

Advanced Post Graduate Diploma in Pharmacovigilance

100% Placement Track Record | Industry Accredited Program | Specialization | Job Oriented

Pharmacovigilance is one of the fastest growing streams of the health sciences industry, and in the 4 years, global Pharmacovigilance outsourcing business is expected to touch US\$15 billion.

According to WHO, Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines. Pharmacovigilance begins at the clinical stage and continues throughout the life cycle of the drug, mainly divided as pharmacovigilance during the clinical phase and post marketing. The process of collection of such information about a drug begins in phase I of the clinical trial, before approval of the drug, and continues even after approval; several post-market safety studies are conducted, with many made mandatory by drug regulatory agencies around the world.

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 has starting off shoring their Pharmacovigilance activities to the markets like India. In a typical Pharmacovigilance department or specialized Pharmacovigilance company, there are several positions. Pharmacovigilance offers excellent growth prospects. Some of the positions are Drug Safety Associate; Drug Safety Scientist; Aggregate Report Scientist; Team Leaders.

Cliniminds has been at the forefront of providing clinical research training and consulting solutions to the life sciences industry for the last several years. We have already trained over 5000 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 11years and over 60 batches have passed and have been placed in the pharmaceutical companies, CROs, KPOs and other clinical research organizations. Our students have been placed with the leading companies.

Program Structure

- 6 Months Online extensive education & training on Pharmacovigilance.

Program Details:

The program would cover

- General Overview of Pharmacovigilance
- Key Terms & Terminologies
- Regulatory Guidelines & Laws in Pharmacovigilance
- ICSR

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Disclaimer - This course brochure is for the purpose of creating an awareness about the program and career options. The exact information on course structure would be given to you at the time of orientation, and may vary from this brochure.

- Medical Dictionary for Drug Regulatory Activities MedDRA
- Diagnosis And Management of Adverse Drug Reactions
- AE/ADR Reporting Systems & Forms
- Medical Evaluation of Adverse Events
- Narrative Writing
- Expedited Reporting Requirements
- Periodic Safety Update Reports (PSURs) For Marketed Drugs (ICHE2C)
- Signal Detection Tools
- Risk Assessment, Evaluation And Management
- Quality System in Pharmacovigilance
- SOPs in Pharmacovigilance
- Pharmacovigilance Database
- An Overview of Pharmacovigilance Software

Entry Level Career Options Upon Completion of the Program:

- Drug Safety Physician
- Pharmacovigilance Officer
- Drug Safety Associate
- Drug Safety Officer

Advantages of Cliniminds Program

- Industry Accredited / Certified
- Completely Job Oriented
- Accredited by Accreditation Council for Clinical Research Education, US.
- 100% placement – Excellent Placement Record

Mode : Online

Duration : 6 Months

Eligibility : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharm,
Graduate/ Nursing, Biochemistry, and all professionals working with
Pharmaceutical companies, CROs and Hospitals.

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- Methodology** : 6 Months Online, Online access to study materials, Printed study materials
- Examination** : Distance / Online – MCQs
- Certificate** : Certificate would be awarded upon successful completion of the program.
Program is Certified by the Pharmaceutical Society of India.
- Accreditation** : Program is Accredited by Accreditation Council for Clinical Research Education US.
- Job Assistance** : Placement support would be provided to the successful candidates.
- 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 the company bank account. We also accept Credit/ Debit Cards.
- International
Payments** : Through Debit/Credit cards using Paypal or wire payment through banks

Course Objective :

- Candidate should be 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.

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