



# Executive Certificate Course in **Signal Detection** (Pharmacovigilance)





# 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 industry-oriented value-added, skill development courses, corporate training, and career consultation to individuals and institutions/universities.

## About the Course

In the dynamic field of pharmacovigilance, effective signal management is essential for the timely detection & assessment of potential safety issues associated with medicinal products. This specialized course is designed to equip professionals with the knowledge and skills needed to excel in signal detection, evaluation, and communication. Participants will gain practical insights into best practices and regulatory requirements governing signal management.

### Course Highlights:

01

*Fundamentals of Signal Detection*

02

*Risk-Benefit Analysis*

03

*Signal Detection and Evaluation Techniques*

04

*Integration of Real-World Evidence*

05

*Expert-Led Training and end-to-end engagement*



# Syllabus

## **1 : Introduction to Pharmacovigilance and Signal Detection**

- *Overview of Pharmacovigilance*
- *Importance of Signal Detection*
- *Regulatory Framework*

## **2 : Adverse Event Reporting and Data Collection**

- *Adverse Event Definitions*
- *Data Collection Methods*
- *Sources of Safety Data*

## **3 : Pharmacovigilance Databases and Systems**

- *Introduction to Pharmacovigilance Databases*
- *Electronic Health Records (EHRs) in Signal Management*
- *Integration of Systems*

## **4 : Basic Concepts in Signal Detection**

- *Signal vs Noise*
- *Data Mining Techniques*
- *Statistical Methods in Signal Detection*

## **5 : Signal Triage and Prioritization**

- *Triage Process*
- *Criteria for Prioritizing Signals*
- *Risk-Benefit Assessment*

## **6 : Signal Validation and Assessment**

- *Validation Criteria*
- *Assessment of Causality*
- *Expert Review in Signal Assessment*

## **7 : Signal Investigation and Root Cause Analysis**

- *Investigative Techniques*
- *Root Cause Analysis Methods*
- *Case Studies in Signal Investigation*

## **8 : Signal Management Communication**

- *Internal Communication in Signal Management*
- *Communication with Regulatory Agencies*
- *Stakeholder Communication*



## **9 : Risk Management Plans**

- *Development and Implementation*
- *Integration with Signal Management*
- *Evaluation of Risk Mitigation Strategies*

## **10 : Signal Management in Clinical Trials**

- *Signal Detection in Clinical Trials*
- *Protocol Amendments for Safety Monitoring*
- *Collaboration with Clinical Teams*

## **11 : Real-world Evidence in Signal Management**

- *Use of Real-world Data*
- *Observational Studies*
- *Post-Marketing Surveillance*

## **12 : Signal Management in Special Populations**

- *Pediatric Signal Detection*
- *Geriatric Population Considerations*
- *Pregnancy and Lactation*

## **13 : Signal Management in Biologics and Biosimilars**

- *Unique Considerations*
- *Immunogenicity Monitoring*
- *Comparative Safety Assessments*

## **14 : Advanced Signal Detection Methods**

- *Machine Learning in Signal Detection*
- *Signal Detection in Big Data*
- *Emerging Technologies*

## **15 : Signal Management Challenges and Solutions**

- *Global Harmonization Challenges*
- *Emerging Safety Concerns*
- *Case Studies in Signal Management*

## **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 28, 2024



**Last Date of Registration:**  
January 20, 2024



**Course Fees:**  
2249/- INR (50% Institution Introductory Discount on 4499/-INR)



**Registration Link**  
<https://rzp.io/I/CEESDPV>



## 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.