Good Manufacturing Practices and Recent Inspection Findings for Human OTC Drug Products
November 12 -13, 2018

Agenda

Day 1: Monday, November 12

10:00 – 10:10 am – Jen Ahearn
Introductions and Seminar Objectives
  ● Introduce Presenters
  ● Review Course Objectives

10:10 – 10:20 am – Jen Ahearn
Overview of Laws, Regulations and Monographs
  ● History of the Law
  ● GMP Regulations
  ● OTC Monographs

10:20 – 11:00 am – Jen Ahearn
Subpart B: Organization & Personnel/Q10
  ● Responsibilities of quality control unit
  ● Personnel qualifications
  ● Personnel responsibilities
  ● Consultants
  ● Q10 – Pharmaceutical Quality Systems

11:00 – 12:00 pm – Jen Ahearn
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
12:00 - 1:00 pm
Lunch

1:00 – 1:15 pm – Dan Spankie
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

1:15 – 2:00 pm – Dan Spankie
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

2:00 – 2:15 pm – Jen Ahearn
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

2:15 – 2:30 pm – Jen Ahearn
Subpart H: Holding and Distribution
- Warehousing procedures
- Distribution procedures

2:30 – 2:45 pm – Jen Ahearn
Subpart K: Returned & Salvaged Drug Products
- Returned drug products
- Drug product salvaging

2:45 – 3:00 pm
Break
3:00 – 3:45 pm – Dan Spankie  
Subparts I: Laboratory Controls  
- General requirements  
- Testing and release for distribution  
- Stability testing  
- Special testing requirements  
- Reserve samples  
- Laboratory animals

3:45 – 4:15 pm – Dan Spankie  
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

4:15 – 5:00 pm  
FDA’s Risk Based Approach to cGMPs

Day : Tuesday, November 13

8:30 – 10:30 am – Jen Ahearn  
FDA Inspection trends

10:30 – 12:30 pm – Dan Spankie  
Data Integrity: Current expectations and guidance, including data integrity and compliance with CGMP