PREPARING FOR A REGULATORY INSPECTION

PREPARING FOR AN FDA INSPECTION

- Is your organization prepared for an FDA inspection?
- Does your organization have a culture of compliance?
- Does your organization practice and prepare for FDA and other regulatory inspections?
- Does your organization have a Standard Operating Procedure (SOP) governing how to handle and manage regulatory inspections?
- Do site personnel who are likely to interact with the FDA receive detail training and instructions?

FDA INSPECTORS ARE:

- Well trained
- Skilled at asking leading questions
- Observant (they don't see everything but don't miss much)
- Maybe an expert in the products your plant manufactures
- Has a virtually unlimited resource pool
- Has read your plant's previous FDA inspection file
- Looks to verify whether deficiencies noted in previous inspections are in place and being followed

INSPECTION PREPAREDNESS

- Does your site have a Site Inspection Management Team to handle all regulatory inspections?
- The Site Inspection Management Team should be comprised of individuals from different areas of the facility (cross functional).
- The roles and responsibilities for each individual should be documented.
- Individuals should be trained and roles rehearsed regularly.
- Does your plant have a documented internal audit program?

CONDUCTING MOCK INSPECTIONS

- Essential to use a war room or coordination room to manage the inspection process
- The war room coordinator should be familiar with all aspects of the site, is organized, and is good at documenting request for information, data, procedures, documents and other items.
- Must maintain an accurate log of the items requested
- Must ensure documents are accurate and current (SSOPs, Procedures, logs, check sheets)
- Maintain a state of calm and order

CONFERENCE ROOM SELECTION

- Conference Room FDA Inspectors use should be off the beaten path
- Conference Room FDA Inspectors use should not have open files and documents
- Conference Room FDA Inspectors use should be comfortable
- Conference Room FDA Inspectors use should not be adjacent or close to the War Room
- Conference Room FDA Inspectors use should be clean and 5Sed.

- Site Inspection Leader communicates with HQ and Legal
- Audit Control Room (War Room) Leader—Manages flow of traffic and documents
- Subject Matter Experts
- Scribes (note takers)
- Escorts
- Document Request Coordinator
- Document Runners
- Administrative Personnel
- Conference room for FDA use inspected and ready

SUBJECT MATTER EXPERTS

- Subject Matter Experts should be identified and selected based on their ability to completely and clearly answer questions from the inspector.
- SMEs must answer questions concisely and accurately. Only answer the question asked.
- Do not provide information not requested.
- Must perform well under stressful situations
- Must not complain about state of equipment or training of personnel.
- Be confident and professional when interacting with the inspector
- Refer to SOPs and written procedures when answering questions

DAILY INSPECTION CLOSE-OUT AND NEXT DAY PREPARATION

- Request daily close out meeting each day
- Ask for any potential concerns the investigator may have to date
- Ask for items the investigator may want to discuss\review upon their return to faciliy
- Verify all documents and materials requested by the investigator have been provided
- Determine if documents remaining in the war room are needed
- Have SMEs review\prepare documents investigators have requested upon their return

CONCLUSION OF A FDA INSPECTION

- Should the investigator not offer a 483, don't ask for one
- Listen carefully to comments by the investigator
- If a 483 is issued, ask for clarification, do not argue the issue
- Respond to the Form 483 in writing within 15 days
- Compile a response that clearly addresses each observation with specific details
- Use an index to clearly identify the response to each observation
- Should the FDA accept your response, an Establishment Inspection Report (EIR) will be issued.

ESTABLISHMENT INSPECTION REPORT

- Should the FDA accept your response to the Form 483, an Establishment Inspection Report will be issued
- The Establishment Inspection Report is the official confirmation the firms response to the Form 483 is accepted.
  - What the inspectors looked at
  - Concerns or questions that might have not resulted in an observation
  - Discussions about any refusals a firm might have received regarding providing information request by the inspectors
  - The EIR should be filed with the Form 483 and should be reviewed as part of the inspection readiness program