

## Advanced Post Graduate Diploma in Pharmacovigilance

Mode : Online

Duration : 6 Months – Flexi Duration

Pharmacovigilance is critical to ensure the continued safety of drugs, as information on potential harms of a drug is incomplete when the drug is launched. There are several stakeholders, however, health professionals, drug companies and regulators worldwide play a key role in pharmacovigilance.

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 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 started 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 career growth prospects. Some of the positions are Drug Safety Associate; Drug Safety Scientist; Aggregate Report Scientist; Team Leaders, Safety Processing Expert, Patient Safety Specialist, Drug Safety Specialist, Drug Safety Reviewer, Medical Coder.

### Course Objective :

- ✎ Candidate should be able to understand the 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.

**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 Learning System

**Examination :** Online MCQs

### Program Details :

The program would cover

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| ☞ General Overview of Pharmacovigilance              | ☞ Narrative Writing   |
| ☞ Key Terms & Terminologies                          | ☞ Expedited Reporting Requirements                                    |
| ☞ General & Systemic Principles of Pharmacology      | ☞ Periodic Safety Update Reports (PSURs) For Marketed Drugs (ICH E2C) |
| ☞ Regulatory Guidelines & Laws in Pharmacovigilance  | ☞ Signal Detection Tools  |
| ☞ ISCR   | ☞ Risk Assessment, Evaluation And Management                          |
| ☞ Medical Dictionary for Drug Regulatory Activities  | ☞ Quality System in Pharmacovigilance                                 |
| ☞ MedDRA   | ☞ SOPs in Pharmacovigilance   |
| ☞ Diagnosis And Management of Adverse Drug Reactions | ☞ Pharmacovigilance Database  |
| ☞ AE/ADR Reporting Systems & Forms                   | ☞ An Overview of Pharmacovigilance Softwares – Argus, Arisglobal      |
| ☞ Medical Evaluation of Adverse Events               |   |

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International : US | UK



### 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 :

Limited placement support would be provided to the successful candidates. CVs of successful candidates would be forwarded to the potential employers.

### Fee payment :

Fee Payable by Cash, Cheque/Bank draft in the name of "TENET HEALTH EDUTECH PVT LTD." payable at New 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

