PHARMACEUTICAL QUALITY ASSURANCE

- Ms. Shital M. Rokade
- Ms. Madhuri B. Raskar
- Ms. Shital B. Kshirsagar
- Ms. Pooja S. Wankhede
- Ms. Pranali S. Mahajan

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Ms. Shital M. Rokade
Assistant Professor, Navsahyadri Institute of Pharmacy,
Naigaon, Nasarapur, Pune.

Ms. Madhuri B. Raskar
Assistant Professor, Marathwada Mitra Mandal's College of
Pharmacy, Thergaon, Pune.

Ms. Shital B. Kshirsagar
Assistant Professor, Navsahyadri Institute of Pharmacy
Naigaon, (Nasrapur) Pune.

Ms. Pooja S. Wankhede
Assistant Professor, Navsahyadri Institute of Pharmacy,
Naigaon, Nasarapur, Pune.

Ms. Pranali S. Mahajan
Assistant Professor, Womens College of Pharmacy,
Peth Vadgaon, Kolhapur.

Kripa-Drishti Publications, Pune.

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Authored By: **Ms. Shital M. Rokade,**
Ms. Madhuri B. Raskar,
Ms. Shital B. Kshirsagar,
Ms. Pooja S. Wankhede,
Ms. Pranali S. Mahajan

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PREFACE

A thorough manual that explores every facet of quality assurance in the pharmaceutical sector is **"Pharmaceutical Quality Assurance."** This book, which was written especially for industrial pharmacists, covers every topic covered in the Pharmacy Council of India's (PCI) recommended curriculum for pharmaceutical quality assurance in both B.Pharm and M.Pharm programs.

This book offers a plethora of information in a clear, concise format that is intended to make the subject more engaging and understandable. It guarantees that readers acquire the most recent information in this quickly changing field by including the most recent guidelines and regulations pertaining to drug development, manufacture, and supply.

In order to eliminate Import Alerts and Consent Decree, this book attempts to create a tool that will significantly reduce the number of Inspectional Observations and Warning letters. Simplified SOP guidelines, plant layouts to implement quality metrics for pharmaceutical manufacturing systems in tablets, capsules, liquid orals, and semi-solid dosage forms, and pharmaceutical quality guidelines are all covered in this book, which is intended for the pharmaceutical industry and students of pharmaceutical quality assurance.

Abbreviations

Analytical Method Validation (AMV)
Annual Product Quality Reviews (APQR)
Asia Pacific Laboratory Accreditation Cooperation (APLAC)
Batch Manufacturing Record (BMR)
Bills of Materials (BOMs)
Building Management System (BMS)
Code of Federal Regulations (CFR)
Common Technical Document (CTD)
Component Qualification (CQ)
Comprehension of The Key Process Parameters (CPPs)
Computer Software Assurance (CSA)
Continued Process Verification (CPV)
Corrective and Preventative Activities (CAPA)
Critical Quality Attributes (CQAs)
Cross-Functional Team (CFT)
Customer Relationship Management (CRM)
Design Qualification (DQ)
Detectability (D)
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Environmental Control System (ECS)
Environmental Management System (EMS)
Equipment Qualification and Validation (EQV)
European Medicines Agency (EMA)
Expert Committee on Biological Standardization (ECBS)
External Quality Assessment Schemes (EQAS)
Food and Medication Administration (FDA)
Good Clinical Practice (GCP)
Good Documentation Practice (GDP)
Good Laboratory Practice (GLP)
Good Manufacturing Practice (GMP)
Good Warehousing Practices (GWP)
Heating Ventilation Air-conditioning (HVAC)
High-Efficiency Particulate Air (HEPA)
Installation Qualification (IQ)
Internal Quality Control (IQC)
International Laboratory Accreditation Cooperation (ILAC)
International Organization for Standardization (ISO)

Limit of Detection (LOD)
Limit of Quantitation (LOQ)
Master Production Record (MFR)
Material Handling Equipment (MHE)
Material of Construction (MOC)
Material Requirements Planning (MRP)
Material Safety Data Sheet (MSDS)
Measurement (M)
Measuring System Analysis (MSA)
Natural Work Teams (NWTs)
Occurrence (O)
Operation Qualification (OQ)
Organization for Economic Cooperation and Development (OECD)
Over-The-Counter (OTC)
Performance Qualification (PQ)
Personal Protective Equipment (PPE)
Pharmaceutical Inspection Co-operation Scheme (PIC/S)
Problem-Solving Teams (PSTs)
Process Analytical Technology (PAT)
Process-Failure Mode Effect Analysis (pFMEA)
Product Annual Review (PAR)
Programmable Logic Controllers (PLCS)
Quality Assurance (QA)
Quality by Design (QbD)
Quality Control (QC)
Quality Improvement Teams (QITs)
Quality Management (QM)
Quality System Regulation (QSR)
Severity (S)
Standard Operating Procedures (SOP)
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Validation Master Plan (VMP)
Validation Risk Assessment (VRA)
Warehouse Management Systems (WMS)
Work Instructions (WIs)

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ABOUT THE AUTHORS

Ms. Shital M. Rokade Currently working as Assistant professor in Navsahyadri Institute of Pharmacy, Naigaon, Nasarapur, Pune. She has completed M.Pharm in Quality Assurance in Annasaheb Ramesh Ajmera College of Pharmacy, Dhule from North Maharashtra University Jalgaon. Her research interest in Development of UV Spectrophotometric Method of Gliclazide and Rosiglitazone Maleate Simultaneously in Bulk and Pharmaceutical Dosage Form." And "Synthesis and Spectral Characterization Of Certain Heterocyclic Compounds. She has many patents grand also She published review as well as research papers in various UGC Care Scopus Journals. She has 6+ years experience in the pharmacy field including pharma industry as well as academics.

Ms. Madhuri B. Raskar is currently working as Assistant Professor in Marathwada Mitra Mandal's College of Pharmacy, Thergaon, Pune. She has been graduated and post graduated in Pharmaceutical quality assurance from Savitribai Phule Pune University. She is having more than 3 years of teaching experience. She has published various review and research papers in national as well as international journals. She has also registered 02 Indian patents on her name. She has written guidelines and SOP's for small scale pharmaceutical industry. Her area of research is guidelines and scope followed for quality assurance audit and quality improvement. She is register pharmacist.

Ms. Shital B. Kshirsagar is currently working as Assistant Professor at Navsahyadri Institute of Pharmacy Naigaon, (Nasrapur) Pune. She has completed M. Pharm in Quality Assurance Techniques in Shivnagar Vidya Prasarak Mandal's College of Pharmacy Malegaon BK. from Savitribai Phule Pune University, Pune. Her research interest includes RP-HPLC Method Development and Validation for Simultaneous Estimation of Itraconazole and Terbinafine Hydrochloride in Pharmaceutical Dosage Form. She published review as well as research papers in various UGC Care, Scopus Journals. She has more than 5 years of teaching experience.

Ms. Pooja S. Wankhede is currently working as Assistant Professor at Navsahyadri Institute of Pharmacy, Naigaon, Nasarapur, Pune. She has completed Master of Pharmacy in Pharmaceutical Chemistry from Dr. Babasaheb Ambedkar Marathwada University, Chh. Sambhajinagar. His research includes Synthesis and biological evaluation of Novel Ethyl-(5-SubstitutedPropanamido)-3-(Methylthio)-1-Phenyl-1H-Pyrazole-4-carboxylate derivative, herbal formulation, and Cosmetic formulation. She is reviewer and editor of many journals. She published review as well as research papers in various UGC care, Scopus journals.

Ms. Pranali S. Mahajan Currently working as assistant professor in Womens College of Pharmacy, Peth Vadgaon, Kolhapur. She has completed M.Pharm in Quality Assurance in Appasaheb Birnale College of Pharmacy, Sangli from Shivaji University Kolhapur. Her research interest include herbal formulation & evaluation in arthritis. She published review as well as research paper in various UGC Care, Scopus Journal. She is member of Association of Pharmacy Teachers in India.

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A-503 Poorva Heights, Pashan-Sus Road, Near Sai Chowk,
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