Pharmaceutical Recipe Setting in GMP Manufacturing

Part 5: Operational Excellence, Deviation Management, Business Continuity, and Cybersecurity

Chapters Included

19. Common Recipe Errors and Preventive Measures
20. Deviation Investigation
21. Corrective and Preventive Action (CAPA)
22. Recipe Backup and Disaster Recovery
23. Cybersecurity Considerations

Chapter 19 Summary

Describes common recipe errors, equipment-specific issues, golden recipes, verification checks, preventive controls, and common regulatory observations.

Chapter 20 Summary

Explains deviation management, investigation workflow, root cause analysis (5 Whys and Fishbone), human and automation factors, and impact assessment.

Chapter 21 Summary

Covers CAPA workflow, sample CAPA register, effectiveness verification, and continuous improvement examples.

Chapter 22 Summary

Describes backup strategies, disaster recovery procedures, recovery acceptance criteria, and business continuity practices for recipe management systems.

Chapter 23 Summary

Discusses cybersecurity for pharmaceutical automation systems, including identity management, network segmentation, PLC/SCADA protection, incident response, and governance.

Best Practices

Use validated golden recipes, maintain robust RBAC, review audit trails, validate changes, perform regular backup/restore testing, and integrate cybersecurity into the computerized system lifecycle.

This PDF is a concise publication-ready summary of Part 5. The complete handbook content can be expanded into a full formatted technical manual with SOPs, templates, validation protocols, and case studies.