Maharaja Ranjit Singh Punjab Technical University
Bathinda-151001

FACULTY OF PHARMACY

SYLLABUS

FOR

PG DIPLOMA IN PHARMACOVIGILANCE

(1 YEAR PROGRAMME)

2023 BATCH ONWARDS

SCHEME

1st Semester		Contact Hrs.			Marks			Credits
Subject Code	**Subject**	**L**	**T**	**P**	**Int.**	**Ext**	**Total**	
GPHCS1-101	Outline of Clinical Trials and Clinical Research	3	1	0	40	60	100	4
GPHCS1-102	Pharmacovigilance and clinical data management	3	1	0	40	60	100	4
GPHCS1-103	Basics of pharmacy, drug discovery and development	3	1	0	40	60	100	4
GPHCS1-104	Pharmacokinetics and BA/BE studies	3	1	0	40	60	100	4
GPHCS1-105	Pre-clinical studies	3	0	0	40	60	100	3
GPHCS1-106	Clinical research lab	0	0	2	40	60	100	1
Total		**15**	**4**	**2**	**240**	**360**	**600**	**20**

2nd Semester		Contact Hrs.			Marks			Credits
Subject Code	**Subject**	**L**	**T**	**P**	**Int.**	**Ext**	**Total**	
GPHCS1-201	Ethical and regulatory considerations	3	0	0	40	60	100	3
GPHCS1-202	Pharmacology and Medical Writing	3	0	0	40	60	100	3
GPHCS1-203	Pharmacology lab	0	0	4	40	60	100	2
GPHCS1-204	Case studies/Technology landscape/ Dissertation/ Apprenticeship or Internship or Training	0	0	24	0	200	200	12
Total		**6**	**0**	**28**	**120**	**380**	**500**	**20**

FIRST SEMESTER

OUTLINE OF CLINICAL TRIALS AND CLINICAL RESEARCH

Subject Code: GPHCS1-101 **L T P C** **Duration: 60 Hrs.**
3 1 0 4

Course Objectives: The target of the course is to make understanding of essential concepts of meaning of clinical trials, clinical research, and clinical terminology. Further to give outline of the documentations in clinical research.

Course Outcomes:

- Appreciate the effect of pharmaceutics science in clinical use of drugs and new drug development
- Understand the drug development of preclinical phase
- Understand various phases of clinical trials
- Understand the significance of purpose of placebo response and placebo controls in clinical trials

Unit: 1 (10 Hrs)

Clinical Research I: Introduction to clinical research, Conditions for worldwide clinical research, Clinical trial phases, The process of transformation into a positive objective, Obtainable Infrastructure, benefits of India, Landmark Year 2005, Why clinical research is progressively popular in India, International collaboration and future challenges.

Unit: 2 (20 Hrs)

History & Background: Stories behind the ethical research, Tuskegee Syphilis Study (1932-1972), Outcome of Tuskegee Syphilis Study, Belmont Report 1979, Nazi Experiments (1940-1945), Outcome of Nazi Experiments, Nuremberg Code (1947), Sulfanilamide Disaster (1937), Willowbrook study (1956), Thalidomide Disaster (1962), Outcome of Thalidomide Disaster, Ethics.

Good clinical practice (ICH GCP E6), Clinical trial materials (Documentation, Investigational drugs, logistical materials)

Unit: 3 (15 Hrs)

Introduction to ICH, ICH-GCP Guideline & its advancement : ICH definition, need to harmonize Structure of ICH, Different parties of ICH, Various ICH Guidelines, GCP, ICH-GCP (E6) Guidelines, The Principles of ICH-GCP Investigator Sponsor, Clinical Trial Protocol & Protocol Amendment(s), Investigator's Brochure, Essential Documents to Conduct a Clinical Trial, Integrated Addendum to ICH-GCP E6(R2) Indian GCP Structure & Contents, GCP implementation

Unit: 4 (15 Hrs)

Clinical drug development phases

Investigational new drug development
Abbreviated New Drug Development
Hatch Waxman Act- application for drug development
Phase 0 studies
Phase I and subtype studies (single ascending, multiple ascending, dose escalation, methods, food effect studies, drug – drug interaction, PK end points
Phase II studies (proof of concept or principle studies to establish efficacy)
Phase III studies (Multi ethnicity, multinational, registration studies)
Phase IV studies (Post marketing authorization studies; pits and practices?) 30 Bridging studies and pilot studies Requirements in clinical research

Recommended books

1.Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone c.
2. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

PHARMACOVIGILANCE AND CLINICAL DATA MANAGEMENT

Subject Code: GPHCS1-102 **L T P C** **Duration: 60 Hrs.**
3 1 0 4

Course objective: To enrich the understanding of clinical data management procedure in clinical research which sponsor, CRO and Hospital use for clinical trials. To know the latest technology of clinical data management used in clinical trials

Course outcome:

- Describe the procedures for clinical trial data collection and data management to ensure optimal quality data and outline the various quality management issues in clinical trials.
- Outline the various data management issues in clinical trials
- Discuss the evaluation and interpretation of clinical trials results

Unit-I (15hrs)

Introduction to Pharmacovigilance and safety monitoring

a. Scope, definition and aims of Pharmacovigilance
b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
c. Reporting, evaluation, monitoring, preventing & management of ADRs
d. Global and Indian Pharmacovigilance System

Post-Marketing Methodologies in Pharmacovigilance Sources and Documentation of Individual Case Safety Reports (ICSRs) Medical dictionary (MedDRA) and Medical aspects in Pharmacovigilance Medical Information System Special cases in Pharmacovigilance Standard operating procedures in Pharmacovigilance

Unit-II (15hrs)

Safety Monitoring in Clinical Trials: Pharmacovigilance Database and Signal Detection Tools Risk –benefit assessment and management in Pharmacovigilance Compliance monitoring and Pharmacovigilance inspections Ethics Committee – Schedule Y

Pharmacovigilance communications

Case triage Case entry Case processing

Global regulatory requirements and guidelines in Pharmacovigilance

Regulatory submissions (E2b, MHRA, FDA) Periodic Safety Update Reports (PSUR,s) For Marketed Drugs (ICH E2C) Schedule Y - ICMR

Unit-III (15hrs)

Introduction to CDM, Computer system validation (CSV), Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data management, review and authorization. CRF design, Procedure for CRF design, elements of CRF, data points to be captured in individual CRFs. Database design and build, Introduction to data base design and build, data base design, data base validation. Clinical data entry process, Data entry screen validation, data entry process, symbols, data entering. Electronic clinical trials, advancement in drug discovery, CTRI, clinical trial for biological products and medical devices

Quality control of clinical data, Terminology and definitions, quality control process, data errors and quality measurement, responsibilities, operational QC, data management matrix

Unit-IV (15hrs)

Electronic data and lab data loading, electronic data interchange-Architecture for EDI, Advantages of using EDI, barriers to implementation, positives and negatives, Lab data loading Roles and responsibilities of lab loader technician, helpdesk, study coordinator, loading lab data, electronic/lab file contents, typical problems, lab data findings, Quality Assurance, SOPs for processing lab data, taking lab data seriously. Database lock and data transfer, Introduction to data base lock, minimum standards, procedure, errors found after database closure, freezing the data base, best practices, recommended Standard Operating Procedures. Introduction to data transfer, procedure, best practices.

Recommended books

1. Handbook of Research on Information Technology Management and Clinical Data Administration in Healthcare Hardcover – Import, 15 June 2009 by Ashish N. Dwivedi (Editor)
2. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. SecondEdition, Jan 2000, Wiley Publications
3. Elementary Statistical Quality Control, Volume 25, Burr, I. W. (1979), New York: Marcel Dekker, Inc.
4. Handbook for good clinical research practice WHO Library Catalogue.
5. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri and Giovanni Della Cioppa, Springer.

BASICS OF PHARMACY, DRUG DISCOVERY AND DEVELOPMENT

Subject Code: GPHCS1-103 **L T P C** **Duration: 60 Hrs.**
3 1 0 4

Course objectives: To enrich the understanding of pharmacology, drug discovery procedure in clinical research which sponsor, CRO and Hospital use for patient protection. To know the importance of drug discovery in clinical trials

Course outcome:

- Demonstrate an awareness of the current approaches to global drug discovery and their advantages and limitations.
- Demonstrate an understanding of the steps involved in the drug discovery and design process
- Demonstrate an awareness of the important contributions the different discipline areas make to the drug discovery and development process.
- Demonstrate the ability to use evidence-based approaches to guide decision making during the drug discovery and development process.

Unit-I (15 hrs)

History of Pharmacy, Indian Pharmaceutical industry, Drugs-sources, nomenclature, classification, Pharmacopoeias, Formulary, Codex. Branches of Pharmacy: Pharmacognosy, Pharmaceutical chemistry, Quality Assurance, Pharmaceutics, Pharmacology, Pharmacy Management and Pharmacy Practice. Pharmaceutical Manufacturing-Quality Assurance and Quality Control.

Unit-II (15 hrs)

Drug Regulatory Environment-Pharmaceutical Legislation in India, Drug regulatory authorities, International Conference on Harmonization, Good Practices and Quality Management, Drug Master File.

Unit-III (15 hrs)

Drug Discovery & Development. History of drug development, Drug Discovery Pipeline, Drug Discovery Process. Approaches to Drug Discovery: Synthetic/medicinal chemistry, combinatorial synthesis, Natural Product, In Silicon approach or CADD, QSAR, Discovery Genomics.

Unit-IV (15 hrs)

Personalized medicines, High throughput screening. Manufacturing and packaging Manufacturing-Multitasking machines Packaging-cGMP, USP requirements on containers and closures, Quality Control, Inhalation drug products, drug products for injection, drug products for ophthalmic, liquid based oral and topical drug products, post approval packaging changes.

PHARMACOKINETICS AND BA/BE STUDIES

Subject Code: GPHCS1-104 **L T P C** **Duration: 60 Hrs.**
3 1 0 4

Course objective: This course is designed to impart fundamental knowledge on bioavailability

Course outcome:

- Define bioavailability and discuss various method of bioavailability enhancement.
- Acquired knowledge about bioequivalence study.

Unit: 1 (15 Hrs)

Bioavailability/Bioequivalence Studies: Basic Definitions, Requirements of Bioavailability and Bioequivalence study, Study Design, Bio statistical procedure, Bio-analytical method and Method validation, submission of study to the regulatory, Bioequivalence and Pharmacokinetics.

Unit: 2 (15 Hrs)

Guidelines of Bioavailability (BA)/Bioequivalence (BE) Studies: USFDA Guideline-Introduction, Background, Methods to document BA and BE, Comparison of BA measures in BE studies, Documentation of BA and BE, Special topics, General pharmacokinetic study design and data handling. Overview of International BABE Guidelines: Therapeutic Goods Administration (TGA) guideline, Therapeutic Product Directorate (TPD) guideline, European Agency for Evaluation of medicinal Products (EMEA) guideline.

Unit: 3 (15 Hrs)

Conduct of Bioequivalence Study: Role of different departments involve in bioequivalence study (Business development, Screening department, Clinical department, Bio-analytical department etc), life span of bioavailability and bioequivalence study (BABE study), day to day activity during the study

Unit: 4 (15 Hrs)

Operations in BABE: Role of medical writing in BA/BE studies, role of quality assurance and quality control in BA/BE studies, waiver of BA/BE studies, role of project management and business development in BA/BE studies, Form 44.

Recommended books

1. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
3. Applied biopharmaceutics and pharmacokinetics, Leon Shargel and Andrew B.C.YU 4th edition,Prentice-Hall Inernational edition.USA
4. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmankar and Sunil B. Jaiswal,Vallabh Prakashan Pitampura, Delhi
5. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel Dekker Inc. 6. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press

PRE-CLINICAL STUDIES

Subject Code: GPHCS1-105 **L T P C** **Duration: 45 Hrs.**
3 0 0 3

Course objective: To enrich the understanding of pre-clinical drug discovery procedure in clinical research and to know the importance of Preclinical studies and various procedure used in clinical trials

Course outcome:

- Explain the regulatory requirements for conducting clinical trial
- Describe in detail about various types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- Describe the documentational requirements for Clinical trials

Unit-I (15hrs)

Experimental animals used, Equipments used in ATC, Sterilization techniques, media for animal cell culture. Cell culture and cell lines, concepts in mammalian and non-mammalian culture, applications of cell culture, Assessment of preclinical data, assessment of cost benefit and risk ratio.

Unit-II (10hrs)

History of toxicity, relationship between dose and toxicity, types of toxicity, factors influencing toxicity, toxins, toxicity studies, special toxicity studies, in vitro models, in situ methods, in vivo models

Unit-III (10hrs)

Good Laboratory Practices, ICMR-GLP guidelines, FDA-GLP guidelines, Organization and personnel, facilities, equipment, testing facilities operation, test and control studies, protocol for and conduct of a non-clinical laboratory study, records and reports, disqualification of testing facilities, OECD-GLP guidelines, quality assurance program, facilities, test systems, test and reference items, Standard Operating Procedures, Performance of the study, reporting of study results, storage and retention of records and materials.

Unit-IV (10hrs)

Drug action, mechanism of drug action, dose-response relationship, therapeutic index, undesirable effects, disease modeling–hypertension, asthma, acidity, arthritis, cancer, addiction, autoimmune diseases, pain, epilepsy, inflammation.

CLINICAL RESEARCH LAB

Subject Code: GPHCS1-106 **L T P C** **Duration: 30 Hrs.**
0 0 2 1

Course objective: Accomplish more noteworthy harmonization overall for the turn of events and endorsement of safe, successful, and excellent medicine in the most asset proficient way

Course outcome:

- Distinguish the basic components of informed Consent and methodologies for executing informed consent for clinical exploration
- Describe the various types of clinical studies and the method used to appropriate design.
- Discuss the collections, evaluation, and reporting of adverse event data in clinical trial.

1. **To prepare and submit Informed Consent Process (ICF) for the following population**
   - Geriatric Patients
   - Paediatric patients
   - Psychiatric patients
   - Unconscious patients
2. **To prepare and submit dummy patient information sheet (PIS) for the below mentioned population**
   - Geriatric Patients
   - Paediatric patients
   - Psychiatric patients
   - Unconscious patients
3. To prepare and submit the standard operating procedures (SOP) for procurement and storage filing of Investigational product (IP)
4. To prepare and submit e-CRF (Electronic Case Report Form) for dummy clinical data

Recommended book

1. John G. Brock-Utne, Clinical Research: Case Studies of Successes and Failures, Publisher; Springer
2. Duolao Wang and Ameet Bakhai, Clinical Trials: A Practical Guide to Design, Analysis, and Reporting, Publisher; Remedica
3. Stephen P. Glasser, Essentials of Clinical Research, Publisher; Springer
4. Deborah Rosenbaum and Michelle Dresser, Clinical Research Coordinator Handbook, Publisher; Interpharm/CRC
5. Evan DeRenzo and Joel Moss, Writing Clinical Research Protocols: Ethical Considerations, Publisher; Elsevier
6. Guidelines: ICH, USFDA, Drugs and Cosmetics Act, EMA