

Advanced Internship Program in Pharmacovigilance

Topics Covered in Online Modules

1. Introduction to Clinical Research & ICH GCP Principles
2. An Overview in Pharmacovigilance
3. Standard Terms and terminologies in Pharmacovigilance
4. Regulatory guidelines and Laws in Pharmacovigilance
5. AE/ADR Reporting systems and Forms
6. Medical Evaluation of Adverse Events
7. Diagnosis and Management of Adverse Drug Reactions
8. Expedited reporting Requirements in India, US, EU
9. Risk Assessment, Evaluation & Management
10. Pharmacovigilance Database and Signal Detection Tools
11. PSURs – Periodic Safety Updated Reports/ PADERs
12. Individual Case Safety Reports, ASRs , Single Case processing
13. Medical Dictionary for Drug Regulatory Activities MedDRA
14. Case Narrative Writing
15. Quality Systems in Pharmacovigilance
16. Pharmacovigilance Audits and Inspections
17. SOPs in Pharmacovigilance
18. An overview of Pharmacovigilance software

Topics Covered During Contact Program

1. Introduction of Kyron
2. Brief history and development of drug safety, PV, Benefit Risk Assessment
3. The role of Drug Safety in the drug development process
4. Current Regulatory Environment
5. Single Case Processing
 - a. Requirements, Definitions and Case types
 - b. Sources of data
 - c. Safety Databases
 - d. Workflow concepts
 - e. Data Entry
 - f. Follow Ups
 - g. Term Extraction and MedDRA Coding
 - h. Products involved and Drug Dictionaries
 - i. Quality Control

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International : US | UK

6. Medical Review
 - a. Causality assessment
 - b. Labeling assessment
 - c. Seriousness assessment
 - d. Special interest cases and Follow Ups

7. Aggregate Reports
 - a. Requirements, Definitions and Report types
 - b. Timelines
 - c. Sections and Content

8. Introduction to Benefit Risk Assessment
 - a. Requirements, Definitions and Document types
 - b. General Concepts

9. Overview and Q&A

Fee : US\$3,000

Mode : Online & Contact Program

Online : Online access would be provided upon receipt of the fee. Username and password would be sent via email.

Contact Program : To be conducted by Kyron. Schedule to be provided after registration and payment.

Certificate : Joint Certification by Cliniminds & Kyron would be provided upon successful completion of the program.

**For more information, please contact
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