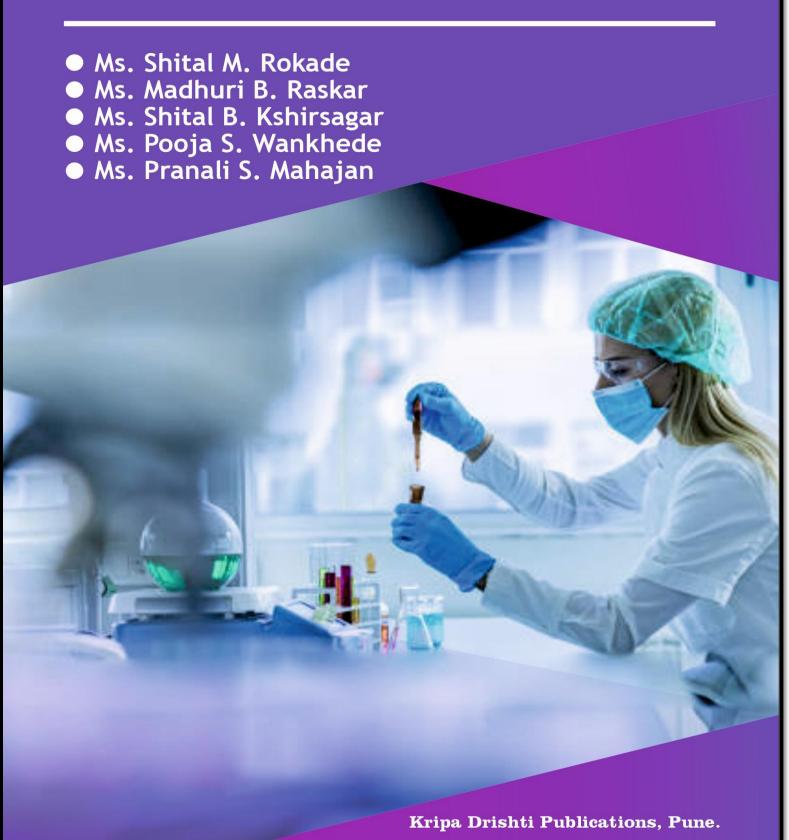
PHARMACEUTICAL QUALITY ASSURANCE



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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)

Total Quality Management (TQM)

User Requirement Specification (URS)

Validation Master Plan (VMP)

Validation Risk Assessment (VRA)

Warehouse Management Systems (WMS)

Work Instructions (WIs)

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