RafflesUniversity,Neemrana, Alwar,Rajasthan-301705	
PREREQUISITES	
Course:PHARMACEUTICAL REGULATORY SCIENCE	**Number o f Prescribed Hours:45**
AcademicYear:2023-24 **Programme:B.Pharmacy**	
NameofFaculty:Mr. Mantun Prasad Gupta	**Year/Semester:4YearVIIISem**

RAFFLES UNIVERSITY

TEACHING PLAN: PHARMACEUTICAL REGULATORY SCIENCE (THEORY)

TEACHINGPLAN: PHARMACEUTICAL REGULATORY SCIENCE

SCHOOL: (SOP)SCHOOL OFPHARMACY		**ACADEMICSESSION:2023-24**		**FORSTUDENTS'BATCH:2023-24**	
1	**Course No.**	BP804T			
2	**CourseTitle**	PHARMACEUTICAL REGULATORY SCIENCE			
3	**Credits**	**8**			
4	**Learning Hours**		**ContactHours**	**45**	
			Assessment	**10**	
			GuidedStudy	**20**	

5	**Course Objective**	This course is designed to impart the fundamental knowledge on the regulatory requirements for approval of new drugs, and drug products in regulated markets of India & other countries like US, EU, Japan, Australia,UK etc. It prepares the students to learn in detail on the regulatory requirements, documentation requirements, and registration procedures for marketing the drug products.
6	**Course Outcomes**	Upon completion of the subject student shall be able to; 1. Know about the process of drug discovery and development 2. Know the regulatory authorities and agencies governing the manufacture and sale of pharmaceuticals 3. Know the regulatory approval process and their registration in Indian and international markets
7	**Outlinesyllabus:**	

7.01	**Unit**	**Introduction**	**Lectures Hours**
7.02	**Unit I**	**New Drug Discovery and development** Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.	10

7.03	**Unit II**	**Regulatory Approval Process** Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.	5
		Regulatory authorities and agencies Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications)	5

7.04	**Unit lll**	**Registration of Indian drug product in overseas market** Procedure for export of pharmaceutical products, Technical documentation, Drug Master File , Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.	10
7.05	**Unit IV**	**Clinical trials** Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance – safety monitoring in clinical trials	8

7.06	Unit V	**Regulatory Concepts** Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	7
8	**Course Evaluation**		
8.1	**CA:30%**		
8.11	**Attendance**	--	
8.12	**Homework**	4 Assignments,10%	
8.13	**Quizzes**	4Quizzes, 80%	
8.14	**Projects**	1Project,5%	
8.15	**Presentation**	1Presentation,5%	
8.16	**Anyother**	--	
8.2	**MTE**	20%	
8.3	**End-termexamination:50%**		
9	**TextBooks &References**		
9.1	**Textbook**	**Recommended books (Latest edition):** 1. Drug Regulatory Affairs by Sachin Itkar, Dr. N.S. Vyawahare, Nirali Prakashan. 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 / SandyWeinberg. 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. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143 7. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams 8. Principles and Practices of Clinical Research, Second Edition Edited by John I. Gallin and Frederick P. Ognibene 9. Drugs: From Discovery to Approval, Second Edition By Rick Ng	