Pharmaceutical Master Validation Plan: The Ultimate Guide to FDA, GMP, and GLP Compliance

Haider, Syed Imtiaz

ISBN-13: 9781574443301

Table of Contents

Performance Qualification Protocols
Process Validation Protocols
Validation Final Reports
Validation Package
Certificate for Use in Manufacturing
Required Protocols and Procedures for Dry Production: Building A
Required Protocols and Procedures for Liquid and Semisolid Production: Building B
Required Protocols and Procedures for Parenterals Production: Building C
CALIBRATION PROGRAM SUMMARY
PREVENTATIVE MAINTENANCE PROGRAM SUMMARY
KEY STANDARD OPERATING PROCEDURES (SOPS)
VALIDATION OF BUILDING
Civil Work
Drainage System
VALIDATION OF UTILITY SYSTEMS
Plant Steam
Pure Steam
Water for Injection (WFI)
Compressed Air
Nitrogen (N2)
Heating Ventilation and Air Conditioning (HVAC)
Emergency Power (Standby Generator)
PROCESS DESCRIPTION BUILDING A DRY PRODUCTION: BUILDING A
Process Flow, Variables and Responses: Tablets
Process Flow, Variables and Responses Powder for Suspension
Process Flow, Variables and Responses: Capsules
PROCESS DESCRIPTION LIQUID AND SEMISOLID PRODUCTION: BUILDING B
Process Flow, Variables, and Responses: Syrup, Suspension, and Drop Products
Process Flow, Variables and Responses: Cream Ointment, and Suppository Products
PROCESS DESCRIPTION FOR PARENTERALS PRODUCTION FACILITY: BUILDING C
Process Flow, Variables, and Responses: Aseptic Fill Products
Process Flow, Variables, and Responses: Ready-to-Use Disposable Syringes
Process Flow, Variables, and Responses: Terminal Sterilization Products
Process Flow, Variables and Responses: Lyophilized Products
QUALIFICATION OF PROCESS EQUIPMENT
Commuting Mill
Dryer
V-Shell Blender
Tablet Compression
Capsulation
Powder Filing
Capsule Polisher
Tablet Coating
Syrup Manufacturing Vessel
Suspension Manufacturing Vessel
Drops Manufacturing Vessel
Mixer
Filter Press
Cream/Ointment/Suppository Manufacturing Vessel
Syrup, Suspension, and Drop Filling Machine
Cream and Ointment Filling Machine
Suppository Filling Machine
Labeling Machine
Capping Machine
Cartonator
Shrink-Wrapping Machine
Over-Printing Machine
Autoclave (Steam Sterilizer)
Hot Air Tunnel (Dry Heat Sterilizer)
Vials / Ampoules Washing Machine
Vials / Ampoules / Syringes Filling Machine
Freeze Dyer (Lyophilizer)
Laminar Flow Unit
Pass Through
VALIDATION OF SUPPORT PROCESS
Washing of Components
Sterilization of Components
Depyrogenation of Components
Aseptic Filling Validation (Media Fill Studies)
Cross-Contamination Control
Computerized Pharmaceutical System