Department of Technology,
Savitribai Phule Pune University
(Formerly University of Pune)

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

Semester 1

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCR101	Anatomy and Physiology	3	1		4
2.	PGCR102	Medical and Scientific Writing	2		2	4
3.	PGCR103	Bioavailability, Bioequivalence Studies	2		2	4
4.	PGCR104	Communication Skills 1		2	2	3
		Total				**15**

Semester 2

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCR201	Pharma Regulatory Affairs	3	1		4
2.	PGCR202	Clinical Data Management and Analytics	3	1		4
3.	PGCR203	Clinical Pharmacology	3	1		4
4.	PGCR204	Mini Project and Seminar		2	2	3
5.	PGCR205	Communication Skills 2		2	2	3
		Total				**18**

Semester 3

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCR301	Perspective in Clinical evaluation : Introduction to Clinical Research	3	1		4
2.	PGCR302	Molecular Mechanism of Drug Action	3	1		4
3.	PGCR303	Pre Clinical Evaluation of Drug	3	1		4
4.	PGCR304	Site Management organization	3	1		4
5.	PGCR305	Pharmacovigilance		1	4	3
		Total				**15**

Semester 4

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCR401	Mini Project : Open Elective		2	4	4
2.	PGCR402	Internship (OJT) & Thesis submission				10

		Total		**10**
		Total Course Credits		**62**

AUDIT COURSES				
Sr. No.	**Subject Code**	**Subject Name**	**Credits**	**Semester/ Trimester**
1	CYSA	Cyber Security	2	I
2	HRE101	Human Rights & Duties	1	II
3	HRE102/HRE103	Human Rights & Vulnerable Groups/Law Policy , Society & Enforcement mechanism	1	III

ANATOMY AND PHYSIOLOGY **58 Hrs**

Introduction

Characteristic and Function of the system .

- Skeletal system,
- MuscularSystem,
- NervousSystem
- EndocrineSystem
- CardiovascularSystem
- RespiratorySystem
- DigestiveSystem
- UrinarySystem
- Reproductive System

Medical& Scientific writing **48 hrs**

Basic introduction to medical writing

Overview of drug development regulation and sequence clinical background and drug discovery , Pharmacological testing and pre-clinical researchFiling of NDA, Clinical trials protocols , Phases of clinical research , filing of NDA ,Documents of drug submission and for medical community ,Writing of research reports,clinical trial reports , Supportive documents for investigational brochure for clinical research Publication for medical community, authorship and ethical issues

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

PRACTICALS **32 hrs**

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, and country 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 regulatoryrequirement.

Communication Skills 1

Communication Skills I : Course content:

- English Language basics : Articles, prepositions, conjunctions b. Transformation of Sentences (Simple, Compound, Complex) , Vocabulary
- Tenses d. Subject-Verb agreement e. Question Tags
- Direct and Indirect Speech g. Voice
- Reading Skills: Comprehension (unseen passage)
- Reading with fluency and speed • Skimming and scanning • Identifying relevant information • Isolating fact from opinion • Understanding concepts and arguments • Identifying distinctive features of language (Passage should be of 250-350 words of Level I. The passage may be taken from literary/scientific/technical writing fields.)
- Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context
- Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers
- Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment
- Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication
- Communication Styles: Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style
- Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming an Active Listener, Listening in Difficult Situations
- Effective Written Communication: Introduction, 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

Practice LAB :

- Visual Perception
- Communication gap due to loss of information in verbal communication
- Understanding facial reactions
- Reading Skills
- Topic Explaining Skills
- Pronunciations covering the following topics
- Pronunciation (Consonant Sounds)
- Pronunciation and Nouns

REGULATORY AFFAIRS 48 Hrs

Regulatory affairs including audit–

- Revised scheduleY,
- Standard operating procedures(SOPs)
- Good manufacturing practices guide for Active pharmaceuticalingredients
- Pre-appraisal inspections, WHOguidelines
- FDA inspections
- Pharmaceutical equipment validation, a vital component of QA during manufacturing
- Concept of Total Quality Management
- Documentation in pharmaceutical industry
- Table of contents of typicaldossier
- 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 newdrug
- Regulations and requirements for controllingimpurities
- Guidelines for the assessment of herbalmedicines
- 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 andchronic.
- Drug interaction and idiosyncraticreactions.
- Preparation ofSOPs.
- Sample preparations of DMF, NDA and ANDA for differentdrugs.
- Regulatory requirement of controlling impurities and what is the presentstatus.
- Preparation ofdossier.
- International Regulatory Authorities (USA, UK andEurope)
- Importance of protocol

Project:

Dossier Preparation For Regulatory Body submission

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 SASmacros.

Introduction to Databases System Oracle 11g

Basic Concepts of Database,Database System in Organization,Data Sharing and Database: Types of Sharing.Strategic Database Planning.Database and Management Control,Risks and Cost of Databases,Separating Logical and Physical Data Representation.Database Development (Database Development Life Cycle),Data Modeling Using the Entity-Relationship Model (ER-Model),Relational Data Model,Relational Model Concepts,Relational Model Constraints,Update Operations on Relations,DefiningRelations,The Relational Algebra,Additional Relation Operation,Examples of Queries in the Relational Algebra,Relational Database Design Using ER-to-Relational Mapping,Introduction to Relational Calculus,An Introduction to SQL,Data definition in SQL,Queries in SQL,VIEWS in SQL,Record Storage and Primary File Organization,AnIntroduction,Secondary Storage Devices,Buffering of Blocks,Placing File Records on Disk,Operation on Files,Files of Unordered Records (Heap Files),Files of Ordered Records (SortedFiles)

Clinical Pharmacology (Introduction)

1. **Drug DevelopmentProcess :**Review FDA approved process for development and approval of a drug, key player in drug development.

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

3. **GCP Regulation andGuidelines**

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

Sponsor investigator and IRB.

4. **Collection of Regulatory Documents, Review and Submission**
5. **Adverse events (AE) and Serious adverse events (SAE)**
6. Introduction of AE and SAE to the management
7. identification, documentation and reporting of
8. , review process and the system involved in safety management
9. **The Protocol and Data Management**

Siteinteractions ,Managing clinical supply/ laboratories/ Analysis ofSamples

10. **FDAinspections**

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

11. **Source DocumentVerification**
12. **TrainingOrientation**

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.

13. **Interimvisits**

Site Monitoring Visits, Data Correction

14. **Site close out audit andinspections**

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

Semester 2 : Subject 4 : Mini Project and Seminar

Communication skill 2 :

- 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

Recommended Books: (Latest Edition)

- Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
- Communication skills, Sanjay Kumar, Pushpalata, 1stEdition, Oxford Press, 2011
- Organizational Behaviour, Stephen .P. Robbins, 1stEdition, Pearson, 2013
- Brilliant- Communication skills, Gill Hasson, 1stEdition, Pearson Life, 2011
- The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5thEdition, Pearson, 2013
- Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
- Communication skills for professionals, Konar nira, 2ndEdition, New arrivals – PHI, 2011
- Personality development and soft skills, Barun K Mitra, 1stEdition, Oxford Press, 2011
- Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
- Soft skills and professional communication, Francis Peters SJ, 1stEdition, Mc Graw Hill Education, 2011
- Effective communication, John Adair, 4thEdition, Pan Mac Millan,2009 12. Bringing out the best in people, Aubrey Daniels, 2ndEdition, Mc Graw Hill, 1999

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) 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 inclision /exclusion criteria
4. A possible method of appraisal
5. A possible format for a clinical evaluation report
6. Clinical evaluation checklist for Notified Bodies.

MOLECULAR MECHANISM OF DRUG ACTION

INTRODUCTION, HISTORY, DRUG TARGET TYPES , RECEPTOR MEDIATED MECHANISMS :

Ligand gated ion channels (Ionotrophic receptors); G-protein coupled receptors (Metabotropic receptors); Adenylcyclase pathway/cAMP pathway, Phospholipase C/inositol pathway, Ion channels, RhoA/Rho kinase; Kinase linked receptors - Receptor tyrosine kinase, Serine/theonine kinases, Cytokine receptors, Guanylylcyclase linked recptors , Nuclear receptors - Homodimers,Heterodimers

SIGNALING PATHWAYS

Receptor desensitization; Receptor regulation- Up and down; Receptors and diseases Non receptor mediated mechanisms; Ion channels: Voltage activated Na+ channel, K+ channels, Ca+ channels, TRP channels; Enzymes: Competitive inhibition, Non competitive inhibition, Transporters- Neuronal transporters, Non neuronal transporters, Cholesterol transporters, Nucleoside transporters, Glucose transporters, Na+ H" antiporter ,Recent advances - GPCR oligomerization, Signaling by internalized GPCR

PRECLINICAL EVALUATION OF DRUGS

INTRODUCTION AND DRUG DISCOVERY PROCESS:

Principles, techniques and strategies used in drug discovery. High throughput screening, human genomics, Preclinical models employed in the screening of new drugs; Preclinicalevaluation of drugs

a) CNS Pharmacology: Sedatives, hypnotics, anxiolytics, antidepressants,Muscle relaxants(Central). CNS stimulations, anticonvulsants, antipsychotics, Noortropics, antiparkinsonian agents, Analgesics, antipyretics, anti-inflammatory agents and local anesthetics.

b)Gastrointestinal drugs: Antiulcer agents, laxatives

c)Respiratory pharmacology: bronchodilators, antitussives,

d)Diuretics.e)Histamine antagonists

f)Reproductive pharmacology: anti fertility agents

g) Anticancer Agents

BIOASSAYS: BASIC PRINCIPLES OF BIOASSAYS

a)Biological standardization of vaccines and sera: Pertussis vaccine, rabies vaccine and Plague vaccine.

b) Cellculture technology: Animal cell culture- General requirements for establishing the animal cell culture,media, conditions and methods for cell cultures

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

Investigator's Meeting / Project Kick-off Meeting Management, Clinical Trial Fund & Finance Management, Clinical Trial Supply Chain / Logistics Management, Clinical Trial Project Monitoring & Compliance Management , Adverse Events & Risk Management, Clinical Study / Project wrap-up Management

Clinical Trial Site wrap-up & Study-closure Management,

Pharmacovigilance- 48 hrs

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 thier 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.

ELECTIVE - MEDICAL THERAPEUTIC AREA(Any one)

UNIT 1: CARDIOLOGYNASCULAR DISEASES

Diseases having to do with the structure and function of the heart and blood vessels: heart failure,

coronary artery disease, high cholesterol, blood clots, circulation disorders, and others. AND Dermatology: Fields concerned with skin disorders and the reconstruction or replacement of deformed, damaged, or lost parts of the body. Also concerns , cosmetic. Studies in these areas include: acne, congenital skin diseases, genital herpes, genital warts, liposuction, psoriasis, skin wounds, athlete's foot, venous leg ulcers, and others.

Endocrinology: Field relating to hormone-manufacturing glands such as the pituitary, thyroid,parathyroid, and adrenal glands, as well as the ovary and testis, the placenta, and the pancreas:diabetes and diabetes-related disorders, diet and nutrition, hormone-replacement therapy, menopause, obesity and others.

UNIT 2: GASTROENTEROLOGY

The study of the gastrointestinal organs and diseasesrelating to them, this includes any part of thedigestive tract from mouth to anus, liver, biliary tract, and the pancreas. Studies in this area Include:constipation, Crohn's disease, diarrhea, gall bladder disease, heartburn, hemorrhoids, Irritable SowelSyndrome (ISS), ulcers, liver disease, stomach cancer, and others

AND

Hematology: Field regarding blood, blood-formingtissues, and the diseases associated withthem: anemia, blood clots, bone marrow transplant,leukemia,plateletdisorders,red-cell disorders,T-cell lymphoma, vitamin deficiencies,white-cell disorders, and others.Immunology/Infectious Diseases: Diseases affecting the defense mechanisms of the body: AIDS, auto-immune diseases, bacterial infections, chronic fatigue syndrome, common cold, genital herpes, genital warts, hepatitis, HIV infections, immunosuppressive, influenza, Iyme disease, meningitis,parasite and protozoan infections, strep throat, vaccines, viral infections, and others.

UNIT 3: MUSCULOSKELETAL

Field having to do with the muscles and the bones of the body: aging, bone density, bone fractures,chronicback pain, hip replacement, osteoarthritis, osteoporosis, rheumatoid arthritis, spinal cordinjuries, and others. AND

Nephrology/Urology: The studies and the treatment of diseases of the kidney and the urinary tract: bladder cancer, impotence, kidney disease, kidney stones, mastectomy, nocturia, renal cell carcinoma, urinary tract infections, and others.

Neurology: Field concerning the nervous system, especially the brain, peripheral nerves, and spinal cord: Alzheimer's disease, Attention Deficit Hyperactivity Disorder (ADHD), Carpal Tunnel Syndrome, Huntington's Disease, dementia, memory loss. migraine headaches, multiple sclerosis. muscular dystrophy, Parkinson's Disease, strokes, Tourette's Syndrome, and others. AND Obstetrics/Gynecology: Research pertaining to the care of women during pregnancy and childbirth, as well as to the study of the women's reproductive system in general: contraception, hormone-replacement therapy, menopause, menstrual disorders, ovarian cysts, PMS, pregnancy/labor/delivery, yeast infections, and others.

Oncology: The medical, surgical, and radiation treatment of tumors (cancerous, especially).

Studies in this area Include most types of cancer and treatment thereof.

UNIT 4: OPHTHALMOLOGY

Field concerning the eye and eye diseases: cataracts, eye infections, glaucoma, macular Degeneration, near-sighted corrective surgery, and others AND

Pediatrics/Neonatology:

The medical treatment and study of children and infants, respectively'

anorexia, asthma, Attention Deficit Hyperactivity Disorder (ADHD), birth defects. cancers in children, child depression, growth deficiencies, Juvenile diabetes, obesity. strep throat, vaccines, and

ClinicalPharmacology/ToxicologyThe science of drugs and poisonous materials (respectively) and their effects on the body: diet and nutrition; overdoses; and vitamin deficiencies.

Psychiatry/Psychology: Fields relating to mental disorders and their treatment and prevention. Also,the study of human behavior: addictions, anxiety, dementia, depression,bipolar disorders, manicdisorders, mood disorders, post-traumatic stress disorders, schizophrenia, social phobia, substanceabuse, and others.

Pulmonary/Respiratory Diseases: Diseases having to do with the lungs and/or breathing:Acute Respiratory Distress Syndrome (ARDS), allergy, asthma, bronchitis, cystic fibrosis,emphysema, lung disease, pneumonia, sinus infections, smoking cessation,andother:.s.