Course Type	Course Code	Name of the Course	L	T	P	Credit
DC	NCYC507	Clinical Trials & Regulatory Affairs	3	1	0	4

Course Objectives

- To understand drug safety aspects, clinical trials and regulatory processes for approval of drug products

Learning Objectives

Students will learn

- Clinical trials and pharmacovigilance basics
- ADR reporting systems
- Current good manufacturing guidelines
- Drug approval processes
- Protecting innovation in pharmaceuticals as intellectual property

Unit	Topics to be covered	Lecture Hours	Learning outcomes
1	Clinical Trials in drug development: clinical trial stages; primary & secondary questions; choice of control group; randomization and masking; study population; parallel, cross-over, factorial designs	9L+3T	• Understanding the various aspectes involved in design of clinical trials
2	Pharmacovigilance: Need and evolution of PV; Active and Passive PV; Definitions; ADRs; Classification of ADRs; VigiBase; Vaccine safety surveillance;	7+3T	• Understanding how drug safety is monitored post-marketing and various reporting systems
3	Regulatory affairs: 21CFR Part 211; Organizational structure of FDA; Drug approval process; Hatch-Waxmann Act; Para I-IV filings; NDA Classification codes; Generic drugs; Biosimilars;	9+3T	• Understanding CGMP guidelines and the FDA protocols for drug approval • Understanding the generic drug market and the approval process
4	Intellectual property rights: Types of IPR, IPR in Pharmaceuticals; Section 3 of Indian Patent Act;	8+3T	• Understanding how pharmaceuticals are protected by intellectual property with special emphasis on Indian territory.
5	Case studies from pharmaceutical industry: clinical trials, FDA warning letters, mergers & acquisitions, IPR and ANDA filings.	9+2T	• Going through various case studies related to the pharmaceutical market.
	Total	42L+14T	

Textbooks:

1. Mann's Pharmacovigilance, E.B. Andrews, N. Moore, Wiley, 2014
2. B S Kuchekar, A M Khadtare, S C Itkar, Forensic Pharmacy, Nirali Prakshan, 33rd edition/2019

Reference Books:

1. Textbook of Pharmacovigilance, S.K.Gupta, S.Srivastava, Jaypee Brothers Medical Publishers, 2nd Edition, 2018