CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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