EAS Consulting Group

Good Manufacturing Practices for OTCs Two-Day Seminar

1. Introductions and Seminar Objectives

2. Overview of Laws, Regulations and Monographs

- History of the Law
- GMP Regulations
- OTC Monographs

3. Subpart B: Organization & Personnel/Q10

- Responsibilities of quality control unit
- Personnel qualifications
- Personnel responsibilities
- Consultants
- Q10 – Pharmaceutical Quality Systems

4. Subpart C: Buildings & Facilities, Subpart D: Equipment

- Design and construction features
- Lighting
- Ventilation, air filtration, air heating and cooling
- Plumbing
- Sewage and refuse
- Washing and toilet facilities
- Sanitation
- Maintenance Equipment design, size, and location
- Equipment construction
- Equipment cleaning and maintenance
- Automatic, mechanical, and electronic equipment
- Filters

5. Subpart E: Control of Components & Drug

- General requirements
- Receipt and storage of untested components, drug product containers, and closures
- Testing and approval or rejection of components, drug product containers, and closures
- Use of approved components, drug product containers, and closures
- Retesting of approved components, drug product containers, and closures
- Rejected components, drug product containers, and closures
- Drug product containers and closures

6. Subpart F: Production & Process Controls

- Written procedures; deviations
- Charge-in of component
- Calculation of yield
- Equipment identification
- Sampling and testing of in-process materials and drug products
- Time limitations on production
- Control of microbiological contamination
- Reprocessing

7. Subpart G: Packaging and Labeling Control

- Materials examination and usage criteria
- Labeling issuance
- Packaging and labeling operations
- Tamper-evident packaging requirements for over-the-counter (OTC) human drug products
- Drug product inspection
- Expiration dating

8. Subpart H: Holding and Distribution

- Warehousing procedures
- Distribution procedures

9. Subpart K: Returned & Salvaged Drug Products

- Returned drug products
- Drug product salvaging

10. Subparts I: Laboratory Controls

- General requirements
- Testing and release for distribution
- Stability testing
- Special testing requirements
- Reserve samples
- Laboratory animals

11. 21 CFR, Part 211 - Subparts J: Records & Reports

- General requirements
- Equipment cleaning and use log
- Component, drug product container, closure, and labeling records
- Master production and control records
- Batch production and control records
- Production record review
- Laboratory records
- Distribution records
- Complaint files

12. FDA's Risk Based Approach to cGMPs

- FDA development of inspection priorities
- FDA inspection approach
- Risk assessment tools
- Risk management

13. Contract Manufacturing

- FDA Guidance Contact Manufacturing of Drugs
- Who's Responsible
- Critical Activities

14. Quality Risk Management

- Principles of quality risk management
- Risk management process
- Methods and tools
- Potential applications

15. FDA's cGMP and Pre-Approval Inspection Program

- Compliance program objectives and strategy
- Inspection priorities
- FDA systems inspection approach
- Changes to FDA Pre-approval program

16. Process Validation: General Principles and Practices

- Process Validation and Drug Quality
- Approach to Process Validation

17. How to Manage an FDA Inspection

- Pre-preparation – SOP
- Employee training
- Site procedures

18. Data Mining FDA

- FOIA
- Dockets Management Branch
- FDA's Website