Certificate in Aggregate Report Writing

- Arise provides an opportunity for all the freshers/working professionals to enhance their knowledge and skills in the field of Safety Aggregate Reporting and Risk identification. Aggregate reporting includes the collection of safety data information for a drug throughout an expanded period of time, rather than single-case reporting which, by definition, includes just individual Adverse Event reports. The work profile of a Drug Safety Aggregate Associate is to assess the safety of the drugs once they are into their Phase IV i.e., Post marketing surveillance. They assess the adverse events and report whether these events are related to that medicinal product or not. These reports help the regulators in assessing the risk Benefit Profile of drug over a period of time.
- This program is devised with an all-intensive and thorough research to impart complete conceptual knowledge of Pharmacovigilance safety reports, their significance, preparation and their types along with some case studies. Professionals working in Pharmacovigilance and Clinical Research industries will benefit from this program.

Program Modules

1. **Introduction to Aggregate Report in Pharmacovigilance**
   - Definition and Significance of Aggregate Reporting
   - Regulatory Framework (e.g., ICH E2E(R2), FDA, EMA)
   - Types of Aggregate Reports (e.g., PSUR, DSUR, PBRER)

2. **Data collection and compilation**
   - Sources of Safety Data (Clinical Trials, Spontaneous Reports, Literature)
   - Data Extraction and Integration
   - Data Quality Assurance and Validation

3. **Periodic Benefit-Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMPs)**
   - Structure and Content of PBRERs
   - Benefit-Risk Assessment in PBRERs
   - Components of RMPs and Risk Communication Plans

4. **Preparation of Periodic Safety Update Reports (PSURs) and Development Safety Update Reports (DSURs)**
   - Structure and Content of PSURs
   - Structure and Content of DSURs
   - Writing and Compilation of Aggregate Reports

5. **Communications and Stakeholder Engagement**
   - Effective Communication of Safety Information
   - Engaging with Healthcare Professionals, Patients, and Regulatory Authorities
   - Transparency and Accountability in Reporting

6. **Regulatory Compliance and Reporting**
   - Regulatory Requirements for Aggregate Reporting
   - Submission Timelines and Formats
   - Interaction with Regulatory Authorities

7. **Periodic Benefit-Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMPs)**
   - Structure and Content of PBRERs
   - Benefit-Risk Assessment in PBRERs
   - Components of RMPs and Risk Communication Plans

8. **Periodic Benefit-Risk Evaluation Reports (PBRERs) and Risk Management Plans (RMPs)**
   - Structure and Content of PBRERs
   - Benefit-Risk Assessment in PBRERs
   - Components of RMPs and Risk Communication Plans

Program Modules

9. Documentation and Quality Control Measures
- Documentation Standards for Aggregate Reports
- Quality Control Checks and Validation
- Archiving and Retention of Aggregate Reports

10. Benefit Risk Assessment
- Principles of Benefit-Risk Evaluation
- Cumulative Benefit-Risk Profile
- Use of Quantitative and Qualitative Approaches

11. Signal Detection and Evaluation
- Methods for Signal Detection
- Data Mining and Statistical Signal Detection
- Signal Evaluation Criteria (e.g., Temporal Relationship, Biological Plausibility)

12. Risk Minimization Strategies
- Risk Minimization Measures (e.g., Risk Communication, REMS)
- Evaluation of Effectiveness of Risk Minimization Strategies
- Regulatory Requirements for Risk Minimization

Eligibility: Drug Safety Physician and Associates, Aggregate Report Writing, Experienced Signal Detection and Risk Management Professionals, Medical Reviewer, All Professionals working in Pharmacovigilance/Drug Safety

Mode: Online and/or Offline Sessions

Duration: 30 to 35 Hours Live Sessions

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

Complementary courses:

1. Microsoft Excel and Word (Required skills to prepare the reports)
2. Preparation of CV and interview questions