

Regulatory Affairs (Theory)

BP707T

A Textbook for B. Pharm Semester VII

As per the new Pharmacy Council of India (PCI) Syllabus 2026 (NEP 2020)

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Preface

Regulatory affairs is the discipline through which a medicine is brought to market lawfully and kept on it safely. It sits at the meeting point of pharmaceutical science, law, and ethics, and it has become one of the largest professional fields open to a pharmacy graduate, particularly in India, whose pharmaceutical industry supplies medicines to much of the world. This book is written for the student of the B.Pharm seventh-semester course in Regulatory Affairs (BP707T), and it follows the prescribed syllabus unit by unit.

The book is built on a single conviction: that the rules of regulation are best learned through the reasons behind them. Almost every requirement in this subject was written in response to a real failure, and almost every one exists, in the end, to protect the patient. The chapters that follow therefore explain not only what the rules are but why they exist, and they keep the Indian regulatory frame and the major international systems side by side throughout, so that the reader can compare rather than memorize in isolation. The content is current to the developments of recent years, including the New Drugs and Clinical Trials Rules, 2019 and the most recent revision of the international good clinical practice guideline.

Each chapter opens with measurable learning outcomes tied to the official Course Outcomes, develops the topic in a connected argument with original figures and comparison tables, and closes with a graded self-assessment of multiple-choice, short-answer, and long-answer questions with model answers, written to the pattern of the university examination. A small number of precise values that depend on the current text of the law or the compendium, exact fees, statutory timelines, and form numbers, change with each amendment and are marked for the reader to confirm against the current official source; the principles around them are stable and are taught in full.

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Acknowledgement

To my beloved children, Tejas and Jeeyansh, you are my greatest inspiration. Your innocent smiles, curiosity, and boundless energy gave me the motivation to keep going even on the most challenging days. This book is as much yours as it is mine.

Finally, I dedicate this work to all aspiring and experienced professionals in Regulatory Affairs. I hope this book serves as a guiding light and adds value to your journey, just as the support of so many has enriched mine.

Mr. Ashish Vishwakarma

I bow in gratitude to Shri Guru Granth Sahib Ji for divine guidance and strength throughout this journey.

I wish to express my sincere appreciation to my mentors, colleagues, and the academic community for their guidance and intellectual support in the completion of this work.

I am grateful to my father, Mr. Amar Nath Arora, and my mother, Mrs. Anju Arora, whose unwavering encouragement and steadfast belief in my abilities have been a constant source of strength.

Mr. Rohit Arora

I would like to express my sincere gratitude to my mentors, colleagues, and academic institution for their guidance and support throughout the preparation of this book. Their encouragement and valuable suggestions have greatly contributed to this work. I am especially thankful to my father Sh. Hari Singh and my mother Smt. Maya Devi for their blessings, sacrifices, and constant support. Their faith in me has been my biggest strength and motivation.

Ms. Mohini

Course Objectives

The objectives of this course are to:

1. Understand the drug discovery and development process.
2. Identify key regulatory authorities and their roles in drug regulation.
3. Describe the regulatory approval processes in India and international markets.
4. Understand the documentation and registration procedures for drug products.
5. Describe the laws and guidelines governing the pharmaceutical industry.

Course Outcomes

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

1. Describe the fundamental concepts and organizational structures of regulatory affairs and global regulatory authorities governing pharmaceutical products.
2. Describe the drug discovery and development process, including preclinical, clinical, and regulatory documentation requirements.
3. Summarize the regulatory framework, approval procedures, and legal requirements for pharmaceuticals in India.
4. Compare regulatory approval processes and submission formats across major international markets.
5. Understand clinical trial requirements, ethics committee roles, informed consent, GCP guidelines, and pharmacovigilance requirements.

Syllabus

Unit	Topics	No. of lectures
I	Fundamentals of Regulatory Affairs Introduction to Drug Regulatory Affairs, Overview of regulatory authorities in India and major international markets (US FDA, EMA, PMDA), Role and responsibilities of Regulatory Affairs Professionals, Organizational structure of regulatory bodies. a) Basic regulatory terminologies: Guidance, Guidelines, Regulations, Laws, Acts. b) Regulatory reference resources: Orange Book, Purple Book, Federal Register, Code of Federal Regulations (CFR).	6 Hours
II	Regulatory Requirements in Drug Development a) Drug discovery and development process, Drug development teams and their functions. b) Non-clinical drug development: Pharmacology, Drug metabolism, Toxicology. c) Regulatory documentation: Investigational New Drug (IND) application, Investigator's Brochure (IB), Clinical research protocols, Biostatistics in pharmaceutical product development, Bioequivalence (BE) studies, Data presentation for regulatory submissions.	6 Hours
III	Indian Regulatory Framework and Approval Process a) Central Drugs Standard Control Organization (CDSCO) and State Licensing Authorities: Organization and responsibilities, Regulatory requirements for import, manufacture, and sale of pharmaceuticals in India, Certificate of Pharmaceutical Product (COPP), Regulatory approval procedure for new drugs in India, Clinical trial regulatory requirements in India, phytopharmaceutical regulations, Good Clinical Practice (GCP) guidelines and Schedule Y, Innovator and generic drugs, Generic drug product development. b) Phytopharmaceutical regulation by AYUSH and CDSCO.	6 Hours
IV	International Regulatory Systems & Global Drug Registration a) Types of regulatory applications: Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). b) Drug Master Files (DMF), Common Technical Document (CTD), electronic CTD (eCTD), ASEAN CTD (ACTD). c) Registration procedure for Indian drug products in overseas markets, Post-approval changes to NDA and ANDA.	6 Hours
V	Clinical Trials, Ethics, and Post-Marketing Surveillance a) Clinical research phases (I-IV), Clinical trial documents, Institutional Review Board (IRB) and Independent Ethics Committee (IEC): Formation and functions. b) Informed consent process and documentation, Good Clinical Practice (GCP) obligations of investigators, sponsors, and monitors, Management and monitoring of clinical trials, Pharmacovigilance: Safety monitoring during clinical trials and post-marketing.	6 Hours

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