



Technology and Quality in Industrial Pharmacy: Theory and Practice in Pharmaceutical Sciences

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Editors

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Technology and Quality in Industrial Pharmacy: Theory and Practice in Pharmaceutical Sciences

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About the Editorial Author



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Preface

The pharmaceutical industry plays a crucial role in advancing healthcare, providing life-saving medicines, and ensuring their safety and efficacy. This book is very carefully crafted to empower students and professionals with the fundamental and advanced knowledge required for thriving careers in pharmaceutical manufacturing, quality assurance, and regulatory affairs. It bridges the gap between theoretical concepts and practical applications, providing a comprehensive understanding of essential practices such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), process validation, and the innovative approach of Quality by Design (QbD).

This book is designed for individuals to learn the skills and knowledge to excel in those critical roles in production, R&D, packaging, and regulatory compliance. Integrating academic rigor with industry relevance, it also serves as a guide for entrepreneurial ventures and will help readers explore opportunities in pharmaceutical technology and related fields, all in an age of increasing global demand for pharmaceuticals.

This book will be of tremendous value to aspiring students, established professionals, and entrepreneurs alike. It is conceptualized to inspire critical thinking, foster innovation, and build confidence in the face of challenges in the ever-evolving pharmaceutical landscape. By its structured chapters, practical insights, and emphasis on real-world applications, this book guarantees that its readers are equipped to contribute meaningfully to the global pharmaceutical industry.

We hope that this book will be a trusted companion in your academic journey and a foundation for your professional aspirations in the pharmaceutical sector.

Varda S. Joshi
Sachin S. Mali
Durgacharan A. Bhagwat
Pavan V. Chavan

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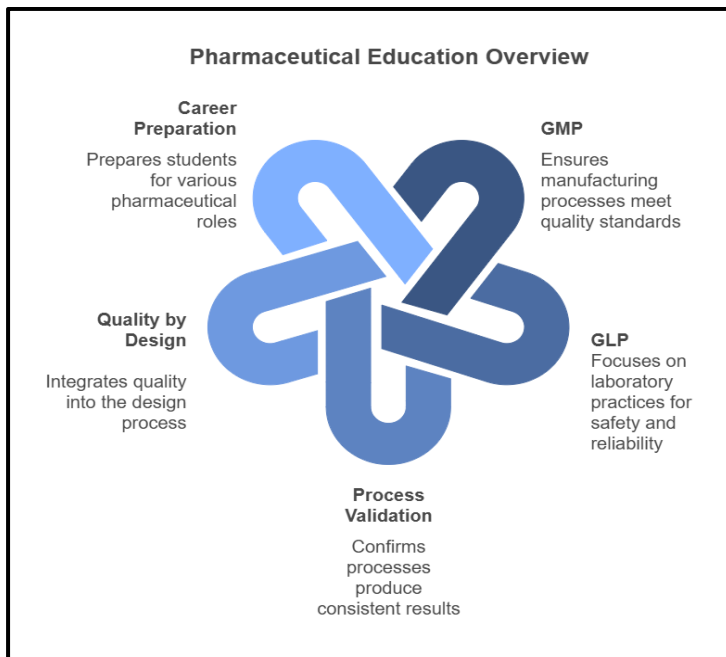
Scope

Provides essential knowledge for careers in pharmaceutical manufacturing, quality assurance, and regulatory affairs. It focuses on GMP, GLP, process validation, and Quality by Design, preparing students for roles in production, R&D, packaging, and compliance. The subject also supports entrepreneurial ventures and further studies in pharmaceutical technology or regulatory fields, ensuring readiness for the growing global pharmaceutical industry.

Objectives

Upon completion of the subject student shall be able to

1. Know the process of pilot plant and scale up of pharmaceutical dosage forms
2. Understand the process of technology transfer from lab scale to commercial batch
3. Know different Laws and Acts that regulate pharmaceutical industry
4. Understand the approval process and regulatory requirements for drug products



Content

Unit-I Pilot Plant Scale Up Techniques

1.1. Introduction, 1.2. General Considerations Including Significance of Personnel Requirements, 1.3. Need of Pilot Plant studies, 1.4. Use of Pilot Plant, 1.5. GMP Consideration, 1.6. Pilot Plant Scale Up, 1.7. Pilot Plant Techniques for Tablets, 1.8. Pilot Plant Techniques for Capsules, 1.9. Scale Up Liquid Orals, 1.10. Semi Solids Dosage Form, 1.11. Pilot Plant Operation, 1.12. SUPAC Guidelines, 1.13. Introduction To Platform Technology.

Unit-II Technology Development and Transfer

2.1. Introduction, 2.2. Who Guidelines For Technology Transfer (Tt): Terminology, 2.3. Technology Transfer Protocol, 2.4. Quality Risk Management, 2.5. Transfer From R & D to Production (Process, Packaging And Cleaning), 2.6. Granularity Of TT Process (Api, Excipients, Finished, Products, Packaging Materials) Documentation, Premises And Equipments, Qualification and Validation, 2.7 Quality Control, 2.8. Analytical Method Transfer, 2.9. Approved Regulatory Bodies and Agencies, Commercialization- Practical Aspects and Problems (Case Studies), 2.10. TT Agencies In India- APCTD, NRDC, TIFAC, BCIL, TBSE /SIDBI; TT related Documentation- Confidentiality Agreement, 2.11. Licensing, 2.12. MOUs, 2.13. Legal Issues

UNIT-III

3.1. Introduction, 3.2. Aspect of History, 3.3. Regulatory authorities, 3.4. Professionals in Regulatory Affairs are Responsible, 3.5. Drug Approval Regulatory Requirements, 3.6. Pharmaceutical Drug Development, 3.7. Non- Clinical Phase of Drug Development, 3.8. Investigational New Drug Application (IND), 3.9. The Investigator's Brochure (IB), 3.10. Application for New Drugs (NDA), 3.11. Clinical Trial Protocol, 3.12. Biostatistics in Pharmaceutical Product Development.

UNIT-IV Quality Management Systems

4.1. Total Quality Management, 4.2. Quality by Design (QbD), 4.3. Six Sigma, 4.4. Out of Specifications (OOS), 4.5. Change control, 4.6. Quality Standard – ISO 9000, 4.7. ISO 14000, 4.8. NABL, 4.9. GLP

UNIT-V Indian Regulatory Requirements

5.1. Introduction, 5.2. Central Drug Standard Control Organization (CDSCO), 5.3. Organization of CDSCO, 5.4. State Drugs Control Organization, 5.5. Certificate of Pharmaceutical Product (COPP).

Syllabus

UNIT-I

10 Hours

- **Pilot plant scale up techniques:** General considerations- including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II

10 Hours

- **Technology development and transfer:** WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization-practical aspects and problems (case studies), TT agencies in India- APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation- confidentiality agreement, licensing, MoUs, legal issues.

UNIT-III

10 Hours

- **Regulatory affairs:** Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals
- **Regulatory requirements for drug approval:** Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV

08 Hours

- **Quality management systems:** Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V

07 Hours

- **Indian Regulatory Requirements:** Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs

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About the Editors



Ms. Varda S. Joshi (M. Pharm.) is currently working as an Assistant Professor at Ashokrao Mane College of Pharmacy, Peth-Vadgaon. She is having 1 year of academic experience in pharmaceuticals department. She completed her B. pharmacy from Reputed institute Krishna Vishwa Vidyapeet "Deemed to be University"; Krishna Institute of Pharmacy, Karad. and M. Pharmacy in Pharmaceuticals from YSPMs YTC Faculty of Pharmacy, Satara.



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