Experience with FDA inspections of PET manufacturing sites

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- Topics to cover
  - Evolution of inspections
  - Recent areas of focus
  - Lessons learned
  - Recommendations for improvement
Evolution of inspections

• In the beginning – “Getting to know you”
  – Tours
  – Explanation of operation
  – Discussion of regulatory status
  – Looking for a QMS
Evolution of inspections

• Phase 2 – “Let’s take a closer look”
  – Deeper dive into records, processes, training
  – 211 perspective
  – Reconciliation of differences
  – Identification of “real” expectations
  – Most of this phase was when Part 212 was still in draft
Evolution of inspections

• Phase 3 – “No longer a mystery”
  – Districts making interpretations of requirements
  – Challenges to operating procedures
  – Observations going beyond system level
  – Focus on finer points
Evolution of inspections

- **Takeaways**
  - Legitimate observations from outside eyes
  - Gap between DC and districts
  - Aimed at where we thought the target was
  - Some targets clarified in process
    - GPT, for example
  - Painful trial and error process
  - Interestingly, some districts have not performed routine inspections
Recent areas of focus

- Microbiology
  - Growth promotion
  - Operator qualification procedures
  - Media for anaerobes
- Analytical testing
  - Operator calculations
  - Validated spreadsheets if used
  - Equipment validation and calibration
- NCRs and Deviations
  - Investigation write ups
  - RCA
  - CAPA
  - Impact analysis
Lessons learned

- It’s not all about documentation but a lot is!
- Certain inspection basics facilitate the process
  - MVP
  - Process map
  - Organized records
- Dedicate extra resources – future concern with PAIs
- Have Part 212 available and know it well
- Ask questions
- Follow your own procedures
- Learn the language and speak it
Recommendations

• Clarify PET guidelines and differences and similarities to 2004 guidelines for aseptic processing facilities
• Clearer guidance that districts and manufacturers can reference
• Industry participation in clarification of operating expectations
• Continued training and communication from Center to districts
Thank you!