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

SECOND SEMESTER

ETHICAL AND REGULATORY CONSIDERATIONS

Subject Code: GPHCS1-201 **L T P C** **Duration: 45 Hrs.**
3 0 0 3

Course objectives: The objective of the course is to understand the ethics of clinical trials, evolution of regulatory control, regulatory aspects, regulatory guidelines in clinical research.

Course outcome:

- Use a methodical structure for assessing the morals of a clinical exploration convention
- Identify, define and consider ethical issues in the conduct of human subject research.
- Apply proper codes, guidelines, and different records administering the moral lead of human subject exploration to their own examination
- Investigate the ethical requirement of fair subject determination and its application

Unit: 1 (20 Hrs)

Evolution of Regulatory Control: European Medicines Agency (EMA) Vaccine Act, Biological Control Act, Pure food drugs act, Food and Drug Administration (FDA), Kefauver Harris amendments act, Waxman Hatch act, Code of federal regulations, Prescription Drug User Fee Amendments (PDUFA) International Council for Harmonisation (ICH)

Declaration of Helsinki: Introduction to World Medical Association & Declaration to Helsinki (DOH) History of development of ethical principles for medical research involving human subject's General principles of DOH, Risks, Burdens and Benefits, Vulnerable Groups and Individuals, Scientific Requirements and Research Protocols

Unit: 2 (10 Hrs)

Regulatory Aspects of Different Regions Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Paper NDA Market authorization holders (MAH), its procedures Regulation of medical devices Regulation of vaccines Safety Report filing Regulation of Complementary Medicine Regulation of non-prescription drugs

Unit: 3 (15 Hrs)

Ethics in Clinical Research Evolution of ethics in clinical research: Thalidomide disaster, Tuskegee experiment, Nuremberg Code, Declaration of Helsinki, Belmont report Establishment of Council for International Organizations of Medical Sciences (CIOMS), National Institutes of Health (NIH) and Indian Council of Medical Research (ICMR) guidelines Compensation to subjects/patients for clinical trial related injuries.

PHARMACOLOGY AND MEDICAL WRITING

Subject Code: GPHCS1-202 **L T P C** **Duration: 45 Hrs.**
3 0 0 3

Course objective: This subject will give a potential chance to understand about the drug with regard to classification, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, aside from general pharmacology, drugs acting on autonomic nervous system, central nervous system, cardiovascular system, blood and blood forming agents and renal system will be taught.

Course outcome:

- Upon completion of the subject student shall be able to (Know, do, appreciate) Comprehend the pharmacological aspects of drugs falling under the above-mentioned sections
- Handle and carry out the animal experiments
- Appreciate the importance of pharmacology subject.

Unit: 1 (10 Hrs)

General Pharmacology and mechanism of drugs action

a) Introduction, definitions and scope of pharmacology
b) Routes of administration of drugs
c) Pharmacokinetics (absorption, distribution, metabolism and excretion)
d) Pharmacodynamics
e) Factors modifying drug effects

Pharmacology of drugs acting on ANS

a) Adrenergic and antiadrenergic drugs
b) Cholinergic and anticholinergic drugs
c) Neuromuscular blockers
d) Mydriactics and miotics
e) Drugs used in myasthenia gravis
f) Drugs used in Parkinsonism

Unit: 2 (15 Hrs)

Pharmacology of drugs acting on cardiovascular system

a) Anti-hypertensives
b) Anti-anginal drugs
c) Anti-arrhythmic drugs
d) Drugs used for therapy of Congestive Heart Failure
e) Drugs used for hyperlipidemias

Pharmacology of drugs acting on Central Nervous System

a) General and local anesthetics
b) Sedatives and hypnotics
c) Anticonvulsants
d) Analgesic and anti-inflammatory agents
e) Psychotropic drugs

Unit: 3 (10 Hrs)

Pharmacology of Drugs acting on Respiratory tract

a) Bronchodilators
b) Mucolytics
c) Expectorants
d) Antitussives
e) Nasal Decongestants

Pharmacology of Hormones and Hormone antagonists

a) Thyroid and Anti-thyroid drugs
b) Insulin, Insulin analogues and oral hypoglycemic agents
c) Sex hormones and oral contraceptives

Chemotherapy of microbial diseases

a) Anti- tubercular agents, Antifungal agents, antiviral drugs, anti-leprotic drugs.
b) Chemotherapy of protozoal diseases, Anthelmintic drugs.
c) Chemotherapy of cancer.

Unit: 4 (10 Hrs)

1. **Introduction of medical writing:** Understand the term medical writing, different types of medical writing, qualities required in medical writing
2. **Writing process:** Steps in the writing process: prewriting strategies, drafting, revising and refining
3. **Researching for the content:** Internet research, journals and medical databases
4. **Copyrights and plagiarism:** Copyrights and plagiarism
5. **Basic rules of writing:** The fundamental components of writing, the fundamentals of grammar, and general principles of writing.
6. **Scientific writing:** Scientific reviews, writing research papers for journals, case reports and drug monographs
7. **Regulatory writing:** Medical writing in clinical research, study designs, ICH, GCP, Roles of IRB/IEC, The role of investigators and Pharmacovigilance

PHARMACOLOGY LAB

Subject Code: GPHCS1-203 **L T P C** **Duration: 60 Hrs.**
0 0 4 2

Course objective: At the end of the course the students will be equipped with the basics knowledge about, Medicine which would lay the foundation for their courses in the next semester.

Course outcome:

- Knowledge: defining, listing and recognizing the drugs.
- Understanding, characterizing, explaining, identifying and locating the various drugs that are useful in treatment and management of diseases.
- Performing, demonstrating, implementing and applying the concept of basic pharmacology which help in appropriate diagnosis and treatment of systematic diseases.
- Analyzing, categorizing, comparing and differentiating type of drugs.

List of Practical's:

1. Practical based on General Pharmacology
   a. Mechanisms or drug action
   b. Dose–response relationship
   c. Pharmacokinetics of drug absorption, distribution, biotransformation, excretion and toxicity, Factors influencing drug metabolism of drug action

2. Study of different doses forms.
   a. Introduction to Drug Doses
   b. Introduction to Routes
   c. Calculation of Drug Dose

3. Experimental and Clinical Pharmacology Practical
   a. Animal Care, and Sex Determination
   b. Animal Handling

CASE STUDIES/TECHNOLOGY LANDSCAPE/ DISSERTATION/ APPRENTICESHIP OR INTERNSHIP OR TRAINING

Subject Code: GPHCS1-204 **L T P C**
0 0 24 12

Course objective: This will solidify students' knowledge in training and helps them improve skills in lacking areas. Projects generate a real-life situation that truly reflect the actual needs of the professional environment. The projects are designed and planned to meet the professional needs related to problem solving, strategic planning, simulating research environments, data acquisition, collation, statistical analysis and reporting/presentation

Course outcome:

- Case studies/training is an observational procedure in which a person is able to learn practically from their theoretical knowledge.
- This would provide practical knowledge to the student

Contents

The student shall write a case study or Dissertation or submit a Project Work on any area/topic pertaining to Pharmacovigilance and clinical research. The research proposals submitted by the students shall be examined by a committee of teachers teaching the course. The committee shall work under the Chairmanship of the Course Coordinator, who shall also alot a supervisor to each student or a group of students to carry his project work. The topic may include:

1. Case Studies: a. Adverse Drug Reaction Reporting: Analyzing the impact of different reporting systems on pharmacovigilance practices. b. Drug Safety Monitoring: Investigating the role of pharmacovigilance in detecting and managing safety concerns in clinical trials. c. Signal Detection and Risk Assessment: Examining case studies to identify emerging safety signals and assessing their potential risks. d. Real-world Evidence in Pharmacovigilance: Analyzing the use of real-world data to enhance drug safety surveillance and post-marketing studies.
2. Technology Landscape: a. Digital Health Technologies in Clinical Research: Exploring the use of wearables, mobile apps, and electronic health records in data collection and monitoring patient safety. b. Artificial Intelligence in Pharmacovigilance: Assessing the applications of AI, natural language processing, and machine learning algorithms in adverse event detection and signal management. c. Blockchain in Drug Safety: Investigating the potential benefits of blockchain technology in enhancing data integrity, traceability, and transparency in pharmacovigilance processes.
3. Dissertation Topics: a. Impact of Regulatory Changes on Pharmacovigilance Practices: Analyzing the implications of evolving regulatory requirements on drug safety surveillance and reporting. b. Comparative Analysis of Pharmacovigilance Systems: Evaluating the strengths and weaknesses of different pharmacovigilance systems across various countries or regions. c. Patient Engagement in Pharmacovigilance: Investigating strategies to improve patient involvement in adverse event reporting and enhancing medication safety. d. Pharmacovigilance in Precision Medicine: Exploring the challenges and opportunities of pharmacovigilance in personalized medicine approaches.
4. Apprenticeship/Internship/Training: a. Contact pharmaceutical companies, clinical research organizations (CROs), or regulatory agencies to inquire about apprenticeship or internship

opportunities in pharmacovigilance and clinical research. b. Look for training programs or courses offered by renowned institutions or organizations specialized in pharmacovigilance and clinical research, such as the Drug Information Association (DIA) or Society for Clinical Research Sites (SCRS).