



Executive Certificate Course in **International Pharmacovigilance Regulations**

Three Months Skill Development Program



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 an interconnected pharmaceutical landscape, adherence to international regulatory standards is paramount for ensuring the safety and efficacy of medicinal products. This specialized course offers a comprehensive exploration of the global regulatory requirements governing pharmacovigilance. Participants will gain insights into the expectations of major regulatory authorities, enabling them to navigate the complex terrain of global pharmacovigilance effectively.

Course Highlights:

01

In-Depth Exploration of Major Regulatory Guidelines

02

Comparative Analysis of Reporting Systems

03

Global Compliance Strategies

04

Case Studies and Practical Applications

05

Expert-Led Training and End-to-end Engagement

Syllabus

1 : Introduction to International Pharmacovigilance Regulations

- Overview of the global regulatory landscape for pharmacovigilance.

2 : ICH Guidelines Overview

- Understanding the International Council for Harmonisation (ICH) guidelines relevant to pharmacovigilance.

3 : EU Pharmacovigilance Regulations

- In-depth exploration of European Union (EU) pharmacovigilance requirements and the role of the European Medicines Agency (EMA).

4 : FDA Regulations in the United States

- Overview of the U.S. Food and Drug Administration (FDA) regulations related to pharmacovigilance.

5 : Japanese Pharmacovigilance Regulations

- Understanding pharmacovigilance requirements set by the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan.

6 : Health Canada Pharmacovigilance Requirements

- Exploring the pharmacovigilance regulations in Canada and the role of Health Canada.

7 : WHO Pharmacovigilance Guidelines

- Overview of World Health Organization (WHO) guidelines and their impact on global pharmacovigilance.

8 : Good Pharmacovigilance Practices (GVP)

- Understanding GVP guidelines and their application in international pharmacovigilance.

9 : Global Individual Case Safety Reports (ICSRs)

- Handling and reporting individual case safety reports globally.

10 : Harmonization Initiatives and Future Trends

- Exploring current harmonization initiatives and anticipated future trends in international pharmacovigilance.

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 21, 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/CEECIR>



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.