

INTRODUCTION TO PHARMACOVIGILANCE (THEORY)

A Textbook for B.Pharm Semester VII

BP705T

Aligned to the new PCI Syllabus 2026 (NEP 2020)

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Preface

Pharmacovigilance is the science that keeps the promise a medicine makes. When a drug is approved, its benefits have been shown and its common harms are known, but its rarest and most delayed harms are not, because the trials that precede approval are too small and too short to find them. Pharmacovigilance is the organised watch that continues for the whole life of a medicine, detecting the harms that only wide use reveals, assessing whether the medicine is to blame, and acting to protect the patients who take it next.

This book teaches that watch as a single working system rather than a set of separate topics. Every chapter is reached through one practical question: how would a safety professional actually act here? The safety cycle of detection, assessment, decision and communication runs through the whole book, from the first suspected reaction reported by a clinician to the global signal detected across millions of records, and the same method is shown to serve not only medicines but vaccines, blood, devices, cosmetics, herbal products and even the environment.

The treatment follows the PCI syllabus for BP705T closely, so that a student who reads only this book should be able to sit the paper with confidence, while always keeping the Indian context, the Pharmacovigilance Programme of India, the ADR Monitoring Centres and the national regulator, alongside the global machinery of the WHO, the ICH and the major regulators. Each chapter states its learning outcomes, teaches to them, illustrates the ideas with original figures and worked examples, and tests them with graded self-assessment written in the pattern of the university examination.

The aim throughout has been accuracy first: where a fact could not be confirmed it has been stated as a principle rather than guessed, and the primary sources are cited so that current figures can always be checked. It is hoped that the book will serve the first-time learner, the reviser and the night-before reader alike, and that it will convey not only the facts of drug safety but the disciplined habit of mind, careful, honest and vigilant, that the subject exists to instill.

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Course Objectives

The objectives of this course are to enable the student to:

1. Understand the principles, scope and importance of pharmacovigilance in ensuring drug safety and patient care.
2. Become familiar with the classification of adverse drug reactions and the methods used for their detection, assessment, monitoring and prevention within healthcare systems.
3. Explain the concepts and significance of immunovigilance in monitoring and managing adverse events following immunization.
4. Learn the national and international regulatory frameworks, guidelines and reporting systems related to pharmacovigilance and immunovigilance.
5. Analyse pharmacovigilance data and apply risk-management strategies to enhance medication and vaccine safety.

Course Outcomes

Upon successful completion of this course, the student will be able to:

CO	On completion, the student will be able to:
CO1	Explain the core concepts, objectives and significance of pharmacovigilance and immunovigilance.
CO2	Interpret and analyse national and global regulatory frameworks related to drug and vaccine safety.
CO3	Identify, document and report ADRs and AEFIs using appropriate pharmacovigilance systems.
CO4	Evaluate pharmacovigilance data to detect trends, safety signals and risk factors associated with medicinal products.
CO5	Propose and implement risk-management strategies aimed at improving patient safety and public-health outcomes.

Syllabus (BP705T Pharmacovigilance - Theory)

Unit	Topics	Hours
I	Fundamentals of Pharmacovigilance: concept, history and importance; basic drug classification systems (ATC, ICD); drug-related problems and medication safety; drug safety in special populations (paediatrics, geriatrics, pregnancy and lactation).	10
II	Pharmacovigilance Systems and Regulatory Framework: objectives and functions; methods of data collection (spontaneous reporting, cohort and case-control studies); WHO International Drug Monitoring Programme; CIOMS and major regulatory agencies (USFDA, EMA); PvPI; establishment and role of ADR Monitoring Centres.	10
III	Adverse Drug Reactions: classification and types; mechanisms and risk factors; monitoring, detection and reporting; assessment of causality, severity, predictability and preventability; management; online reporting mechanisms and databases (WHO-ART, VigiBase, VigiFlow, Oracle Argus, OpenVigil); MedDRA.	8
IV	Immunovigilance and Other Disciplines: definition, scope and significance of immunovigilance, cosmetovigilance, nutraceutical-vigilance, materiovigilance, herbovigilance, ecopharmacovigilance and haemovigilance; vaccination failure and vaccinovigilance; overview of AEFIs; immunization safety monitoring systems in India.	7
V	Risk Communication, Evaluation, Management and ICH Guidelines: risk evaluation and management strategies; communication in drug-safety crisis management; communication with regulators, business partners and healthcare facilities; real-world case studies; emerging trends and challenges; safety data generation; objectives of ICH guidelines; expedited and aggregate reporting; ICSRs; PSURs; post-approval expedited reporting; GCP (New Drugs and Clinical Trials Rules) 2019; pharmacogenomics and pharmacometrics in pharmacovigilance.	10

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