Certificate Course in Pharmacovigilance

With emphasis on Pharmacovigilance and Pharmacoepidemiology there appears huge need for adequately qualified and trained professional who could understand and take up post marketing surveillance roles in drug companies. Thus, there occurs a need of team of drug safety officers. Clearly this need is proportional to the number of new drugs being launched every year which is always increasing. Arise has stepped forward to tap this growing need as a professional opportunity for those keen for entering this industry by providing innovative regular and web-based education & training offer in Pharmacovigilance.

The Certificate Course in Pharmacovigilance has been structured by experts from the industry themselves and thus comprehensive coverage and understanding of the industry and its functional areas is promised. The goal is to familiarize the participant with the updated theoretical and practical aspects of the Pharmacovigilance. The program has the following tempting features which are definite to benefit one to all participants of the program.

- Better industrial training and skills
- Better knowledge of the industry by making the trainees familiar and able to understand the main epidemiological and statistical principles and concepts that are used in pharmacovigilance practices and research
- Practical and professional training about the Industry regulations and work processes
- Good hold on the framework of PV industry leading to availability of best employment options
- To master basics concepts on how to communicate written and oral scientific results

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Program Modules

1. Introduction to Pharmacovigilance

- Definition and Significance of Pharmacovigilance
- Historical Perspective and Evolution
- Regulatory Framework (e.g., ICH E2E(R2), FDA, EMA)

2. Pharmacovigilance Principles and Concepts

- Adverse Event (AE) vs. Adverse Drug Reaction (ADR)
- Expected vs. Unexpected ADRs
- Causality Assessment and Signal Detection

3. Regulatory Compliance and Reporting

- Global Regulatory Guidelines and Requirements
- Spontaneous Reporting Systems
- Expedited Reporting and PSURs

4. Pharmacovigilance Data Sources

- Adverse Event Data Collection and Sources
- Literature and Non-Clinical Data
- Patient-Reported Data and Social Media Monitoring

5. Safety Data Management and Database Operations

- AE Data Entry, Coding, and Validation
- Safety Database Design and Maintenance
- Data Reconciliation and Quality Control

6. Signal Detection and Management

- Methods for Signal Detection
- Data Mining and Statistical Signal Detection
- Risk-Benefit Assessment and Signal Evaluation

7. Risk Management and Risk Minimization Strategies

- Risk Management Plans (RMPs)
- Risk Communication and Risk Minimization Strategies
- REMS (Risk Evaluation and Mitigation Strategies)

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Program Modules

8. Pharmacovigilance in Clinical Trials

- AE Reporting in Clinical Trials
- Safety Data Integration with Clinical Data
- Safety Monitoring and Data Safety Monitoring Boards (DSMB)

9. Benefit-Risk Assessment and Communications

- Benefit-Risk Evaluation Framework
- Aggregate Safety Reports (e.g., DSUR, PSUR)
- Benefit-Risk Communication to Stakeholders

Eligibility: BTech/Bsc in Biotechnology/ Microbiology/ Botany/ Zoology/ B.Pharm/M Pharm/MSc / MBBS/ BDS/ BHS/ BUMS/ BAMS/ Graduation in Life science disciplines are eligible for the program.

Mode: Online and/or Offline Sessions

Duration: 6 months (Freshers/Students) and 3 months (Working Professionals)

Examination & Certificate: Online MCQ Exam/Dissertation, Certification Accredited by Arise Foundation

Complementary courses:

1. Microsoft Excel (Required skills for the course)
2. Preparation of CV and interview guidance