



Executive Certificate Course in **Aggregate Report Writing** in Pharmacovigilance

Four Months Skill Development Program

**NEW
BATCH**



About the Curio

Curio Training and Research Institute (CTRI) is the Constituent Unit of CliMed Research Solutions India, dedicated to providing Pharma and Healthcare Industry Training. Curio is established to transform the pharma and healthcare landscape by nurturing talent, fostering innovation, and driving excellence in these critical sectors.

Curio commits to producing professionals well-versed in theory and equipped with practical skills to lead, innovate, and create positive change. Curio provides industryoriented value-added, skill development courses, corporate training, and career consultation to individuals and institutions/ universities.

About the Course

Curio’s Executive Certificate in Aggregate Report Writing in Pharmacovigilance is essential in the rapidly evolving landscape of pharmacovigilance, the skillful creation of aggregate reports is crucial for ensuring the ongoing safety and efficacy of pharmaceutical products. This specialized course delves deep into the intricacies of aggregate report writing, offering participants a comprehensive understanding of regulatory requirements, methodologies, and practical applications.

Course Highlights:

<i>In-Depth Report Types Exploration</i>	<i>Advanced-Data Management and Analysis Techniques</i>
<i>Real-World Application</i>	<i>Practical Case Studies</i>
<i>100% Placement Assistance</i>	<i>Expert-Led Training & end-to-end engagement</i>

Syllabus

- 1 : Introduction to Aggregate Safety Reports
 - Overview of the purpose and significance of aggregate safety reports
- 2 : Regulatory Requirements
 - Understanding regulatory guidelines and requirements for aggregate safety reporting
- 3 : Types of Aggregate Safety Reports
 - Exploring different types of aggregate safety reports (PSUR, PBRER, DSUR, etc.)

4 : Data Sources and Collection

- Identifying and collecting relevant safety data for aggregate reports

5 : Writing Principles and Best Practices

- Fundamentals of clear and concise writing for aggregate safety reports

6 : Hands-on Session 1: Writing a DSUR

- Practical exercise in drafting a Development Safety Update Report (DSUR)

7 : Periodic Safety Update Reports (PSUR/PBRER)

- In-depth exploration of PSUR/PBRER structure and content

8 : Risk Management Plans (RMPs)

- Understanding the role of RMPs in aggregate safety reporting

9 : Hands-on Session 2: Crafting a PSUR/PBRER

- Hands-on practice in composing a Periodic Safety Update Report or Periodic Benefit-Risk Evaluation Report

10 : Integrated Summary of Safety (ISS)

- Understanding the purpose and structure of the Integrated Summary of Safety

11 : Narrative Writing for Aggregate Reports

- Techniques for writing compelling narratives within aggregate reports

12 : Quality Control and Assurance

- Implementing quality control measures for accuracy and consistency in reports

13 : Final Project: Comprehensive Aggregate Safety Report

- Students work on a final project to create a comprehensive aggregate safety report incorporating all learned elements, followed by presentations

Eligibility:

- *Any health science student or graduate (B. Pharm/Pharm D/Nursing/Medical/ M Pharm/MSc/Ph.D. in science disciplines)*
- *Industry Delegates who wants to switch or excel their career in this specialized field of PV*

Certification:

- *Students must attend 80% of classes to be eligible to get the certificate*
- *An online MCQ-type exam will be conducted at the end of the course; students have to pass the exam with a minimum score of 60% to avail of the certificate*



Date of Commencement:
January 12, 2025



Last Date of Registration:
December 31, 2024



Course Fees:
2999/- INR (After 50% Discount on 5999/- INR)



Registration Link
<https://rzp.io/rzp/cupvarr>



Course Convener

Dr. Ajit Singh

CEO and Founder, CliMed Research Solutions & Curio
Research Scientist for ICMR, Department of Medicine,
Kasturba Medical College & Hospital, MAHE

Dr. Ajit Singh, Founder, and chief Executive Officer at CliMed Research Solutions & Curio - India, a young entrepreneur & scientist, has completed his Ph.D. in Cardiology from the eminent Manipal Academy of Higher Education (MAHE), a leading organization in research and education in India. Recently, he was appointed as Research Scientist & RAIII for ICMR" at the Department of Medicine, Kasturba Medical College, Manipal. He also serves as 'National Director for Research' at 'World Youth Heart Federation' (WYHF-India) & 'Principal Investigator for 'Manipal Heart Failure Registry (MHFR).' In July 2021, he was appointed as Vice president of the Medical Artificial Intelligence Wing at Idika AI, Mumbai.

He has published more than 40 papers in different streams of medicine, including Cardiology, Cardio-oncology, and Infectious Diseases. He is the investigator and site coordinator for many international clinical trials. Dr. Singh is an honorary reviewer in many reputed journals, including Oxford Group, BMJ Group, and Springer Group of Journals. Dr. Singh has been appointed as Editor-in-chief for the Journal of Basic and Clinical Cardiovascular Research and an editorial board member for several medical journals. He has received several international research and travel grants from esteemed organizations, including the European Society of Cardiology, the Indian Council for Medical Research, DST-SERB, and the American College of Cardiology. He received the 'Young Achievers Award 2019' and 'Yung Scientist Award 2020' in Cardiology Research from reputed international organizations. Dr. Singh has traveled to more than ten countries regarding his research presentations and invited lectures.

