FDA Inspection Prep and Execution

From a Site Perspective

Joe Wesling
Site Preparation and Inspection Performance
Site Prep

• Review Audit Findings, Regulatory Intelligence
• Gap Analysis
• Facility walkabout
• Employee meetings
• Out put – Hot Stories
• Identify Team and roles
• Site Resources
• Execution
Review 483 and warning letter trends. Know areas of focus

Inspector profiles
• Gap Analysis – QMS review by the process owner
Facility walk-through by management

- QMS focus
- Visual Controls
- 5-S
- Environmental controls
- Safety
Engage all employees

- Ideas
- Problems
- Quality Policy and Objectives
- Can the identify the management rep?
- Where are work instructions?
- Auditee Training
Prep-Risk Reduction

- Know your weaknesses
- Previous Audit Findings including near misses
- Develop Hot Stories – Identify SMEs (and backups).
Prep – Site Team

* Front Room Speaker, Back Room Manager, Scribes, SMEs, Runners
* IT and other support, Presenters, Tour Guide/Speakers
* BACKUPS!
* Lunch!
Performance
The Inspection

* No Mobile Phones
* No Social Media
* May need to work extended hours
* May need to work late to get info for the next day
* Develop Work Instruction for how to receive the Inspector.
* Check list at reception desk with names and phone numbers for who to contact (Backups)
* Physical Location Front Room – Close to the entrance
* Crash Cart
Engage top management

Presentation for opening meeting
  * Org Chart – Maintained
  * Clearly Communicate focus of the business
  * Clearly communicate the QMS
Plant tour
Planned route, SMEs at specified spots along the route
Write a script and stick to it
Practice monthly
* Front Room
* Back room
* IT, Wi-Fi, Printers, consumables,
* Hard Copies of Procedures
* Project Questions on Screen
* Question - Form
* White boards – New Questions, Assigned, QA, Front Room Ready
Mock Inspection
Performance
Receiving the Inspector(s)

- Reception – Notify Leadership
- Check credentials
- Form 482, Notification to Inspect
Performance
The Inspection

- Mobilize the team
- Front Room
- Back Room
- Scribes, escorts, runners, SMEs
- Chat from front to back by scribe
- Use of question boards
- Chat to all interested parties
Post Inspection

- 483s
- List of questions
- Notes
- Near misses
- OFI
- Op Mech for readiness
- Communicate to the team and extended team
Recap

* FDA History
* State of the QMS - Prep
* Team Resources
* Site Resources
* Inspection Performance
* Post Inspection
Contact

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