Clinical Research Data Analyst

Class: M.Sc. Part -II

Skill Level: 10

Department of Biotechnology

1. Title: Clinical Research Data Analyst

2. Year of implementation:2020

Structure of Skill Development Course

Skill Level:	Theory Hours	Practical Hours	Total Hours	Credits	No. of students in batch
10	20	30	50	02	20

Syllabus

Learning Objectives:

1. To learn Drug Regulatory Affairs
2. To learn Clinical Safety & Pharmaco vigilance procedures
3. To learnMonitoring of Clinical Trials

Theory Syllabus (20 Hrs)

Unit I

Drug Regulatory Affairs (Clinical Trial):

Regulatory Authority in India (DCGI & CDSCO),Schedule Y of Drugs & Cosmetics Act, International Scenario of Regulatory Aspects: FDA, CFR

Clinical Safety & Pharmaco vigilance procedures: Definitions of AE, ADR, SAE,Recording & reporting: Objectives & Importance, Pharmaco vigilance: International procedures, Pharmaco vigilance in India

Unit II

Monitoring of Clinical Trials and clinical data management:

Monitoring and its role in clinical trials, CRF and other source documents relevant to monitoring.Practical for Protocol Design, CRF Design and source documentation.

Practical Syllabus (30 Hrs)

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

1. Laboratory Data collection formats
2. Medication Data collection formats
3. Database design for a clinical trial data management
4. Clinical Observation Data
5. Introduction of digital image basic concepts applied to medical image
6. Project/ Field Visits/ Industrial Visit----------6 hr

Learning Outcomes:

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

1. Knowledge about Drug Regulatory Affairs
2. Knowledge about Clinical Safety & Pharmaco vigilance procedures
3. Knowledge about Monitoring of Clinical Trials

Recommended Books:

1. Drug interaction, Kven Stockley. Hamsten
2. Drug interaction, Basic Bussiness Publ, Bombay, J.K. Mehra
3. Clinical pharmacology and drug therapy Grahame smith and Aronson,
4. Text Book of Therapeutics Drug and Disease Management Hardbound. Richard A Helms

BOS Sub Committee:

BOS Sub Committee (Department)	BOS Sub Committee (External Expert)
Dr. P. C. Mandave **Dr. S. K. Mujawar**	**Dr. Rajesh Sharma, VidyaPratisthan's school of Biotechnology, Baramati** **Ms.SwapnaliJadhav, Access Health Care Pvt. Ltd., Hinjewadi**