Advanced Post Graduate Diploma in Pharmacovigilance & Medical Writing

Program accredited by Accreditation Council for Clinical Research Education, USA

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

Best Clinical Research & Health Sciences Business Management Institute in India – 2011-2020

Certified & Accredited by ACCRE, US & Pharmaceutical Society of India

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. 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 Safe Scientist; Aggregate Report Scientist; Team Leaders.

Medical Writing : It is ironical that one side there is no dearth of clinical research and advances in medicine, while on the other side, the skills that are required to share it with the world and express the results in a scientifically approved manner is being ignored; field of medical writing. Although the term 'medical writing' is a very broad, it mainly involves writing associated with clinical trials, regulatory submissions, Pharmacovigilance, and marketing or promotional literatures. The key objective of this course is to gain an insight into the various aspects of scientific/ medical writing and will help the writers to make a positive contribution to the medical world, through their documentation.

Background: Global medical writing market size is over US$1 billion and growing at over 20% per annum. There is substantial growth in medical and scientific writing outsourcing as top 50 big pharmaceutical companies have adopted the efficient outsourcing model. The term 'medical & scientific writing' is a very broad; it mainly involves writing associated with clinical trials, regulatory submissions, Pharmacovigilance, medical, marketing or promotional literatures. Professional medical and scientific writer has good understanding of science and the ability to write about it, bringing clarity to complex medical and pharmaceutical science subjects. Careful attention to detail and an ability to analyses both qualitative and quantitative data is essential.

Role of Medical & Scientific Writer: Communicate scientific and clinical data to a wide range of audiences in a wide variety of formats. Audience could be doctors, pharmacy executives, students, trainers, researchers, and patients. Medical & scientific writers combine their knowledge of science and their research skills to present information at the right level for the target audience. Developing clinical trial protocol, clinical study reports, and other documents for submission to the regulatory agencies Preparation of journal articles, conference posters/presentations, internet content, and training, medical affairs, marketing promotional materials

Where do medical & scientific writers work? : Pharmaceutical Companies, Contract research organizations (CROs); Pharmacovigilance Consulting & Service Providers, KPOs and Consulting Firms, Medical Communication Agencies, Academic Institutions, Medical Associations & Societies, Publishers (Books, Journals & Magazines), Websites, Freelance Writers.

Who is qualified to be a part of this industry? : Medical / Science / Pharmacy / Biotechnology Graduates and Post Graduates; Working Professionals from pharmacy, life sciences and healthcare industry.

Advantages of Medical Writing Career: Away from day to day office/bench oriented work, but still involved with science; Freelance and / or flexible hours; Analyze and digest huge amounts of data in a very short period; Interesting work; in demand; Attending national & international conferences; Well-paid / Part time work options.

About Cliniminds

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 8000 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 15+ years and over 150+ 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 consecutively by various agencies like ASSOCHAM, India.

Program Structure

6 Months extensive education & training on Pharmacovigilance (PV) and Medical Writing is provided.

Program Details: The program would cover

PHARMACOVIGILANCE:

- 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 Inspections
- Module 9- Advanced Pharmacovigilance & Analytics
- Module 10- Hands On Training on Case Processing and Report generation

MEDICAL WRITING:

- Introduction to Scientific/ Medical Writing
- Literature search
- Basic Statistics:
- Structure of a manuscript, and writing the introduction
- Methods
- Results
- Discussion
- The rest of the paper: Title, abstract, and keywords, cover letter, acknowledgments, conflicts
- Referencing
- Tables, graphs, figures
- Reviews, Systematic reviews and meta-analyses
- Miscellaneous: Ethics and paper submission
- Writing Better
- Data Visualization

Career Options upon Completion of the Program:

- Pharmacovigilance Physician
- Drug Safety Associate / Senior Drug Safety Associate
- Drug Safety Officer
- Medical Advisor / Medical Affairs Manager
- Associate Manager/Manager/Medical Writer/Leader Medical Writing/Senior Medical Writer
- Research Officer / Research Scientist / Medical Content Writer / Medical Specialist

Advantages of Cliniminds Program:

- Industry Accredited / Certified
- Completely Job Oriented
- Accredited by the Swiss Pharmaceutical Professionals Association (SwAPP)&
- Pharmaceutical Society of India
- Excellent Placement Record
- Training by the team of industry experts – both full time and visiting seniorfaculty

Mode : Online

Duration : 6 Months

Eligibility : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPTM.Pharm/B.Pharm

Methodology : Online access to study materials

Examination : online MCQs exams

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

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Accreditation Council For Clinical Research Education

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, SA

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 Objectives:

- 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.
- On completion of this course, students will have an understanding of the requirements, roles and Responsibilities of medical / scientific content writers
- Skills in language, scientific communication, and data presentation will be enhanced and the expertise and knowledge will enable writers to prepare drafts that are clearly written and follow the relevant guidelines.

Technology & Knowledge Partners

AB-Cube More than softwares | TARA | ADVERA HEALTH ANALYTICS | CLINEVO Technologies | Think i | CRQA Clinical Regulatory Quality Assurance

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