The 10 Best – and 10 Worst – Things to Do When FDA Staff Are On Site to Conduct an Inspection

A Panel Discussion:

Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding LLP

Susan Schniepp, Fellow, Regulatory Compliance Associates, Inc.

John McKay, CEO and Chief Compliance Officer, Q1 Associates LLC

David Elder, Executive Vice President, Greenleaf Health, Inc.

Discussion Overview

- FDA Authority, Restrictions and Expectations
- Companies Rights and Obligations
- Do’s and Don’ts
  - 10 Best
  - 10 Worst
- Concluding Advice
- Questions & Answers

FDA Authority, Restrictions and Expectations

- FDA Inspection Authority comes from Section 704 of the Food, Drug & Cosmetic Act
- FDA's inspections must be conducted with reasonableness: reasonable time, reasonable limits, reasonable manner
- FDA is restricted from accessing financial, sales, pricing, personnel, or 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.
- 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), 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

Do’s and Don’ts

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BEST – The Do's

1. Establish and follow a procedure for hosting inspections and follow your procedure in all material respects
2. Prepare and maintain a site overview slide deck that can be accessed immediately and that covers key products, operations, and people
3. Promptly respond to information/record requests the first time they are asked.

WORST – The Don'ts

1. Don't think you can "wing it" - the downside risk is too great
2. Don't resurrect an outdated deck or a deck used for other purposes (e.g. marketing, internal reviews). This is one of few opportunities during an inspection to be proactive
3. Don't delay in providing records; don't wait for the record to be asked for a second time before providing it.

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BEST – The Do's

4. Ensure the "Back Room" operates like a swiss watch. The Back Room leader is a critical position
5. 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

WORST – The Don'ts

4. Don't diminish the role of the Back Room. For the front room to run smoothly, the backroom may be paddling frantically to keep things moving.
5. 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.

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BEST – The Do's

6. Assure prompt, effective communication between the Front Room and Back Room. Monitor this throughout the inspection.
7. Use Subject Matter Experts (SME) appropriately and be sure any SME is trained and qualified to participate in the inspection

WORST – The Don'ts

6. Don't assume a chat room alone constitutes effective communication.
7. 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. Adjust if needed during the inspection.

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BEST – The Do's

8. Ask questions of the FDA inspection team as needed to fully understand the issue and the concern
9. Maintain an accurate record of questions asked, answers provided, concerns raised, positive observations, and records provided
10. Be honest, always and without exception

WORST – The Don'ts

8. Don't let misunderstandings persist and don't be afraid to ask clarifying questions or to provide additional, unsolicited information, if needed to correct a misunderstanding
9. Don't rely on a full chat room transcript or certainly not on peoples' memories for your record. Summarize key questions and answers, take note of anything positive, and maintain a full list of records and date reviewed (in hard copy or reviewed online)
10. Don't provide anything but truthful, accurate and complete information

Concluding Advice

- Treat the inspection 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
- Recognize areas of potential concern (e.g. identifiable through complaints, field alerts, recalls, data trending) and be prepared to discuss actions 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 “Inspection Ready” every day

Q & A

Potential Q & A Discussion Topics

- What should a company do if an FDA investigator is acting in an unreasonable manner?
- If an investigator identifies a concern in my manufacturing area and pulls out her phone to take a picture, how can I best stop her from taking the picture?
- My inspection has been ongoing for two weeks with no end in sight. How can I best get the inspection concluded?
- The FDA investigator asked for all of my complaints, deviations, and non-conformances on a flash drive. Seems like a fishing expedition – do I have to provide this?
- We had identified issues and were taking actions prior to the start of the inspection but the FDA investigator is indicating he will put the issues themselves on the FDA-483. This doesn't seem fair. What can we do?

Potential Q & A Discussion Topics

- The FDA investigator asked me to sign an affidavit. Should I be concerned?
- The FDA investigator is asking my employees questions. I want all questions directed to me as the head of QA. How best can I get the questions redirected to me?
- The FDA investigators have complained that it's taking too long to get requested records and information. How quickly do I need to provide information?
- One of my employees just answered a question in a way that I know is incorrect. Do I need to correct the answer or let it go?
- I observed a conflict between our front room lead and the FDA investigator – seems to be a lack of trust and increase in tension – is there anything I should do about it or do we just have to live with it and get through the inspection?