

Certificate Program in Signal Detection & Risk Management

Pharmovigilance signal detection plays a critical role in pharmaceutical risk management. Most drugs are tested on a few thousand patients only before they are sold in the market. So, it's very important to study the long-term effects of the drugs as it helps to assess the potency and side-effects of the drugs and manage risks associated with the product more effectively.

Pharmacovigilance Signal detection is an important way in which the adverse effects of the drugs are studied. With new innovations in technology come new means of pharmacovigilance signal detection. Automated signal generation using pharmacovigilance systems has improved signal detection standards and has helped early detection and analysis of signals. Automated signal detection usually compares the reported safety profile of a drug with the existing database using statistical methods to detect early warning signs. This process saves a lot of time, many hours and also helps in managing product risks effectively.

Mode	: Online / Webinar
Duration	: 3 Months
Eligibility	: Professionals involved in pharmacovigilance, clinical research, regulatory affairs, risk management, medical product safety assessment, and data analysis, epidemiology, labeling, quality assurance, compliance, medical information.
Methodology	: Printed Training Modules; Online E learning System and Webinars.
Internship	: An online internship program would be arranged with the CRO, Pharmacovogilance, pharmaceutical or QA firm. Certificate would be awarded upon Successful completion of the internship.
Examination	: Online MCQs
Certificate	: Certificate would be awarded upon successful completion of the program.
Accreditation	: Program is Certified & Accredited by the Swiss Association of Pharmaceutical Professionals (SwAPP) & Swiss Society of Pharmaceutical Medicines.
Job Assistance	: Limited placement assistance would be provided. CVs of successful candidates would be sent to the potential employers.
Fee payment	: Fee can be paid by Credit / Debit card through Paypal. We also accept bank wire transfer.

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International: US | Europe

India: Delhi | Ahmedabad | Bangalore | Bhopal | Chennai | Coimbatore | Cochine-Trivandram | Hyderabad | Jammu | Kolkata | Lucknow | Mumbai | Pune | Vijayawada | Europe

Program Details : The program would cover

- Why signal detection is needed.
- Regulatory requirements.
- Approaches to signal detection.
- Good pharmacovigilance practices.
- What is PSUR.
- How signals are generated for drugs following AEs.
- How to anticipate risks by following a signal.
- Responsibility of a Pharmaceutical company in monitoring safety of the drug and eliminating risks.
- How to create Risk management and Risk minimization plans
- How to communicate about risks, i.e. adequately informing patients and their doctors about how they can use a drug safely or why their drug is no longer available.
- Concepts of premarketing risk assessment and its important role in the development of (REMS).
- How to speak the language of drug safety, signaling, risk management, and pharmacovigilance

Course Objective :

- ✓ Discuss signal; learn methods of signal detection, signal workup,
- ✓ Learn how to investigate a signal and communicate a potential signal with the population.
- ✓ Learn how to follow up on a potential signal.
- ✓ Discuss PSUR- Learn the content of the PSUR report, timelines for submission and renewals.
- ✓ Discuss Risk management plans.
- ✓ Explain the EU risk management strategy, the new approaches to risk assessment and prevention, and the different steps to be considered in the risk management process
- ✓ Describe the components of the EU Guideline on the risk management system, focusing on pharmacovigilance and risk minimization plans.
- ✓ Discuss REMS

Note : This is not the University degree or diploma. The objective of the program is to provide the skill and knowledge which would be helpful for you in finding the suitable job.

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