Regulatory Inspection Do’s and Dont’s

Pre-inspection Do’s:
- Have a Company Inspection Manual
- Have a trained Company Inspection Team
- Identify what FDA (or the state) may inspect
- Be familiar with relevant sections of FDA’s Investigations Operations Manual.
  Company Inspection Manual should include policies on:
  - Photographs
  - FDA record review
  - Complaint file review
  - Providing shipping records
  - Procedures boundaries (areas and interviews of employees)
  - Being accompanied
- Conduct mock inspections periodically
- Review prior inspection reports and check status of any promised corrective action

During the Inspection Do’s:
- Notify Inspection Team
- Review credentials and make a copy
- Review FDA 482 - Notice of Inspection
- Review any FDA 482C presented -- Request for Records
- Hold opening conference to determine purpose and scope
- Present inspection policies, including facility safety procedures
- Be courteous, professional and firm
- Accompany inspector(s) at all times
- Inspection should be consistent with the stated scope
- Protect trade secrets
- Designated company spokesperson(s) must provide answers “I don’t know” is acceptable, if accurate
- If you are uncertain whether to provide certain requested records or other information, inform the inspector that you need time to get guidance
- Use company “reporter” to take notes during the inspection
- Collect duplicate samples/swabs/records, but generally do not test products or environmental samples before getting FDA results and evaluating

During the Inspection Dont’s
- Keep inspectors waiting
- Sign any documents
- Volunteer information
- Be untruthful or deceptive
- Be intimidated
- Admit any wrongdoing
- Allow inspector to go anywhere unaccompanied

Excerpted from the PMA Food Regulatory Inspection Manual
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