Pharmaceutical Recipe Setting in GMP Manufacturing

Part 6: Governance, Regulatory Compliance, Industry Best Practices, Case Studies, and SOP

Chapter 24

Periodic Review Requirements: objectives, review frequency, KPI dashboard, trending, management review, annual periodic review workflow.

Chapter 25

Regulatory Inspection Expectations: FDA, EMA, MHRA, WHO, PIC/S expectations, common inspector questions, inspection readiness checklist, common observations.

Chapter 26

Best Industry Practices: Golden Recipe strategy, standardized recipe library, governance model, modular ISA-88 recipes, QA, Production and Engineering best practices.

Chapter 27

Real Pharmaceutical Case Studies: unauthorized recipe change, wrong recipe download, audit trail review failure, backup failure, incorrect batch scaling, communication failures, RBAC weaknesses, electronic signature issues, alarm optimization, global recipe standardization.

Chapter 28

Standard Operating Procedure (SOP): Purpose, Scope, Responsibilities, Recipe creation, review, validation, approval, execution, change control, retirement, records, references, revision history.

Note: This PDF is a concise publication version of Part 6. The complete chapter text provided in the chat can be inserted into this layout for a full handbook edition.