cliniminds™
Academy for Clinical Research and Healthcare Training & Management
An ISO 9001:2008 Certified Academy

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Post Graduate Diploma in Pharmacovigilance

Regulatory bodies such as the USFDA and EMEA are intensifying safety regulations, thereby boosting the adoption rates of pharmacovigilance systems by pharmaceutical companies. Several countries, including India are in the process of implementing stringent regulations for adoption of pharmacovigilance. There is significant potential for outsourcing/off shoring for mid-sized companies as well. Large number of global drug companies have starting off shoring their pharmacovigilance activities to the markets like India.
In a typical pharmacovigilance department or specialised pharmacovigilance company, there are several positions. Pharmacovigilance offers excellent growth prospects. Some of the positions are Drug Safety Associate; Drug Safe Scientist; Aggregate Report Scientist; Team Leaders.

Mode : Online/Distance Learning

Duration : 6 Months

Eligibility : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, Graduate/Post Graduate Degree in Life Sciences, Mathematics, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and Hospitals.

Methodology : Printed Training Modules; Online e-learning System

Examination : Online MCQs

Certificate : Certificate would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Pharmaceutical Society of India.**

Accreditation : Accreditation would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Swiss Association of Pharmaceutical Professionals** (SwAPP) & **Swiss Society of Pharmaceutical Medicine.**

Job Assistance : Placement support would be provided to the successful candidates. CVs of successful candidates would be forwarded to CROs Hospitals and Pharmaceutical companies and, Interviews would be organized.

Fee payment : Fee Payable by Cash, Cheque/Bank draft in the name of **"TENET HEALTH EDUTECH PVT LTD."** payable at Delhi. Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.

International Payments : Through Debit/Credit cards using Paypal or wire payment through banks

C-101 First Floor ,Sector-2, Noida-201301 (U.P)
Tel: 0120-3004100, 0120-3004101 **Mobile:** +91-9311166940, +91-9311172560,+91-9311188671
Email: info@cliniminds.com **Website:** www.cliniminds.com
India : Delhi | Ahmedabad | Bangalore| Bhopal |Chennai |Coimbatore | Cochine-Trivandram | Hyderabad | Jammu| Kolkata | Lucknow | Mumbai| Pune | Vijayawada
International : US | UK

Program Details **:** The program would cover

- Introduction to Clinical Research & Phases in Clinical Research
- Principles of Good Clinical Practices - ICH GCP
- General Overview of Pharmacovigilance
- Medical Dictionary for Drug Regulatory Activities MedDRA
- Regulatory Aspects in Pharmacovigilance
- Diagnosis And Management of Adverse Drug Reactions
- Medical Evaluation of Adverse Events
- Quality System in Pharmacovigilance
- Expedited Reporting Requirements
- Periodic Safety Update Reports (PSUR,s) For Marketed Drugs (ICH E2C)
- Pharmacovigilance Database And Signal Detection Tools
- Risk Assessment, Evaluation And Management

Course Objective **:**

- ❖ Candidate should able to understand the basic concepts, importance of Pharmacovigilance and Global Pharmacovigilance regulations.
- ❖ Practical aspects of important Pharmacovigilance activities as per the global standards like medical evaluation, casualty assessment, expectedness assessment, case narratives, MedDRA, case processing preparation of safety report etc.