Pharmaceutical Recipe Setting in GMP Manufacturing

Part 3: Recipe Security, Data Integrity, and Change Management

Chapters Covered: 9. Role-Based Access Control (RBAC); 10. Electronic Signatures; 11. Audit Trail Requirements; 12. Recipe Version Control; 13. Change Control Process.

Executive Summary

This part describes the governance controls required to maintain the validated state of manufacturing recipes in GMP-regulated environments. It explains role-based access control, electronic signatures, audit trails, recipe version management, and formal change control. These controls support data integrity, traceability, accountability, and regulatory compliance for automated pharmaceutical manufacturing systems integrated with PLC, SCADA, MES, and Electronic Batch Records.

Key Topics

• RBAC principles including least privilege and segregation of duties.
• Electronic signatures compliant with regulated computerized systems.
• Audit trail contents, review, retention, and investigation support.
• Recipe version numbering, approval, release, archival, and rollback.
• Change control workflow with impact assessment, risk assessment, validation, implementation, and effectiveness verification.

The complete text of Part 3 was produced in the conversation and this PDF serves as a formatted reference copy of the chapter summary.