

# Do's and Don'ts for FDA Inspections: Analysis from Former FDA Investigators

## **A Panel Discussion:**

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# Discussion Overview

- FDA Authority, Restrictions, and Expectations
- Companies - Rights and Obligations
- Inspectional Do's and Don'ts
  - On-site Inspections
  - Remote FDA Interactions and Record Requests
- Concluding Advice
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# FDA Authority, Restrictions, and Expectations

- FDA's Inspectional Authority derives from Section 704 of the Federal Food, Drug & Cosmetic Act.
- Inspections must be conducted with reasonableness: reasonable time, reasonable limits, reasonable manner.
- FDA is restricted from accessing financial data, sales data (other than shipment data), pricing data, personnel data (other than data as to qualification of technical and professional personnel performing regulated functions), and certain research data.
- Inspections reasonably include interviews of company personnel who have direct knowledge of operations, records, investigations, or other pertinent information.
- By policy, FDA chooses not to (routinely) request internal audits, supplier audits, or management review minutes.
- For drug manufacturing inspections, FDA may ask for records in advance of or in lieu of an inspection.
- FDA Guidance, Oct 2014: "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection".
- FDA maintains the right to take photographs during inspections.
- FDA expects truthfulness, responsiveness (substantive and timely), and access to information and facilities.

# Companies - Rights and Obligations

- **Inspected companies have a right:**
  - to inspections that are reasonable
  - to understand the areas of concern
  - to ensure pertinent facts are provided and understood
  - to professionalism
- **Inspected companies have an obligation:**
  - to perform regulated activities in accordance with relevant legal and regulatory requirements
  - to submit to FDA Inspection
  - to provide truthful, accurate, and reliable information to FDA and its representatives

# Inspectional Do's and Don'ts

# On-site Inspections

## The Do's

- Establish and follow an inspection hosting procedure .
- Prepare and maintain a site overview slide deck.
- Promptly respond to information/record requests the first time they are asked.
- Ensure the “Back Room” operates like a swiss watch with a strong leader.
- Staff the “Front Room” with the appropriate key personnel who have the expertise and personality to shine. The Principal Liaison, Scribe, and ‘runners’ are critical positions.

## The Don'ts

- Don't try to “wing it” - the downside risk is too great.
- Don't resurrect an outdated deck or a deck used for other purposes.
- Don't wait for the record to be requested a second time before providing it.
- Don't diminish the role of the Back Room. It is key in facilitating the inspection.
- Don't pick front room personnel based on title alone. The right personality is needed to foster a productive and trusted interaction. Adjust if needed during the inspection.

# On-site Inspections

## The Do's

- Maintain prompt, effective communication between the Front Room and Back Room.
- Use properly qualified Subject Matter Experts (SMEs) appropriately. Assure they are factually knowledgeable and can remain professional under scrutiny.
- Ask questions of the FDA inspection team as needed to fully understand the question, issue, or concern.
- Maintain an accurate record of questions, answers, concerns raised, positive observations, and records provided.
- Be honest, always and without exception.

## The Don'ts

- Don't assume a chat room alone constitutes effective communication.
- Don't over-use or under-use SMEs. As with others in the front room, the right personality is needed to foster a productive and trusted interaction.
- Don't let misunderstandings persist and don't be afraid to ask clarifying questions or to provide additional, unsolicited information.
- Don't rely on a full chat room transcript or certainly not on peoples' memories for your record.
- Don't provide anything but truthful, accurate and complete information.

# On-site Inspections

## The Do's

- Train employees so they know what to expect, how to behave, and how to answer questions effectively.
- Conduct mock inspections, debrief, learn from mistakes, and re-do if time and resources permit.

## The Don'ts

- Offer anything of substantial value to FDA personnel (coffee, tea, water are fine).
- Complain about the government, taxes, or the FDA.
- Ask personal questions of FDA personnel (politics, religion, family, finances).
- Refuse a lawful request from FDA; if challenged, state that you are not refusing but need to confer with upper management or legal counsel before proceeding.



# Remote FDA Interactions and Record Requests

## The Additional Do's

- Ensure your proposed meeting platform and file sharing site are agreeable to FDA and function properly beforehand.
- Establish technological capabilities to host a remote evaluation, including a remote facility evaluation.
- Respond to all documentation requests or email questions completely, promptly, and formally.
- Prepare for interviews of remote workers and ensure professionalism outside of the office environment.

## The Additional Don'ts

- Don't wait to agree upon and test application functionality until the interaction begins.
- Don't stumble through a video facility evaluation or learn you don't have a signal during the inspection.
- Don't treat certain requests (e.g. email question) less formally because they are submitted less formally than an onsite inspection.
- Don't forget that your cameras and microphones may be on.

# Concluding Advice

- Treat an on-site inspection, remote FDA interaction, or record request as the important Business Activity that it is and manage it accordingly.
- Practice – conduct mock inspections of the overall process, including: reception, introductions, site overview presentation, roles of top officials, roles of key inspection management officials, communication system, technological capabilities.
- Recognize your own areas of potential concern (e.g. identifiable through complaints, field alerts, recalls, OOSs, non-conformances, trends, etc.) and be prepared to discuss actions that were undertaken to address such issues.
- Emphasize the need for effective communication within the company and between the company officials and the inspection team; knowledge and understanding supports inspection efficiency.
- Be proud and confident in your operations and of the safety, efficacy and quality of the products you make. Be “Inspection Ready” every day.