GUJARAT TECHNOLOGICAL UNIVERSITY
Integrated Master of Science (Biotechnology)
Semester: 6
Subject Name: Biopharma Regulations
Subject Code: 1360403

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks				Total Marks
				Theory Marks		Practical Marks		
L	T	P	C	ESE (E)	PA (M)	PA (I)	ESE (V)	
4	0	0	4	70	30	0	0	100

Prerequisite:

Students should have brief idea about biotechnological and biopharmaceutical products and their development strategies

Rationale:
In this subjects, students will get the idea about biopharma regulation which are very much useful for increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Content:

Unit No.	Content	No. of Hours	Weightage (%)
1	**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.	12	20
2	**Regulatory Approval Process** Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA) in US. Changes to an approved NDA / ANDA.	12	20
3	**Registration of Indian drug product in overseas market** Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD)research.	12	20
4	**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	12	20
5	**Regulatory Concepts** Basic terminologies, guidance, guidelines, regulations, laws and acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book	12	20
	Total Hours:	60	

Textbook:

1. Finkel, Richard, etal., Lippincott's Illustrated Reviews Pharmacology. IVth Edition. Wolters Kluwer / Lippincott Williams & Wilkins, 2009

Reference Books:

1. Gareth Thomas. Medicinal Chemistry. An introduction. John Wiley. 2000.
2. Katzung B.G. Basic and Clinical Pharmacology, Prentice Hall of Intl. 1995.

Course Outcomes:

No.	Course Outcomes	RBT Level*
1	The knowledge gained in this course would be used to understand and evaluate different pharmaceutical parameters for the current and future biotechnology related products on the market.	UN,RM,AP
2	This course paves a ways to the students to acquire knowledge on novel biotechnological and pharmaceutical products, current medicines and their applications in therapeutic and diagnostic fields.	UN,RM,AP
3	Demonstrate knowledge and understanding of current topical and newly emerging aspects of pharmaceutical biotechnology.	UN,RM,AP
4	Understand the legal steps involved in progressing a new drug to market. Grasping the current regulatory acts and safety norms of the modern pharmaceutical industries.	UN,RM,AP

*RM: Remember, UN: Understand, AP: Apply, AN: Analyze, EL: Evaluate, CR: Create

Suggested Course Practical List:

List of Laboratory/Learning Resources Required

1. https://onlinecourses.nptel.ac.in/noc21_ge14/preview