PHARMACOVIGILANCE

3 Months Online Certificate Course

Any Life Science, Pharmacy student/Faculty can join

JOB PROSPECTS: INDUSTRY/RESEARCH

PART I - MEDICINAL PRODUCTS FOR HUMAN USE

- Guidance and Procedures for Marketing Authorisation Holders
- Guidance and Procedures for Competent Authorities
- Terminology

PART II - VETERINARY MEDICINAL PRODUCTS

- Section 1: Guidance and Procedures for Marketing Authorisation Holders
- Section 2: Guidance and Procedures for Competent Authorities
- Section 3: Guidelines for Post-Marketing Surveillance of Veterinary Medicinal Products
- Section 4 : Terminology

PART III - EU ELECTRONIC EXCHANGE OF PHARMACOVIGILANCE INFORMATION2

- Introduction
- Reference Documents
- Message Format
- Standard Terminology
- Acknowledgement of Safety Reports
- Registration Process for the Electronic Transmission of Individual Case Safety Reports (ICSRs)
- Electronic Submission of Periodic Safety Update Reports (PSURs)

PART IV- REFERENCE LEGISLATIVE AND ADMINISTRATIVE INFORMATION

- Extracts from Relevant Pharmacovigilance Legislation
- Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs
- Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
- List of Pharmacovigilance documents and guidelines: Medicinal products for Human Use

TOPICS TO BE COVERED

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