Savitribai Phule Pune University
(Formerly University of Pune)

Department of Technology
Board of Studies Chemical & Biotechnology (CB)

STRUCTURE OF ONE YEAR FULL TIME POST GRADUATE DIPLOMA IN
Clinical Research Technology(PGD-CRT)

Each Trimester is of 15 weeks followed by examination in subsequent week.

Trimester 1

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCR101	Anatomy & Physiology	3	1	0	4
2.	PGCR102	Clinical Pharmacology	2	1	1	4
3.	PGCR103	Bioavailability, Bioequivalence Studies	2	1	1	4
4.	PGCR104	Regulatory affairs	0	2	2	4
5.	PGCR105	Communication Skills				4
		Total				**20**

Trimester 2

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCR201	Pharma Regulatory Affairs	3	1	0	4
2.	PGCR202	Clinical Data Management and Analytics	3	1	0	4
3.	PGCR203	Clinical Research	3	1	0	4
4.	PGCR204	Pharmacovigilance		2	2	4
5.	PGCR205	Perspective in Clinical Evaluation		2	2	4
		Total				**20**

Trimester 3

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCR301	Internship at site			4	4
2.	PGCR302	Thesis submission			4	4
		Total				**8**

Subject 1 :

ANATOMY AND PHYSIOLOGY **58 Hrs**

Introduction

Characteristic and Function of the system .

- Skeletal system,
- Muscular System,
- Nervous System
- Endocrine System
- Cardiovascular System
- Respiratory System
- Digestive System
- Urinary System
- Reproductive System

Reference:

1. HUMAN ANATOMY & PHYSIOLOGY (RO) (, BHISE)
2. Ross & Wilson Anatomy and Physiology in Health and Illness International Edition (, BSc PhD FHEA Waugh Anne)
3. 2,Anatomy Made Easy 2020 by Ritesh Shah

Subject 2

Subject Clinical Pharmacology,

Branches of Pharmacology,
Orphan drugs, Essential Drugs, Prescription Drugs, Non- prescription Drugs, Drug Nomenclature, Source of Drug, Route of Administration, Drug Transport, Effects of pH on Drug Kinetics, Bioavailability. First pass metabolism, Barrier of drug, Metabolism- biotransformation, Excretion, Pharmacodynamics; Mechanism of drug action, receptor mediated mechanism, Receptor families, Factors modifying drug action, placebo effect, nocebo effect, new drug development, Adverse drug effects, teratogenicity

Reference :

1. Principles of pharmacology (Sharma,)
2. Basic & Clinical Pharmacology (Katzung)
3. A Text Book of General Pharmacology 6th Edition (Dr. N. S. Vyawahare)

Subject 3 :

BIOAVAILABILITYAND BIOEQUIVALENCE STUDIES **12 Hrs**

Background & Definitions, Introduction, Bioavailability, Bioequivalence
In vivo studies and In Vitro studies,
Pharmacodynamics Studies Comparative Clinical ,Studies In Vitro Studies ,
PHARMACO KINETIC STUDY DESIGN AND DATA HANDLING ,
Facilities for Conducting ,
Maintenance of Records &Retention Of Bioavailability / Bioequivalence Studies

Bioavailability and Bioequivalence report preparation

This Dissertation or thesis presents a student's research results, describing the research with reference to relevant work done at a CRO or Site.It will include a description of the methods of research considered, and those Actually employed, andcountry specific requirements for approval of drug in that country. The thesis is the student's own work and must be written by the student .The Internal Layout of the Dissertation or Thesis. it may be changed as per the regulatory requirement.

Reference:

1. Pharacokinetics & Biopharmacuties 4th Edition (N. J. Gaikwad, U. N. Harle)
2. Pharmaceutical Bioequivalence. by Welling, Informa Healthcare
3. Essentials of Biopharmaceutics and Pharmacokinetics by Kar , Elsevier Science

Subject 4

REGULATORY AFFAIRS 48 Hrs

Regulatory affairs including audit–

- Revised schedule Y,
- Standard operating procedures(SOPs)
- Good manufacturing practices guide for Active pharmaceutical ingredients
- Pre-appraisal inspections, WHO guidelines
- FDA inspections
- Pharmaceutical equipment validation, a vital componentof QA during manufacturing
- Concept of Total Quality Management
- Documentation in pharmaceutical industry
- Table of contents of typical dossier
- GMP guidelines on the validation of manufacturing process
- Methods to develop and maintaining strict compliance
- Schedule M requirements and guidelines on clinical trial for import and manufacture new drug
- Regulations and requirements for controlling impurities
- Guidelines for the assessment of herbal medicines
- Finger printing of medicinal plants with markers/biomarkers.
- Preparation of DMF, NDA and ANDA
- ICH harmonization process
- Preparation of protocols for toxicity studies, acute, sub-acute and chronic.
- Drug interaction and idiosyncratic reactions.
- Preparation of SOPs.
- Sample preparations of DMF, NDA and ANDA for different drugs.

- Regulatory requirement of controlling impurities and what is the present status.
- Preparation of dossier.
- International Regulatory Authorities (USA, UK andEurope)
- Importance of protocol

Reference:

1. Drug Regulatory Affairs 2020 By Papiya Bigoniya
2. Drug Regulatory Affairs (Agarwal Gaurav)
3. Drug Regulatory Affairs (Dr. Vyawahare N. S.)

Subject 5

Communication Skills:

- Written Communication: Medical Language Introduction, Initial interactions with Patients , When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication
- Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the Message . Written communication to doctors
- Patients Interview Skills: Purpose of an interview, Do's and Dont's of an interview
- Case Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery
- Group Discussion: Introduction, Communication skills in group discussion, Do's and Dont's of group discussion

Practice LAB

- Public Speaking
- Basic communication covering the following topics
- Meeting People
- Asking Questions
- Making Friends
- What did you do? Do's and Dont's
- Effective Writing
- Interview Handling Skills
- E-Mail etiquette
- Presentation Skills

Reference:

1. COMMUNICATION SKILLS FOR PROFESSIONALS AND STUDENTS (Dr. Amitabh Kishor Dwivedi)
2. Communication Skills and Personality Development (Dhenge, S.A., Patel, V.G, Murai, A.M, Kadam, J.R.)
3. The Science of Effective Communication (Tuhovsky Ian)

Subject 6

Pharmacovigilance (Training on Argus Safety)

Preliminary Module : Principles of Pharmacovigilance

important concepts of Pharmacovigilance which are essential to understand to develop preliminary understanding of Pharmacovigilance before taking the Argus Safety tutorials.

Overview and Navigation

learn the process of logging in and Navigating through the Oracle Argus Safety user interface. This chapter shall also cover the various user interface elements of the Oracle Argus Safety application and the functionality of each element.

: Business Process Workflow

In this chapter we shall discuss the business process and workflow of a basic single case within Argus Safety

Case Entry and Processing

In this chapter we shall discuss how to work with cases using the standard workflow of case management within Argus safety. This would include the process of booking in a case, performing case entry, processing the case, performing medical and coding review and printing medical summaries. The process of performing case operations such as closing, copying and revising a case shall also be discussed.

Case Form Features and Worklists

This chapter will cover the various features of the Case Form and their functions. The various tabs of the Case Form and their utility in the process of management of safety related data shall be discussed.

Coding Terms and MedDRA Browser

This chapter describes the MedDRA (Medical Dictionary for Regulatory Activities) browser and how it is used to encode diseases, symptoms, signs, and so forth. In Argus Safety, using such a dictionary provides consistency when assigning terms for adverse events.

Advanced Conditions

This chapter provides information about Advanced Conditions, a powerful search tool within Oracle Argus Safety, that enables you to build complex queries for retrieving system data.

Dashboard and Utilities

This chapter describes the various types of information available on the dashboard and the utilities functions available that allow the user to view, change or retrieve case related information.

Reporting and Submissions

In this chapter we shall discuss about the regulatory requirement for reporting adverse event cases and the reporting capabilities of the Argus safety suite. We shall also understand the serious adverse event reconciliation process and module as well as the study unblinding process and module.

Course Completion

This course completion module, includes a Final Quiz that you will need to take to complete this course. The marks of the final quiz will be added to the marks of all other graded activities of this course. If your total score in the course is 75% and above, you will be able to see a Course completion certificate which you can then download.

ICSR Case processing, Narrative Writing, Training on Argus/Aereis software 4.SAS Bio-statistics using SAS techniques

It has been designed to provide advance Bio-statistics training and its application with SAS for a diverse range of students. It is primarily aimed at those wishing to become trained professionals and wanting an in-depth theoretical and practical statistical knowledge. From this course candidates will

Demonstrate a broad understanding of the value and basic principles of Bio-statisticsmethods in health and medical/clinical research. Introduction and revision of conventional methods for contingency tables, Chi-square tests. Measures of frequency and associations, odds ratio, relative risk. Distribution theory. Categorical data and GLMs.

Key concepts of estimation and construction of Normal theory. Hypothesis testing, correlation. Role of ANOVA, regressions and confidence interval. Methods of inference based on likelihood theory. Main types of study designs. Sources of error- Chance, bias, confounding, Association of causality. Evaluation of published papers.

Reference:

1. Fundamentals of Pharmacovigilance (Dr Sumit Verma, Dr Yogesh Gulati)
2. Manual of Drug Safety and Pharmacovig (Cobert Barton L.)
3. Good Pharmacovigilance Practice Guide (Medicines, Healthcare Products Regulatory Agency)

Subject 7
Clinical Data Management and Analytics

Introduction and use of SAS

Environment of SAS. Library structure in SAS.Data steps and Procstep.

Manipulating the data- Converting the numeric data to character and viceversa.Using logical operators and where conditions. Merging of the datasets. Writing the data into multiple datasets.

Debugging errors in the program.Writing the procedure- Tabulate, Univerate, Means, Median, Mode, Report, Sort, Mixed, Transpose etc,Creating the html reports.Importing the data to SAS and exporting the data from SAS. Overview of SAS macros.

Reference:

1. Good clinical data management practice A Complete Guide - 2019 Edition (Blokdyk Gerardus)
2. Practical Guide to Clinical Data Management, Third Edition by Susanne Prokscha
3. SAS Clinical Programming : In 18 Easy Steps (Y. Lakshmi Prasad)

Subject 8
Clinical Research

Drug Development Process: Review FDA approved process for development and approval of a drug,

key player in drug development.

Informed consent process and human subject protection, history that have impacted human subject rights, review informed consent process and describe regulatory requirements. Mock Consent Processing

GCP Regulation and Guidelines

GCP regulation guidance ,ICH guide lines. Review mandatory regulations of FDA

Sponsor investigator and IRB.

Collection of Regulatory Documents, Review and Submission

Adverse events (AE) and Serious adverse events (SAE)

Introduction of AE and SAE to the management, identification, documentation and reporting

review process and the system involved in safety management

The Protocol and Data Management

Siteinteractions ,Managing clinical supply/ laboratories/ Analysis ofSamples

FDA inspections

Review the purpose of FDA inspections, preparation for an FDA inspection, activity during an inspection,

Source Document Verification
Training Orientation

Review role of monitor trainee including site objectives, pre-approval requirements for site visits, site visit planning site visit expenses and expense forms

site visits SOPs and documentation and sign of for training to perform independent site visits.

Interim visits

Site Monitoring Visits, Data Correction

Site close out audit and inspections

Familarize new CRAs with activities that occur at the end of a trial and their responsibilities for completion of these activities.

Mini Project and Seminar

Subject 9
SITE MANAGEMENT ORGANIZATION

- INTRODUCTION TO SMO, Definition, Regulatory Guidelines, Ethical Guidelines, Site Management Services, Roles and
- Responsibilities of a Clinical Research Coordinator (CRC), SMO Business scenario
- THE SPONSOR'S PERSPECTIVE:
- Clinical Trial Project Planning Management

- Clinical Trial Project Feasibility Analysis
- Clinical Trial Project Planning and Resource Management
- Total Quality Control Management System (TQCMS) in a Clinical Trial Project
- Clinical Trial Master File & Documents Management
- Clinical Trial Vendors Selection & Services Management
- Clinical Trial Investigators Selection & Regulatory Management
- Clinical Trial Cost & Project Budgeting Management
- Clinical Trial Agreement & Contract Management Clinical Trial Regulatory , Dossier Management

Subject 10

PERSPECTIVE IN CLINICAL EVALUATION

Scope, Definitions, General principles of clinical evaluation, Sources of data/documentation used in a clinical evaluation (Stage 1)

1) Data generated through literature search.

2) Data generated through clinical experience3) Data from clinical investigations. Appraisal of clinical data (Stage 2) Analysis of the clinical data (Stage 3). The Clinical Evaluation Report, The role of the notified body in the assessment of clinical evaluation data . 1 Examination of design dossier.2 Evaluation as part of the quality system procedure.3 Notified body specific procedure and expertise

PROCESS / REQUIREMENT TO BE FOLLOWED. Informed Consent Process, CRF, Patient screening, Inclusion and exclusion criteria, Randomization, Blinding, Recruitment (materials and methods), Retention and Compliance of study subjects, Ethics Committee Submission

FORMAT / TEMPLATE:

1. A possible format for the literature search report
2. A possible methodology for documenting the screening and selection of literature within a literature search report
3. Some examples to assist with the formulation of inclusion /exclusion criteria
4. A possible method of appraisal
5. A possible format for a clinical evaluation report
6. Clinical evaluation checklist for Notified Bodies.

Reference Books

1.Drug Regulatory Affairs 2020 By Papiya Bigoniya

2,Anatomy Made Easy 2020 by Ritesh Shah

3.Textbook Of Anatomy & Physiology For Nurses 2nd Edition 2020 by Indu Khurana

4.Clinical Trials and Human Research

5. Textbook of Clinical Research by Vikas Dhikav