	0	12	0	0	20	100	30

<b>Contents : Unit</b>	<b>Topics</b>	<b>Contact Hours</b>
<b>Total Hours</b>		

### Suggested List of Experiments:

Contents : Unit	Topics	Contact Hours
1	<b>Practical</b> a. Change Management/ Change control, b. Deviations, c. Corrective & Preventive Actions (CAPA)., 2. Documentation of raw materials analysis as per official monographs., 3. Preparation of audit checklist for various agencies., 4. Preparation of submission to FDA using eCTD software., 5. Preparation of submission to EMA using eCTD software., 6. Preparation of submission to MHRA using eCTD software., 7. Preparation of Biologics License Applications (BLA)., 8. Preparation of documents required for Vaccine Product Approval., 9. Comparison of clinical trial application requirements of US, EU, and India of Biologics., 10. Preparation of Checklist for Registration of Blood and Blood Products., 11. Registration requirement comparison study in 5 emerging markets(WHO) and preparing checklist for market authorization., 12. Registration requirement comparison study in emerging markets(BRICS) and preparing checklist for market authorization., 13. Registration requirement comparison study in emerging markets(China and South Korea) and preparing checklist for market authorization., 14. Registration requirement comparison study in emerging markets (ASEAN) and preparing checklist for market authorization., 15. Registration requirement comparison study in emerging markets (GCC)and preparing checklist for market authorization., 16. Checklists for 510k and PMA for the US market., 17. Checklist for CE marking for various classes of devices for EU., 18. STED Application for Class III Devices., 19. Audit Checklist for Medical Device Facility., 20. Clinical Investigation Plan for Medical Devices.	12
<b>Total Hours</b>		<b>12</b>

### 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