

SYMOGEN INDIA

Certificate course in Pharmacovigilance & Pharmacoepidemiology

ABOUT SYMOGEN:

Symogen is a professionally managed organization with a multi-disciplinary team in medical and Pharmaceutical sciences, trained and worked in India, U.K and USA who feel the need to develop ethical conductance of clinical research throughout the life cycle of the product for a disease free future of mankind for a better tomorrow.

Objectives and Goals

Safety, quality, reliability and compliance to guidelines are our specialty. We strive for excellence in our mission to conduct clinical research that conforms to international standards.

Symogen India is committed to result oriented, effective, safe, dedicated management of clinical research studies in India. We believe that clinical research has emerged, as a science by itself, which takes seriously the attempt to sort fact from hypothesis, remains a valid enterprise.

Symogen India specializes in services related to Regulatory Affairs, Clinical Trials Phase II & III, BA/BE studies and Pharmacovigilance studies.

Symogen UK is led by Dr Pipasha Biswas who has over 12 years experience in Pharmacovigilance and Pharmacoepidemiology, both in academia and large MNCs. It aims to provide customers with highest quality services related to proactive Pharmacovigilance, signal detection and RMP throughout the product lifecycle.

OBJECTIVES AND SCOPE:

With the globalization of the pharmaceutical industry, the need to maintain universal standards as well as the demand for qualified and trained professionals to provide valuable inputs on Indian, European Union and American Regulatory, Research & Safety requirements in Pharmacovigilance has propelled the need for a knowledge-packed training in this field.

Pharmaceutical Companies, Clinical Research Organizations (CROs), Business Process Organizations (BPOs) companies, Regulatory Agency i.e. DCGI Office & CDSCO need professionals with good understanding of medical ethics, clinical research, pharmacovigilance practices and patient safety, western regulations and effective communications. This course titled **Certificate Course in Pharmacovigilance & Pharmacoepidemiology** is designed to cover all aspects of Pharmacovigilance and drug safety management. It sensitizes the students and equips them with knowledge on Pharmacovigilance practices worldwide and on the Indian scenario in detail. This course gives young executives an opportunity to remain ahead of competitors in a very nascent yet competitive environment. This course is the first of its kind to be started in India.

VENUE:

Mumbai & Chennai

DURATION:

4 months- January to April.
Classes will be conducted on weekends.

ELIGIBILITY:

Medical graduates and Post graduates: Doctors/Physicians of all disciplines

Pharmacy graduates and postgraduates

Post graduates in Bio-sciences (both MSc and PhD)

Junior professionals in Pharmaceutical and IT Industry, Clinical Research Organizations, BPOs, Academia and Regulatory Agencies.

Number of admissions to each batch is limited, so that personal attention can be paid to each student and this will also facilitate effective discussions, practical hands on training and in conducting mini-workshops during the course of study

COURSE MODULES:

The course is designed as 12 modules spread over 4 months to cover all aspects of Pharmacovigilance, regulatory requirements, safety standards and safety data management with special emphasis on certain topics as required for the Indian scenario. An eight (8) hour classroom session on each weekend, during the duration of the course will be held to include discussions, presentations, case studies, hands-on experiences and queries. There will also be a 4 hours self learning by completing an assignment on the topics covered in class (Total 12 hours/week of study). An assessment will be made at the end of the course.

An orientation program will be held prior to the beginning of the course schedule to include Introductions, Objectives and Scope and Outcome of the course.

Module 1: Principles of Pharmacovigilance

- 1.1 Introduction to Pharmacovigilance and Pharmacoepidemiology
- 1.2 Need for Pharmacovigilance & Pharmacoepidemiology
- 1.3 History and aim of Pharmacovigilance
- 1.4 Definitions of terms and key concepts in Pharmacovigilance
- 1.5 Aspects involved in the study of Adverse Drug Events

Module 2: Medical Aspects of Adverse Drug Reactions from Various System Organ Class (SOCs)

Medical aspects of adverse drug reactions by major body systems including cardiovascular, renal, hepatic, gastro-intestinal. Immunology, respiratory, neurology, dermatology, Psychiatry, endocrine etc. will be covered

Module 3: Pharmacovigilance Reporting Systems and Tools for management of reports

- 3.1 Who should report and what should be reported
- 3.2 How to promote reporting
- 3.3 Adverse reaction terminologies
- 3.4 Drug dictionary including Coding in MedDRA
- 3.5 Literature sources for ADR information
- 3.6 Sample reporting forms and practical experiences on recording

Module 4: Global Pharmacovigilance and Safety Standards

- 4.1 The WHO and safety reporting
- 4.2 CIOMS function and ICH guidelines
- 4.3 Good Pharmacovigilance Practice

Module 5: Pharmacovigilance regulations and guidelines

- 5.1 Understanding of Regulations and guidelines of EU (EMA), FDA, TGA and Japanese regulations
- 5.2 In depth understanding of Indian Regulations with specific inputs on Schedule Y
- 5.3 Individual case safety reports
- 5.4 Periodic safety update reports
- 5.5 Answering queries from regulatory agencies
- 5.6 Safety reporting requirements and follow up of reports
- 5.7 Electronic safety reporting

Module 6: Methodologies in Pharmacovigilance

- 6.1 Pre-marketing methodologies in Pharmacovigilance and clinical trials safety – need including EU Clinical Trials directive
- 6.2 Post marketing methodologies in Pharmacovigilance and post marketing drug safety
 - 6.2.1 Difference in clinical and post marketing safety
 - 6.2.2 Post marketing safety in different regions (UK Yellow Card System & Prescription Event Monitoring (PEM) & MEMO in Scotland Dundee; New-Zealand (Intensive Medicines Monitoring Program (IMMP); Japanese – PEM; Boston Collaborative Drug Surveillance Program (BCDSP), Boston, USA etc)
 - 6.2.3 Spontaneous reporting and monitoring
 - 6.2.4 Causality assessment – principles and case studies

Module 7: Management of Drug Safety Data

- 7.1 Need for quality data
- 7.2 Designing systems for quality data collection
- 7.3 Differing regulations concerning safety data collection requirements
- 7.4 Safety databases used in different parts of the world
- 7.5 Databases used for Pharmacoepidemiological Studies (WHO UMC Database; General Practice Research Database (GPRD), UK; IMS Health Database; Doctors Independent Network (DIN) Database, UK; Saskatchewan Database, Canada; Kaiser Permanente (is this Permanent?) Databases (USA) etc.

Module 8: Signal Detection

- 8.1 Definition of signal and type of signal
- 8.2 Conducting signal detection in clinical and post marketing surveillance
- 8.3 Defining signal in relation to risk/benefit
- 8.4 Signal generation to decision making
- 8.5 Discussions on signals generated from various drugs world wide

Module 9: Benefit Risk Determinations

- 9.1 Definitions
- 9.2 FDA and EU perspectives
- 9.3 Benefit – Risk assessment and reporting
- 9.4 Review of benefit-risk assessments and management
- 9.5 Discussion on various Risk Management Plans for riskier drugs which were initially withdrawn, but have been re-introduced to the market again
- 9.6 Discussion on RMPs of Thalidomide, Clozapine, Alosetron, Roaccutane and many more

Module 10: Communication In Pharmacovigilance

- 10.1 Effective communication in Pharmacovigilance i.e. Erice Declaration
- 10.2 Crisis management
- 10.3 Communicating with Regulatory Agencies, Business Partners, Healthcare Professionals & the Media
- 10.4 How, when and what to write in Dear Doctor Letters to Healthcare Professionals

Module 11: Setting up of Pharmacovigilance Department; Standard Operating Procedures used in Pharmacovigilance & Department links to Pharmacovigilance

Practical Knowledge required for setting up of pharmacovigilance department for companies. Relations with various departments i.e. medical affairs, IT, sales and marketing, legal, commercial, regulatory and medical information department of a company to Pharmacovigilance

- 11.1 Types of SOPs used in Pharmacovigilance departments
- 11.2 Production, sign off and maintenance of SOP
- 11.3 SOP training

Module 12: Pharmacovigilance Compliance and Inspections

- 12.1 Scope of Pharmacovigilance inspection and conduct of inspection
- 12.2 Internal audit of pharmacovigilance activities of a company
- 12.3 Pharmacovigilance inspection reports
- 12.4 Corrective actions
- 12.5 Contracting out Pharmacovigilance Services to niche Pharmacovigilance Organizations

Practicals to be covered in each Module

- 13.1 Hands on experiences and discussions
- 13.2 Projects and presentations
- 13.3 Case studies where required (reporting of ADRs, causality, signal detection, benefit-risk etc)
- 13.4 Discussions on Risk Management Plans

FACULTY FOR THE COURSE

India:

Dr Bhawana S. Awasthy MD DNB – Oncologist & CEO Xlerx, India
Mr Partha Chakrabarty B.Tech MBA – Cognizant, India
Mr Moin Don MPharm – Senior Manager, Dr Reddy's Lab, India
Dr P Dasgupta MD MBA – Ex-DCGI, India
Prof. Y.K. Gupta MD – HOD Pharmacology, AIIMS, India
Prof. Urmila Thatte, HOD Clinical Pharmacology,
Dr Syed Zia-ur Rehman MD – Assistant Professor Pharmacology, AMU, India
Dr Vivek Ahuja, Group Leader, Clinical Research and Pharmacovigilance, Ranbaxy, India
Mr Rakesh Rishi MPharm – Senior Scientific Officer, CDSCO, India
Mr S.Sengupta - Senior Regulatory Consultant, India
Prof. K.S. Reddy, MD,DM, president Public foundation of India, Ex-Head of Cardiology, AIIMS, India
Prof. K.C.Singhal, MD, PhD, Dsc, WHO consultant UPPSALA Monitoring Center, Ex-HOD
Pharmacology, JLN Medical College ,AMU, Aligarh
Prof. A. Ray - Head, Dept. of Pharmacology, V.P.Chest Institute, University of Delhi

Overseas:

Dr Arun Biswas MD FFARCSI – Consultant Anaesthetist, NHS, UK
Dr Pipasha Biswas MD MPM DM – Principal Consultant & Director, Symogen, UK
Dr Corrine De Veries PhD – HOD Pharmacoepidemiology, University of Surrey, UK
Dr Brian Edwards MD MRCP – Deputy QP Pharmacovigilance, Janssen Cilag, UK
Dr Patricia Fitzgerald PhD – Managing Director ADAMAS, UK
Dr Malkit Ghotra MD – Director EU Pharmacovigilance, Wyeth Europa, UK
Prof. Munir Pir Muhammed – Professor of Clinical Pharmacology, University of Liverpool, UK
Mr Bruce Hugman MA – Consultant WHO-UMC, Thailand
Dr Marie Lindquist PhD – Deputy Director UMC, Sweden
Mr Sten Olsson MPharm – Manager External Affairs, UMC, Sweden
Dr Peter Schulz MD PhD – Head of Drug Safety Europe & QP Pharmacovigilance, Amgen, UK
Dr Lynda Wilton PhD – Principal Research Fellow, Drug Safety Research Unit & Senior Lecturer, Portsmouth University, UK
Dr. Samia Bouhired, MD, PhD, Senior safety Physician, Oncology, Roche, UK

More senior academicians, professionals from Pharmaceutical industry, WHO India and Government regulatory authorities in UK and other institutions are being contacted for their availability to lecture.

EXAMINATION:

At the end of each four month course students will be assessed on the knowledge of pharmacovigilance. The exams will consist of:

1. A written component of two hours duration consisting of 2 Long Questions and 4 Short Questions
2. Viva: Thirty (30) minutes with two examiners
3. A Short Project to be submitted at the end of the course on the topics to be given by the Faculty on Pharmacovigilance

CERTIFICATION:

Candidates who complete the course will be awarded Certification in “Pharmacovigilance & Pharmacoepidemiology” from SYMOGEN India for participation in the course.

This course is supported by the WHO-Uppsala Monitoring Centre, Sweden and The International Society of Pharmacovigilance.

90 Credits (7.5 Credits per module CME/CPD) approved for the Certificate course in Pharmacovigilance and Pharmacoepidemiology by the Faculty of Pharmaceutical Medicine of The Royal College of Physicians, London, UK.

FEES:

The total fees for this 4 month course will be Rs 85,000 for working Indian professionals and from SAARC countries. The fees for students pursuing higher education will be Rs 50,000 for Indian students and students from SAARC countries and 5000 USD for other international students.

It will cover all course materials and examinations. There will also be provision for coffee and lunch on teaching days.

JOBS OPPORTUNITIES

Many MNCs are now outsourcing their Safety Data Management requirements to India and there is significant growth in demand for qualified and trained Pharmacovigilance experts. Students may also find openings in the following sectors -

- Pharmaceutical Companies (both MNCs & Indian) & Biotech companies
- CROs
- BPOs
- Regulatory Agencies
- Academia

Some of these MNCs are prepared to recruit candidates who successfully complete this course. Symogen will assist all those who successfully complete the course in finding suitable jobs by forwarding their profiles to all such organizations.

Symogen however does not take any responsibility of providing any jobs after completion of the course.

REGISTRATION PROCEDURE

To register for the batch commencing January 2008, fill in your details in the application form and mail it with your CV/Resume to nkjha77@gmail.com.