

Executive Diploma in Pharmacovigilance, Signal Detection & Aggregate Safety Report Writing

7-Month Industry-Oriented Skill Development Program



Particulars	Details
Course Name	Executive Diploma in Pharmacovigilance, Signal Detection & Aggregate Safety Report Writing
Total Duration	7 Months
Theory Training	4 Months
Online Industrial Internship	3 Months
Class Schedule	Every Sunday
Mode	100% Live Online
Course Start Date	Sunday, 12 July 2026
Last Date to Register	30 June 2026
Total Fee	₹6,999/- (Actual Value ₹30,000/-) (Two instalment available)
Instalment Structure	1st Instalment: ₹4,000/- at Registration 2nd Instalment: ₹2,999/- after Completion of 3 Months
Certifications	Executive Diploma Certificate + Industrial Internship Certificate + ICH-GCP E6 (R3) Guidelines Training Certificate
Study Material	Complimentary Pharmacovigilance Study Material Book Delivered to Doorstep

Registration Link (First Instalment): <https://rzp.io/rzp/medocj>



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About Curio Training & Research Institute (CTRI)

Curio Training & Research Institute (CTRI), a constituent unit of CliMed Research Solutions, India, is dedicated to developing industry-ready healthcare professionals through specialized skill development programs. CTRI focuses on bridging the gap between academic learning and industry requirements by providing practical, application-based training delivered by experienced professionals from pharmaceutical, biotechnology, CRO, medical device, and healthcare industries.

About the Program

The Executive Diploma in Pharmacovigilance, Signal Detection & Aggregate Safety Report Writing is a comprehensive industry-oriented training program designed to prepare students and professionals for careers in Drug Safety, Pharmacovigilance Operations, Signal Management, Risk Management, Aggregate Report Writing, Medical Review, and Regulatory Safety functions.

The program provides a complete understanding of global pharmacovigilance systems, safety reporting workflows, signal detection methodologies, aggregate report preparation, regulatory requirements, safety databases, and post-marketing surveillance activities.

Participants will receive practical exposure through industry assignments, case studies, aggregate report writing exercises, safety data analysis projects, and a dedicated three-month internship focused on real-world pharmacovigilance activities.

Why This Diploma?

Pharmacovigilance has evolved beyond case processing. Today, pharmaceutical companies require professionals who can contribute to:

- *Signal Detection & Signal Management*
- *Aggregate Safety Report Writing*
- *Benefit-Risk Evaluation*
- *Risk Management Planning*
- *Safety Surveillance*
- *Medical Review*
- *Safety Data Analytics*
- *Regulatory Compliance*

This diploma prepares participants for these advanced industry roles.



Program Highlights

- ✓ *100% Online Learning & Internship*
- ✓ *4 Months Theory + 3 Months Industrial Internship*
- ✓ *Hands-on Aggregate Report Writing Training*
- ✓ *Signal Detection & Signal Validation Projects*
- ✓ *Drug Safety Database Exposure*
- ✓ *Safety Analytics & Trending Exercises*
- ✓ *Real-World Case Processing Simulations*
- ✓ *Industry-Based Assignments*
- ✓ *Live Interactive Sessions*
- ✓ *Session Recordings Available*
- ✓ *Resume Building & Mock Interviews*
- ✓ *Personalized Mentorship*
- ✓ *Complimentary Pharmacovigilance Study Material Book Delivered to Doorstep*
- ✓ *Industry Templates & Safety Report Samples*
- ✓ *Additional ICH-GCP E6 (R3) Guidelines Training*
- ✓ *Separate ICH-GCP E6 (R3) Certification*



Who Can Attend?

- *PharmD Students & Graduates*
- *BPharm & MPharm Students*
- *MBBS, BDS & Medical Graduates*
- *Nursing Students & Professionals*
- *Life Science Graduates*
- *Biotechnology Professionals*
- *Clinical Research Professionals*
- *Pharmacovigilance Professionals*
- *Regulatory Affairs Professionals*
- *Medical Writers*
- *Healthcare Professionals*
- *Freshers aspiring for PV careers*



Course Curriculum

4 Months Theory Training

Module 1

Introduction to Pharmacovigilance & Drug Safety



Module 2

Drug Development & Safety Monitoring

Module 3

Global Pharmacovigilance Regulations



Module 4

Individual Case Safety Reports (ICSRs)

Module 5

Case Processing Workflow

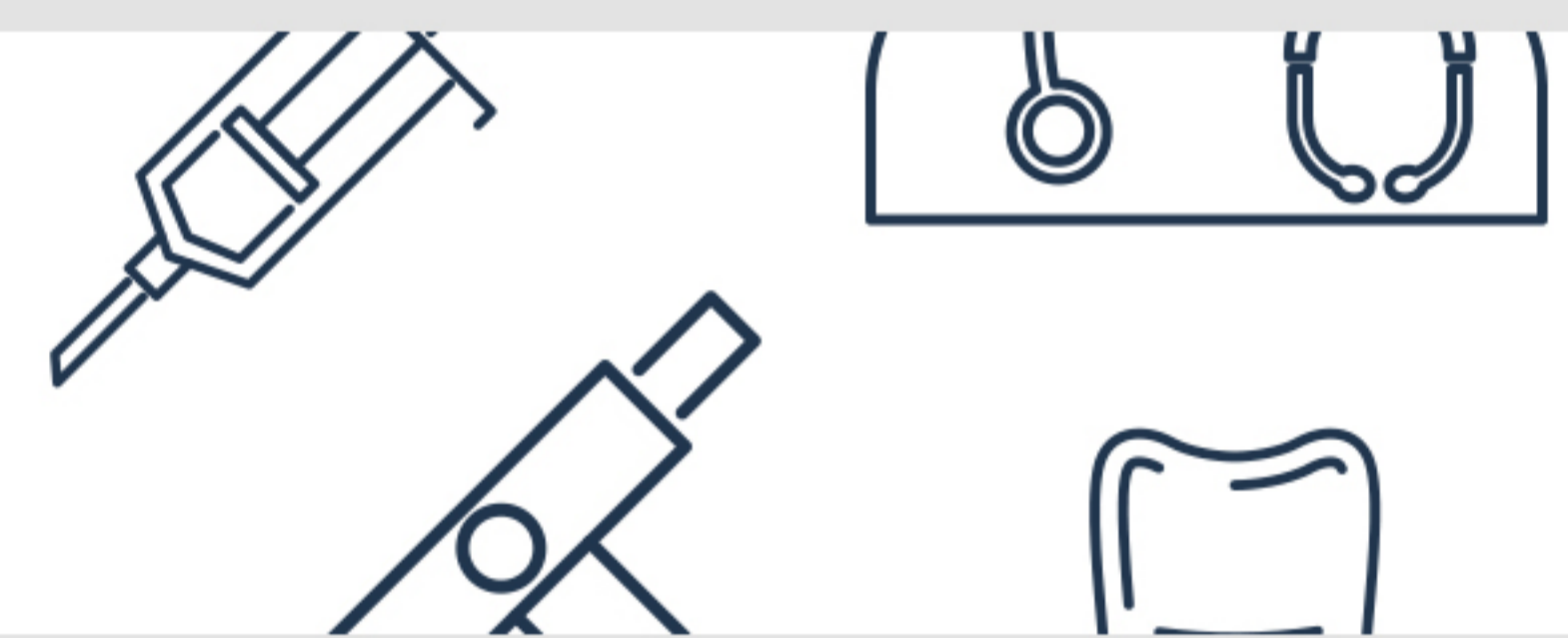


Module 6

Medical Coding & Safety Dictionaries

Module 7

Signal Detection & Signal Management



Module 8

Signal Detection Tools & Methodologies

Module 9

Aggregate Report Writing – I



Module 10

Aggregate Report Writing – II

Module 11

Risk Management & Benefit-Risk Evaluation



Module 12

Medical Review & Safety Assessment

Module 13

Pharmacovigilance Audits & Inspections



Module 14

Safety Databases & Technology

Module 15

AI & Data Analytics in Pharmacovigilance

Module 16

Professional Development & Capstone Project

Special Certification Program

ICH-GCP E6 (R3) Guidelines Training

All participants will undergo exclusive training on the latest ICH-GCP E6 (R3) Guidelines.

Coverage

- *Fundamentals of Good Clinical Practice*
- *Key Updates in E6 (R3)*
- *Investigator Responsibilities*
- *Sponsor Responsibilities*
- *Risk-Based Quality Management*
- *Patient Safety & Ethics*
- *Data Integrity*
- *Inspection Readiness*

Certification



Separate Certificate in ICH-GCP E6 (R3) Guidelines Training

Industrial Internship

3 Months Project-Based Industry Internship

Internship Domains

1. Pharmacovigilance Operations

- *ICSR Review Exercises*
- *Narrative Writing*
- *Case Assessment Activities*

2. Signal Detection

- *Signal Identification Projects*
- *Trend Analysis Exercises*
- *Safety Data Interpretation*

3. Aggregate Report Writing

- *PSUR/PBRER Components*
- *DSUR Sections*
- *Benefit-Risk Evaluation*
- *Safety Summary Development*

Internship Features

- *100% Online Internship*
- *Assignment-Based Learning*
- *Project-Based Training*
- *Weekly Mentor Reviews*
- *Industry Case Discussions*
- *Individual Performance Evaluation*
- *Portfolio Development*
- *Internship Completion Certificate*

4. Safety Analytics

- *Signal Trend Evaluation*
- *Safety Metrics*
- *Dashboard Interpretation*

Assessment & Evaluation

Participants will be evaluated through:

- ➔ *Assignments*
- ➔ *Case Studies*
- ➔ *Safety Narratives*
- ➔ *Aggregate Report Exercises*
- ➔ *Signal Detection Projects*
- ➔ *Internship Assessments*
- ➔ *Final Evaluation*

Certifications Awarded

-  *Executive Diploma in Pharmacovigilance, Signal Detection & Aggregate Safety Report Writing*
-  *Industrial Internship Completion Certificate*
-  *Certificate in ICH-GCP E6 (R3) Guidelines Training*

Career Opportunities

Graduates can pursue careers as:

- *Drug Safety Associate*
- *Pharmacovigilance Associate*
- *Senior Case Processor*
- *Aggregate Report Writer*
- *Signal Detection Associate*
- *Signal Management Specialist*
- *Risk Management Associate*
- *Medical Reviewer*
- *Safety Scientist*
- *Pharmacovigilance Officer*
- *Drug Safety Analyst*
- *Safety Surveillance Associate*
- *Regulatory Safety Associate*
- *Pharmacovigilance Consultant*



Registration Details:



Course Starts:

Sunday, 12 July 2026



Full Course Fee:

₹6,999/- ~~₹30,000/-~~



Last date to register:

30 June 2026

Instalment Structure

- **1st Instalment:** ₹4,000/- *at the time of registration*
- **2nd Instalment:** ₹2,999/- *after completion of 3 months of theory training*

This introductory fee structure is provided under a limited-period professional skill development initiative to make industry-oriented healthcare documentation training accessible to students and healthcare professionals.

Program Convener



Dr. Ajit Singh

Founder & CEO,
CliMed & Curio,
India



Registration Link (First Instalment)

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