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TEXT BOOK ON PHARMACOVIGILANCE

Pharmacovigilance for B.Pharm VIII Sem is designed specifically for B.Pharm students, and it aligns with the Pharmacy Council of India's (PCI) curriculum guidelines for the VIII semester an in-depth understanding of pharmacovigilance.

An essential component of pharmaceutical sciences that focuses on monitoring and improving drug safety. This book provides a clear introduction to the development of pharmacovigilance as a scientific field, covering essential concepts such as terminology, global pharmacovigilance frameworks, and various methods of generating safety data and signal detection.

Features

- Comprehensive Coverage Explores pharmacovigilance history, terminology, and global regulations.
- Practical Insights Details signal detection, clinical trials, and post-marketing surveillance.
- Structured Approach Organized into five focused units: Pharmacovigilance, Drug & Disease Classification, Safety Data & ICH Guidelines, Clinical Trials, and Pharmacogenomics & CIOMS.

Whether you are student, educator or industry professional, this book offers a clear, practical guide to drug safety and regulatory practices.

Dr. Kamta Prasad Namdeo | Ms. Yogita Dhurandhar Mr. Shubham Tomar

(Contents)

- Introduction
- Introduction to Adverse Drug Reactions
- Basic Terminologies Used in Pharmacovigilance
- Drug and Disease Classification
- Drug Dictionaries and Coding in Pharmacovigilance
- Information Resources in Pharmacovigilance
- Establishing Pharmacovigilance Programme
- Vaccine Safety Surveillance

- Pharmacovigilance Methods
- Communication in Pharmacovigilance
- Safety Data Generation
- ICH Guidelines for Pharmacovigilance
- Pharmacogenomic of ADRs
- Drug Safety Evaluation in Special Population
- CIOMS
- CDSCO (India) and Pharmacovigilance

