

Experience with FDA inspections of PET manufacturing sites



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Experience with FDA inspections of PET manufacturing sites

- 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!

