Pharmaceutical Recipe Setting in GMP Manufacturing

Part 4: Validation, System Integration, Data Integrity, and Risk Management (Chapters 14–18)

This PDF contains the Part 4 handbook section covering:

Chapter 14: Validation Requirements (URS, FS, DS, Configuration Specification, Traceability Matrix, IQ/OQ/PQ, Validation Deliverables).
Chapter 15: Recipe Testing During IQ/OQ/PQ including installation verification, operational testing, performance qualification, boundary testing, alarms, interlocks, security testing, and audit trail verification.
Chapter 16: Integration of ERP, MES, SCADA, PLC, HMI, LIMS, Historian, and Electronic Batch Records, with conceptual data flow architecture and interface considerations.
Chapter 17: Data Integrity Controls based on ALCOA+, metadata management, backup, disaster recovery, periodic review, and governance practices.
Chapter 18: Risk Assessment using FMEA, including workflow, example failure modes, equipment-specific risks, mitigation strategies, and lifecycle risk management.

This document is intended as Part 4 of the larger handbook. The detailed chapter content corresponds to the Part 4 text previously generated in this conversation and is suitable for inclusion in a GMP training manual after review and approval according to your organization's procedures.