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

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Editors

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About the Editorial Author

Ms. Varda S. Joshi (M. Pharm.) is currently working as an Assistant Professor at Ashokrao Mane College of Pharmacy, Peth-Vadgaon Dist.Kolhapur. She is having 1 year of academic experience in pharmaceutics 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 Pharmaceutics from YSPMs YTC Faculty of Pharmacy, Satara. She has published 5 Review articles. She attends national and international conferences, as learning is a never-ending process. Research area where he finds interests includes Academics, Formulation development, Research Development (R&D) and Regulatory Affairs.

Dr. Sachin S. Mali, (M. Pharm; Ph.D.) an excellent pharmacist with remarkable achievements in the field of Teaching, Research and Publication under Pharmacy. Currently, as Assistant Professor, PG, Department of Pharmaceutics, Bharati Vidyapeeth college of Pharmacy, Shivaji University, Kolhapur, he is flying his wagon with the fine projects he has worked upon, including Expulsion by Ionic Complexation; Nano-structured lipid carrier gel for topical delivery of ketoconazole. His art of work can be seen reflected under his own publication with a book-name as Factorial Design Approach as a Tool of Optimization Methodology Formulation, Development and Evaluation of Transdermal Patch; also, his articles and the reviews, which are finely curated on each topic under Pharmacy. Not only Dr. Sachin holds the editorial memberships of National and International Pharma Journals, also holds the membership of Scientific and Professional Studies. He attends national and international conferences, as learning is a never-ending process. With a copyright registration of literary/dramatic, he has excelled in the world of Pharmacy. Being a masterpiece in his field of

work, he has been awarded as a “Best Young Teacher National Award” and holds honorary awards as well as recognition for his work and achievements.

Dr. Durgacharan A. Bhagwat (M. Pharm.; Ph.D.) is currently working as an Associate Professor & Head, Bharati Vidyapeeth college of Pharmacy, Kolhapur 416 013, India. With extensive expertise in pharmaceutics, he has made significant contributions to drug delivery systems, nanotechnology, and bioavailability enhancement. Dr. Bhagwat has authored numerous highly cited research articles in reputed journals and is recognized for his innovative work on solid self-emulsifying drug delivery systems and anticancer therapeutics. His academic influence is reflected in an h-index of 15 and i10-index of 20, with over 894 citations. Dr. Bhagwat continues to advance pharmaceutical research while mentoring future scientists.

Mr. Pavan V. Chavan (M. Pharm. MBA) is currently working as an Assistant Professor at Ashokrao Mane College of Pharmacy, Peth-Vadgaon Dist. Kolhapur. He has successfully completed his M. Pharm in Pharmaceutics and holds an MBA degree, showcasing a strong blend of technical and managerial expertise. His academic and research accomplishments include a design patent, copyright and the publication of five research review articles, highlighting his innovative contributions and analytical skills in the pharmaceutical sciences. He attended more than 10 national conferences in his tenure.

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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

Contents

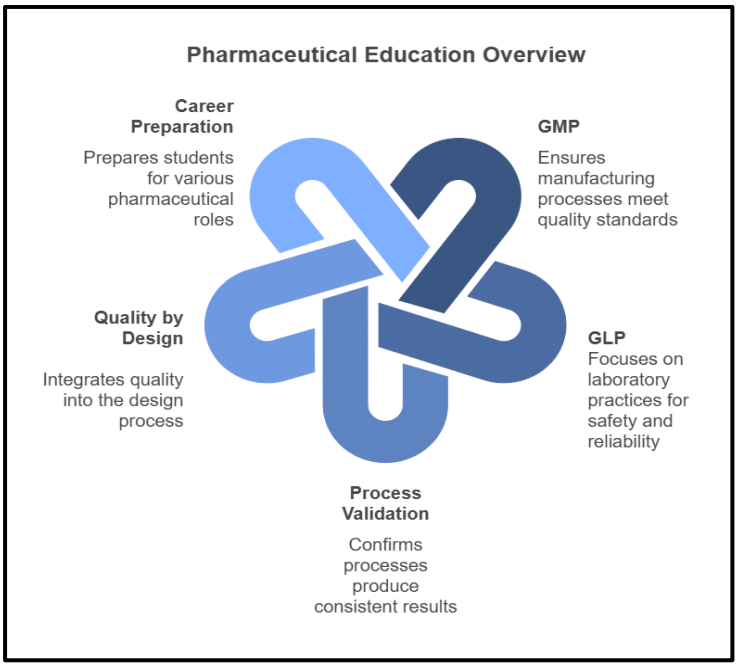
Scope

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 Orgination, 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 FDASubmissions, 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

Figures

Tables

About the Editors

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