

Index

- 1. Food and Drug Administration**
 - a. Background and History
 - b. Agency Structure
 - c. Current Trends
- 2. Current Good Manufacturing Practices**
 - a. The Regulation
 - b. Milestones in Food and Drug Law
- 3. Calibration**
 - a. Purpose and Use
 - b. Frequency
 - c. Procedure
- 4. Change Control**
 - a. Scope and Definition
 - b. Application
 - c. Procedure
 - d. Documentation
- 5. Contamination Control**
 - a. Responsibility
 - b. Sources of Contamination
 - c. Methods of Prevention
- 6. Documentation**
 - a. Scope
 - b. Rules for Completion
 - c. Non-Compliant Practices
- 7. Electronic Records and Signatures**
 - a. General Requirements
 - b. System Performance
 - c. System Controls
- 8. Engineering**
 - a. Facility Design
 - b. Facility Construction
 - c. Utilities and Environmental Monitoring
- 9. Equipment**
 - a. Design and Construction
 - b. Operation, Cleaning and Maintenance
- 10. Consequences of GMP Non-Compliance**
- 11. Investigations**
- 12. Packaging and Labeling**
 - a. Examination and Issue
 - b. Operations and Controls
- 13. Materials**
 - a. Supply and Receipt
 - b. Sampling and Storage
 - c. Controls and Investigations
- 14. Management Responsibility**
 - a. Foundation for Quality
 - b. Motivation for Compliance
- 15. Quality Assurance**
- 16. Quality Control**
- 17. Regulatory Inspections**
 - a. Origin and Background
 - b. Preparation
 - c. The Process
- 18. Standard Operating Procedures**
- 19. Training**
- 20. Validation: Process and Documentation**