cliniminds™
Institute of Health Sciences Training & Management
AN ISO 9001:2015 Certified Academy

Think i

Assuring and Advancing Quality in
Clinical Research Education since1965

Advanced Post Graduate Diploma in Pharmacovigilance

Program in Collaboration with Think*i*-Leading Pharmacovigilance Company

Program accredited by Accreditation Council for Clinical Research Education, USA

HANDS ON TRAINING ON SOFTWARE | ONLINE INTERNSHIPS | SINCE 2004

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 stake several stake holders, 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 Safe 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 6,500 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 – 2020 Including by ASSOCHAM, India

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ACCRE
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Program Structure

- 2 Month 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 E Learn Training is provided.

Program Details

- General OverviewofPharmacovigilance
- Key Terms & Terminologies
- General & Systemic Principles of Pharmacology
- Regulatory Guidelines& Laws in Pharmacovigilance
- ICSR
- 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 (ICH E2C)
- Signal Detection Tools
- Quality System in Pharmacovigilance
- SOPsin Pharmacovigilance
- Pharmacovigilance Database
- Software Training

Advantages of Cliniminds Program

- Industry Accredited / Certified
- ShortDuration
- Application of Pharmacovigilance in real businesslike environment.
- Completely Job Oriented – Hands-on Training
- Optional Internship Certificate willbeprovided by Thinki
- Accredited by the by Accreditation Council for Clinical Research Education, USA (ACCRE) & 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

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

Mode	Online
Duration	06 Months
Eligibility	MBBS; BDS; BAMS; BHMS; BPT, M.Pharm; PharmD and B.Pharm
Methodology	Online
Examination	Online MCQs
Certificate	Post Graduate Diploma would be awarded upon successful completion of the Program. Program is accredited by ACCRE, USA
Accreditation	Program is accredited by Accreditation Council for Clinical Research Education, USA
Placement Guidance	CV Preparation, Mock Interviews and sending CVs to Recruiters
International Payment	Through Debit/Credit cards using Paypal

Course Objective

- Candidate should able to understand the Pharmacovigilance Software, concepts, processes, importance of Pharmacovigilance and Global Pharmacovigilanceregulations.
- 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