

GLOBAL PHARMACOVIGILANCE EDUCATION & TRAINING



The World Health Organization (WHO)

defines pharmacovigilance as:
" The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems ... ".

Aim

The course is aimed to provide candidates with in-depth knowledge and practical training of the Global Pharmacovigilance practices, processing and reporting of the ADR's, regulatory framework, pharmacoepidemiology and risk management systems.

Eligibility

- *Professional qualification in Medicine (MBBS, BAMS, Nursing), Dentistry or Veterinary science.*
- *Masters or PhD in clinical sciences, biosciences or pharmacy*
- *A first class honors degree in clinical sciences, biosciences or pharmacy*
- *Professionals working in drug safety, clinical research, medical device or pharmaceutical industry.*

Other Attributes:

- *A strong motivation with a professional attitude*
- *Eye for detail*
- *Communication skills with a good command over written and spoken English*
- *IT skills.*

Note: Applications without a CV will not be entertained.

Course Outline

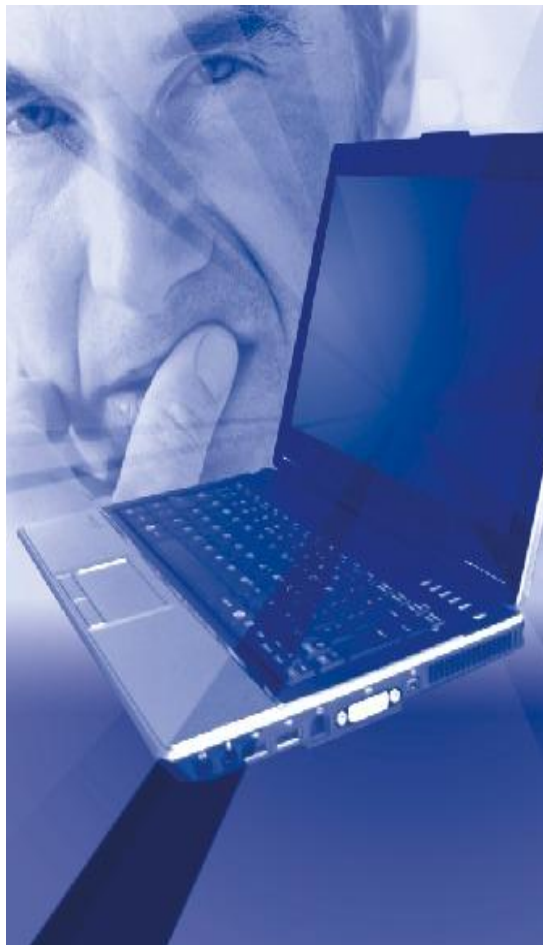
This highly specialized course has been specifically designed to create quality Pharmacovigilance professionals of global standards

The course has been targeted to encompass all the theoretical aspects and practical skills in Pharmacovigilance

The course is first of its kind to provide individuals with hands-on experience on ADR Reporting System

The course allows only limited number of individuals ensuring a focus on quality and effectiveness

The admissions will be based on the individuals credentials and not on 'first come, first serve' basis



Methodology

The course will comprise of 100 hours arranged as:

- 30 hours of taught modules
- 30 hours of Practical training
- 40 hours of individual study and discussions.

The academic modules will be covered in Week -1 to Week -8. Study will include

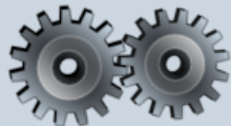
- Taught Modules
- Individual study topics
- Discussions

The practical modules will be taken up from Week -9 to Week -16.

Classes will be held on Sunday (10 AM - 4 PM) with a 30 minutes break for lunch.

Course material shall be provided at the end of each Academic Module session.

Each student will be provided with a laptop.



Content

The course has been designed and tailored specifically to the needs of research industry. The course has been divided into two parts -

Academic modules

1. Introduction to Clinical Research and Pharmacovigilance
2. Global Pharmacovigilance System
3. Sources and Documentation of Individual Case Safety Reports (ICSRs)
4. Case processing and Reporting
5. Medical dictionary (MedDRA) and Medical aspects in Pharmacovigilance
6. Special cases in Pharmacovigilance
7. Medical Information System
8. Safety monitoring in Clinical Trials
9. Signal detection
10. Periodic Safety Update Reports (PSURs)
11. Risk –benefit assessment and management in Pharmacovigilance
12. Standard operating procedures in Pharmacovigilance
13. Compliance monitoring and Pharmacovigilance inspections
14. Global regulatory requirements and guidelines in Pharmacovigilance
15. Pharmacovigilance communications
16. Pharmacoepidemiology

Practical modules

- Problem Based Learning
- Discussions and presentations
- Literature search exercises
- Hands-on training on Global ADR Reporting System
- Introduction of the system
- Case triage
- Case entry
- Case processing
- Regulatory submissions (E2b, MHRA, FDA)
- Query Management
- PSUR and Addendum writing and reporting



Course Dates and Assessment

For the course dates in 2010 contact

Info-hyd@medhimalayas.com

Course Assessment

Course shall be assessed as per the following schedule

Theory (30%)

Theory exam will consist of Extended Multiple Answer Questions (EMAQ's)

Practical (60%)

Practical assessment will be through case processing, regulatory submissions and data management exercises

Viva (10%)

Registration:

You can register online by sending your CV and DD of Rs 500/- in favor of:

MedHimalayas solutions Pvt Ltd

Level 7, Maximus Towers,
Building 2A, Mindspace
Complex,
Hi-Tech City,
Hyderabad,
India - 500081



Educational loan

We provide educational loan assistance to the desiring candidates.

Course Fees

The total fee for this advanced course is INR 1,50,000 for Indian students and USD 4,000 for Overseas students.

Certification

After successful completion of the course, candidates will be awarded

'POST-GRADUATE DIPLOMA IN GLOBAL PHARMACOVIGILANCE' by MedHimalayas, UK.

Placements:

- 100% placement assistance will be provided in India and Overseas to the candidates completing this course.
- Candidates can also be absorbed in our organization in various roles according to candidates credentials and performance.



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