Clinical Drug Development Assistant

Class: M.Sc. Part -I

Skill Level: 9

Department of Biotechnology

1. Title: Clinical Drug Development Assistant

2. Year of implementation:2020

Structure of Skill Development Course

Skill Level	Theory Hours	Practical Hours	Total Hours	Credits	No. of students in batch
9	20	30	50	03	30

Syllabus

Learning Objectives:

1. To learn drug development processes
2. To learn different phases in clinical trails
3. To learnGood Clinical Practice

Theory Syllabus (20 Hrs)

Unit I

Introduction to clinical research and Drug Development Process

Overview of Drug Development Process, briefing of clinical trials phases

Protocol and clinical trial Designing:

Definition of protocol, its importance and purpose, Protocol format: Chapters (Headings) and broad contents of protocol, Important scientific and administrative aspect included in protocol, Introduction to Research Methodology, Protocol writing team and role of each member, Clinical trial design: Types of study designs, Sampling, sample size, randomization, Inclusion & Exclusion criteria, Phases of clinical trial & Types of trials.

Unit II

Good Clinical Practice (GCP) ICH regulations:

Ethical Principles and their origin, Ethics in clinical research: As per ICMR & GCP, Ethics committees: Roles & responsibility of IEC and IRB, Ethics in relation to vulnerable groups & special situations, Responsibilities of Sponsors, Investigators & Regulators, ICH: Purpose, regulations & guidelines, Informed consent and Informed consent form, Essential Documents

Practical Syllabus (30 Hrs)

List of Experiments:----------24 hr

1. Data management plan (DMP) development
2. Data Collection Strategy
3. Case Report Form Development
4. Data quality assessment
5. Process of Data Transfer
6. Project/ Field Visits/ Industrial Visit

Learning Outcomes:

After the successfully completion of the course the students can acquires the :-

1. Knowledge about drug development processes
2. Knowledge about different phases in clinical trails
3. Knowledge about Good Clinical Practice

Recommended Books:

1. Basic and Clinical Pharmacology, Prentice hall, International, Katzung, B.G.
2. Clinical Pharmacology, Scientific book agency, Laurence, DR and Bennet PN.
3. Clinical pharmacokinetics, Pub. Springer Verlab, Dr. D.R Krishna, V. Klotz
4. Remington Pharmaceutical Sciences, Lippincott, Williams and Wilkins

1 Kotler Philip, Keller Kevin Lane, *Marketing Management*, Saddle River: Prentice Hall, 15th edition, 2015 pp

BOS Sub Committee:

BOS Sub Committee (Department)	BOS Sub Committee (External Expert)
Dr. V. M. Nalavade **Dr. S. K. Mujawar**	**Dr. Rajesh Sharma, VidyaPratisthan's school of Biotechnology, Baramati** **Ms. Swapnali Jadhav, Access Health Care Pvt. Ltd., Hinjewadi**