

# FDA Inspection Prep and Execution

From a Site Perspective  
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ASQ®

# Regulatory Inspection

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



# Prep-Risk Management

- \* Review 483 and warning letter trends. Know areas of focus
- \* Inspector profiles



# Prep-Risk Management

- Gap Analysis – QMS review by the process owner



# Prep-Risk Management

## Facility walk-through by management

- QMS focus
- Visual Controls
- 5-S
- Environmental controls
- Safety



# Prep-Risk Management

## 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

# Prep

- \* 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



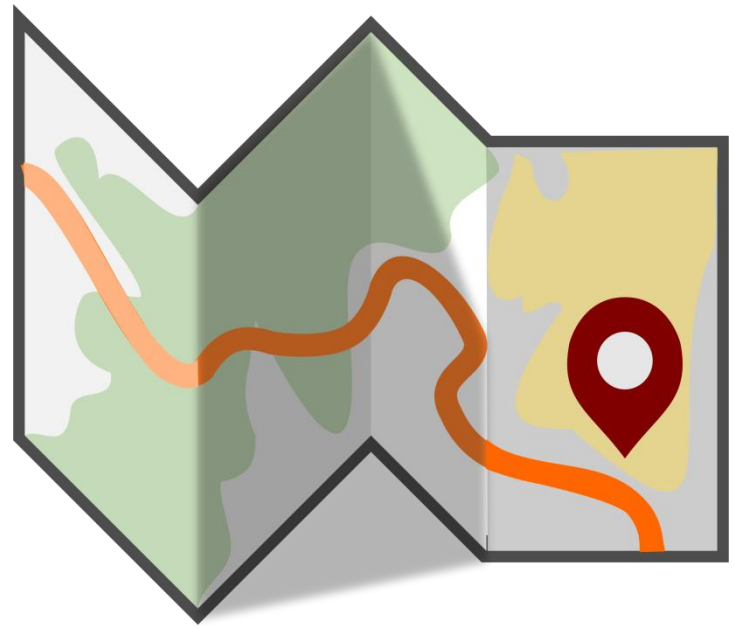
# Prep

- \* Engage top management
- \* Presentation for opening meeting
  - \* Org Chart – Maintained
  - \* Clearly Communicate focus of the business
  - \* Clearly communicate the QMS



# Prep

- \* Plant tour
- \* Planned route, SMEs at specified spots along the route
- \* Write a script and stick to it
- \* **Practice monthly**



# Prep

- \* 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



# Prep

- \* 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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