CURRICULUM

Course Title: Post-Doctoral Certificate Course (PDCC) in Pharmacovigilance (Pharmacology)

Duration: 1 year

Eligibility: MD/DNB Pharmacology/ PhD Pharmacology

Program Structure: The program is divided into two semesters, each containing theoretical modules, practical sessions, a research component, and electives.

Introduction: The PDCC in Pharmacovigilance is designed to provide advanced education and training in the field of drug safety. This program aims to develop expertise in the monitoring, detection, assessment, and prevention of adverse effects with pharmaceutical products.

Programme Goal:
To prepare professionals who can contribute to the enhancement of public health by ensuring the safety and efficacy of medicinal products.

Programme Objectives:

- To provide comprehensive knowledge of the regulatory framework and methodologies used in pharmacovigilance.
- To develop skills in risk assessment, risk management, and data interpretation related to use of medicines.
- To integrate therapeutic drug monitoring with pharmacovigilance practices, enhancing drug safety and therapeutic efficacy through precise dosing and monitoring strategies.
- To promote understanding of ethical issues in pharmacovigilance and ensure adherence to best practices.
- To cultivate the ability to conduct independent research and contribute to academic and practical advancements in pharmacovigilance.

Teaching and training activities

- Lectures and seminars led by experts in pharmacovigilance.
- Hands-on training with pharmacovigilance software and databases.
- Case studies and role-playing exercises to simulate real-world scenarios.
- Participation in ongoing research projects and initiatives.
- Laboratory training in instrumentation, analysis and interpretation of Therapeutic drug monitoring.

Syllabus

Semester 1:

1. **Basics of Pharmacovigilance**-

- Definition and scope of pharmacovigilance
- Historical milestones and key developments
- Role of pharmacovigilance in public health

2. **Pharmacovigilance Systems and Regulations**-

- Overview of international regulatory framework
- Pharmacovigilance in clinical trials vs post-marketing
- ADR reporting systems and signal detection

3. Research Methodology & Biostatistics -

- Statistical methods for signal detection
- Application of epidemiological methods in pharmacovigilance
- Design of post-marketing surveillance studies

4. Risk Management and Communication-

- Risk-benefit analysis
- Design and implementation of risk management plans
- Strategies for effective communication of risks

Semester 2:

1. Advanced Pharmacovigilance Practices-

- Pharmacovigilance for biologics and vaccines
- Special populations and their considerations
- New frontiers in pharmacovigilance (e.g., digital health technologies)

2. Quality Assurance and Audit Preparation-

- Quality systems and standards in pharmacovigilance
- Preparation for regulatory inspections
- Implementation of CAPA systems

3. Special Topics in Pharmacovigilance-

- Pharmacovigilance for biologics and vaccines
- Special populations and their considerations
- New frontiers in pharmacovigilance (e.g., digital health technologies)

4. Ethics and Legal Issues-

- Ethical considerations in data collection and reporting
- Patient rights and informed consent in pharmacovigilance
- Confidentiality and ethical use of data

Laboratory posting

2 months (4 weeks in each semester).

Competencies

- Upon completion of the program, graduates will be able to:
- Effectively manage pharmacovigilance data and perform signal detection.
- Apply international regulations and guidelines in real-world settings.
- Design and implement risk management strategies.
- Conduct ethical pharmacovigilance research and practice.
- Communicate effectively with stakeholders including regulatory authorities.

Research project

Students will conduct a research project under the supervision of faculty. The project should focus on a current issue in pharmacovigilance, culminating in a report that is to be presented and defended at the end of the course.

Electives:

- Pharmacogenomics and personalized medicine
- Specialized software training (e.g., ARGUS, Oracle AERS)
- Training/internship in Industry or Indian Pharmacopoeia Commission on the basis of application of student and acceptance (1 month).

Log book

Each trainee will maintain a log book detailing:

- All educational activities participated in, including workshops, seminars, and conferences.
- Detailed reports of practical training and case studies handled.
- A summary of the research project including methodology, results, and conclusions.
- Feedback from supervisors and peers.

Evaluation:

- At the end of the course an evaluation will be done
- Theory examination: 50 marks
- Practical examinations: 50 marks
- Project presentation: 100 marks

Note:

This curriculum is designed to provide a comprehensive educational experience that equips graduates with the necessary skills and knowledge to excel in the field of pharmacovigilance, contributing to the safety and efficacy of pharmaceutical products worldwide.