



# Executive Diploma In Pharmacovigilance

Six months Skill Development Value Added Diploma

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



## About the Course

Pharmacovigilance is a field of science that primarily deals with determining, verifying, quantifying, analyzing, and reducing the ill effects of medical drugs, devices, or biologicals, thus ensuring their safety. Pharmacovigilance plays an anchor role throughout the life cycle of new drugs and devices due to a demand created by the requirement of new medical treatments and their legislation.

Curio's Executive Diploma in Pharmacovigilance & Drug Safety program is devised to meet the increasing demand by the industry for drug safety and quality assurance professionals. The program is carefully designed by experienced faculty from the industry, especially to provide an understanding of core quality assurance methods, processes, and practices. The program enables the professional to develop a solid foundation in Pharmacovigilance & helps cultivate advanced skills & competence to manage and deliver quality systems and results.



# Course Highlights

Exclusive (4+2) Course Design

Mock Interviews &  
Soft-skill Development Sessions

Comprehensiveness with  
a wide coverage

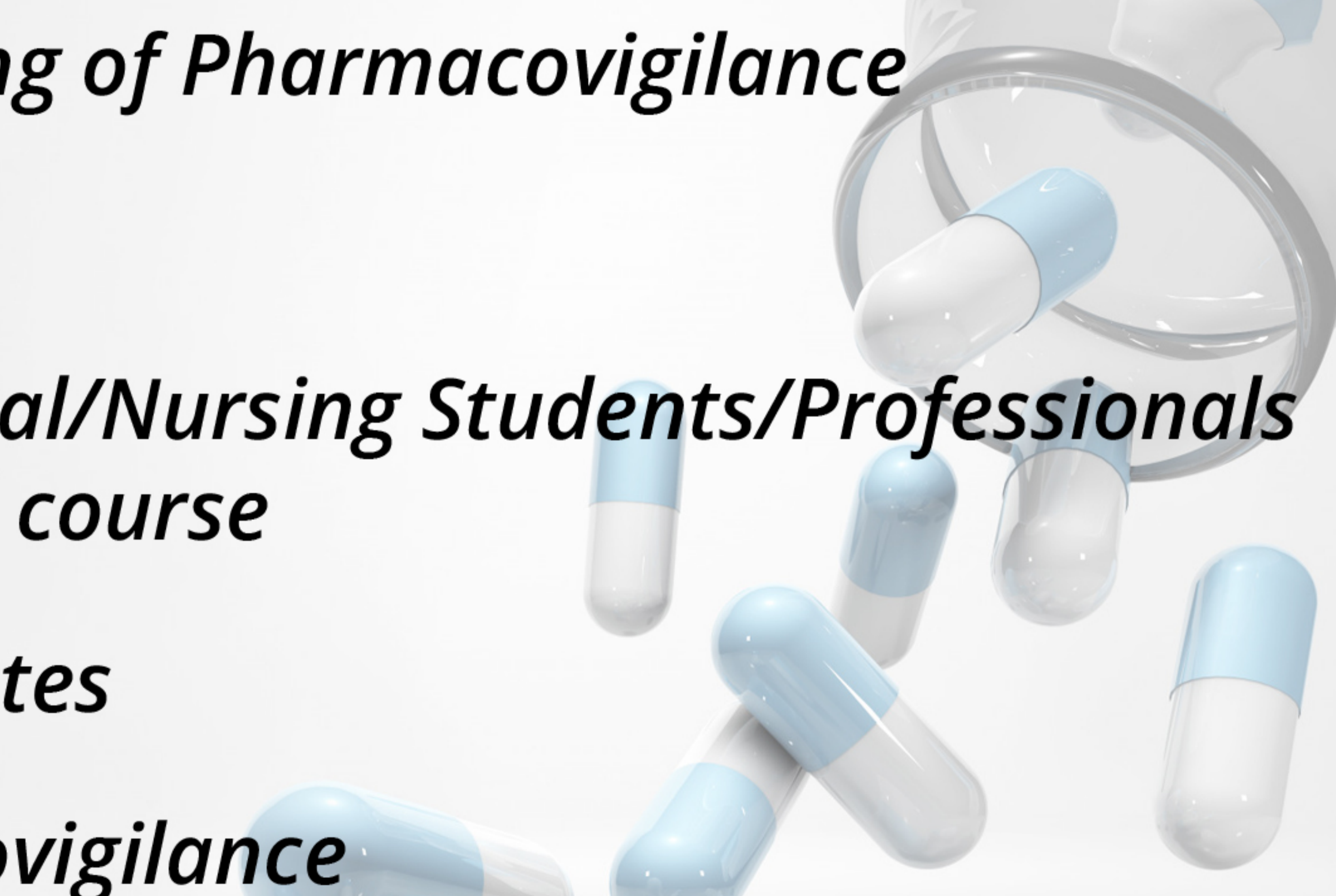
Course Material Book will be delivered  
Doorsteps for Free

Affordable price with  
numerous discount facilities

100% Live classes with real-time query  
resolution & end-to-end engagement

Leadership Dialogues (Live virtual interaction with A-level corporates and academicians)

## Who can Attend?

- ➔ *Beginners to develop an understanding of Pharmacovigilance*
  - ➔ *Intermediate to Improve the Skills*
  - ➔ *Pharmacy/Life sciences/Medical/Dental/Nursing Students/Professionals irrespective of their year of study and course*
  - ➔ *Student/academician/industry delegates*
  - ➔ *Anyone who wants to learn Pharmacovigilance*
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# Syllabus of the Course

1. *Introduction to Pharmacovigilance.*
2. *Basics of Pharmacovigilance*
3. *International Pharmacovigilance and Safety Regulations*
4. *Methodologies in Pharmacovigilance- 1(e.g., Active/ passive surveillance, spontaneous reports, case series etc.)*
5. *Methodologies in Pharmacovigilance- 2 (e.g., Drug event monitoring, registries, cross-sectional, case-control, descriptive, cohort & comparative observational studies, etc.)*
6. *Case processing in Pharmacovigilance (Triage, DE, QC, MR, and Submission)*
7. *Seriousness, expectedness, and Causality assessment criteria*
8. *Key documents in Pharmacovigilance*
9. *Pharmacovigilance Programme in India (PVPI)*
10. *Signal detection and analysis*
11. *Adverse drug reaction reporting system*
12. *PV Drug Dictionaries (MedDRA & WHO Dictionaries etc.)*
13. *ICH & other regulatory requirements for drug safety (E2)*
14. *Periodic Safety Update Report (PSUR) and other Aggregate Safety Reports*
15. *Pharmacovigilance data management & safety monitoring*
16. *Pharmacovigilance compliance*
17. *Audits & Inspections in PV*
18. *Introduction to PV software (ARGUS & ArisG)*
19. *Case study/training on case processing & report generation*
20. *Career guidance- interview tips*
21. *The regulatory process for Medical Devices*

## Key Takeaways

1. *Comprehensive understanding of Industrial Pharmacovigilance*
2. *Course Completion Certificate*
3. *Brushed-up skills*
4. *Recorded Video Sessions*

## Faculty Members

*Faculty members & resource persons are from top-notch industries & institutions with multiple years of experience.*



**Mode of Course:**  
Online



**Duration of the course:**  
Six months



**Classes:**  
Weekend Evening  
Classes Live



**Course Commencement:**  
October 03, 2024



**Course Fees:**  
3,999/- INR (50% Curio  
introductory discount on  
7999/-)



**Last Date of Registration:**  
September 29, 2024



**Registration Link**  
<https://rzp.io/l/cupvoc>

**Certificate will be given to all participants based on the performance in in-course assignment & quizzes.**



## 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, Co-founder & Chief Executive Officer at CliMed Research Solutions – 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 is also serving as ‘National Director for Research’ at ‘World Youth Heart Federation’ (WYHF-India) and ‘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 ‘Young Scientist Award 2020’ in Cardiology Research from reputed international organizations. Dr. Singh has travelled to more than ten countries regarding his research presentations and invited lectures.

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