

## Advanced Post Graduate Diploma in Pharmacovigilance

### Accelerated Program for Fast Placements

### Program in Collaboration with Thinki-Leading Pharmacovigilance Consultancy

Program accredited by Accreditation Council for Clinical Research Education, USA

### HANDS ON TRAINING ON SOFTWARE

**100% Past Placement Track Record | Classroom-Online | Industry Accredited Program | Specialization | Job Oriented**

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 specialized pharmacovigilance company, there are several positions. Pharmacovigilance offers excellent career growth prospects. Some of the positions are Drug Safety Associate; Drug Safety Scientist; Drug Safety Physician, Aggregate Report Scientist; Team Leaders, Safety Processing Expert, Patient Safety Specialist, Drug Safety Specialist, Drug Safety Reviewer, Medical Coder.

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 7,500 professionals and successfully placed them in the industry. Cliniminds flagship program, Advanced Post Graduate Diploma in Pharmacovigilance, is in existence for the last 13+ years and over 100+ 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.

Cliniminds has been awarded as the Best Clinical Research & Health Sciences Business Management Institute in India for the year 2011 – 2018 consecutively by Various Award Agencies like ASSOCHAM, India

#### Program Structure:-

- 2-4 Months comprehensive practical knowledge to the clinical research processes, drug development process, regulatory affairs, essential documentation, roles and responsibilities, ethics, monitoring, conduct and management of trials, extensive training on Pharmacovigilance (PV) and various other related issues in intensive Fulltime Classroom Training is provided.

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[www.cliniminds.com](http://www.cliniminds.com) India: Delhi - NCR | Hyderabad | Bangalore | Kolkata | Pune | Mumbai | Ahmedabad | Chennai | Kerala

International: Russia | Saudi Arabia | US | UK

**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.

#### Program Details:

- Module - 1 - Overview of Clinical Research
- Module - 2 –Pharmacology- General Principles
- Module - 3– Introduction, Definition & Methods in Pharmacovigilance
- Module 4- Essentials Documents in Pharmacovigilance
- Module 5- Pharmacovigilance Regulations
- Module 6- Safety Reporting (including Medical Information) and Processing ICSR
- Module 7- Aggregate reports, Signal detection & Risk Management
- Module 8- Audits and Inspection
- Module 9- Advanced Pharmacovigilance & Analytics
- Module 10- Hands On Training on Case Processing and Report generation

#### Entry Level Career Options Upon Completion of the Program

- Trainee Pharmacovigilance Executive/Specialist
- DrugSafety Physician
- Pharmacovigilance Officer/DrugSafety Associate
- TeamLead

#### Advantages of Cliniminds Program

- Industry Accredited /Certified
- ShortDuration
- Application of Clinical Research & Pharmacovigilance in real businesslike environment.
- Completely Job Oriented –Hands-on Training
- Internship Certificate will be provided by Thinki
- Accredited by the Accreditation Council for Clinical Research Education, USA (ACCREDITED) & Certified by Pharmaceutical Society of India
- 100% placement – Excellent Placement Record
- Training by the team of industry experts – both full time and visiting senior faculty
- Small batch – 15 Seats

**Faculty:** Training would be imparted by the full time Thinki & cliniminds faculty and Visiting experts from the industry.

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<b>Mode</b>	:	<b>Interactive</b> Classroom Sessions & Webinars
<b>Duration</b>	:	<b>Two</b> Month –Full Time/ Four Months Weekend
<b>Eligibility</b>	:	MBBS; BDS; BAMS; BHMS;BPT M.Pharm; PharmD and B.Pharm
<b>Methodology</b>	:	Hands on training, online access to study materials, Printed study Materials and Workshops.
<b>Examination</b>	:	Classroom/online exams & Project work
<b>Certificate</b>	:	Post Graduate Diploma would be awarded upon successful completion of the Program. Program is certified by the Pharmaceutical Society of India.
<b>Accreditation</b>	:	Program is accredited by <b>Accreditation Council for Clinical Research Education, USA.</b>
<b>Job Assistance</b>	:	Extensive Placement support would be provided to the successful Candidates. 100% past Placement Track Record.
<b>Key PV Recruiters</b>	:	Cognizant; TCS; Apcer; Parexel; IQVIA; Accenture; Novartis; JSS Medical; Syneos; Sciformix, Kinapse, Icon, Thinki and many more.
<b>Fee Payment</b>	:	Fee Payable by Cash, Cheque/Bank draft in the name of ' <b>TENET HEALTH EDUTECH PVT. LTD.</b> ' payable at Delhi. Fee can also be deposited in the company bank account. We also accept Credit/ Debit Cards.
<b>International Payments</b>	:	Through Debit/Credit cards using Paypal or wire payment through banks.

**Course Objective:**

- Candidate should be able to understand the Pharmacovigilance Software, concepts, processes, 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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