COMPOUNDING PHARMACY OWNER SUMMIT

# On the Business End of an FDA Inspection: A Case Study

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# Inspection Readiness: The Basics

## At some point, FDA will be in your facility

- Routine risk-based inspection
- In response to a complaint
- In response to a recall
- To follow up on a previous inspection

# Inspection Readiness: The Basics

## Basic actions you can take to be prepared:

- **Refamiliarize yourself with FDA's Insanitary Conditions Guidance.**
- **Be conscious that FDA inspectors will take a very broad interpretation of the conditions listed in the Guidance:**
  - The term "adjacent areas" essentially means anywhere in your facility where materials are stored.
  - In nonsterile compounding areas "foreign matter in the production area" includes dust buildup in the cracks of switch plates, floor seams/thresholds, etc., and dust buildup on the filters of powder containment hoods.
  - In sterile compounding areas, any exposed skin, moving "too quickly", "inadequate" smoke study videos, etc. are all interpreted as insanitary conditions.

# Inspection Readiness: The Basics

## Basic actions you can take to be prepared (continued):

- **Perform routine walk-throughs of your facility to identify any areas of opportunity.**
- **Review key policies and procedures:**
  - Cleaning procedures
  - Pest control system
  - ADR/Complaint processes
  - Smoke studies
  - FDA inspection SOP

# During the Inspection

## Signs the FDA inspectors are primarily focused on insanitary conditions:

- **Are they starting their inspection looking at critical processes, such as sterile compounding, or are they starting in areas likely to be the least clean?**
  - Storage areas
  - Powder containment hoods
  - Dumpster
- **Are they taking photos of these areas?**
- **Are they verbally providing you feedback/observations that could fall into the conditions listed in the Insanitary Conditions Guidance?**
- **Are they spending little time focused on basic compliance with 503A and/or USP?**

# Inspection Close Out

**At the inspection close out be mindful of what the observations are on the 483 and what the inspectors are telling you.**

- **Ask the inspector if they observed anything that would indicate a lack of compliance with 503A or USP requirements.**
- **Compare the 483 observations to the Insanitary Conditions Guidance.**
- **If your 483 contains any observations that align in any way with the conditions listed in FDA's Insanitary Conditions Guidance, prepare for further FDA action.**

# Possible FDA Actions

## Possible FDA actions if there are observations related to insanitary conditions on your 483:

- The timing varies, but typically either during or sometime after issuance of a 483 with insanitary conditions observations, FDA will notify you of their recommendation to conduct a recall.
- FDA is not required to provide you with the specific rationale or health hazard assessment they used to determine the necessity or scope of their recommended recall.
- Once notified of FDA's recommendation to initiate a recall, you will typically have 24 hours to respond back as to whether or not you will comply with their recommendation.
- FDA will most likely not grant any requests to extend this 24-hour window or requests to engage in any further discussions regarding the basis for their decision.
- If you do not agree to initiating the recall FDA suggests, FDA will issue its own public announcement warning the public of the dangers associated with using compounded medication from your facility.

# How to Position Your Business to be Prepared for FDA Action

## Have a pre-planned "what if" strategy for defending your business in the event FDA determines you need to conduct a recall.

- Outside consultants/experts to perform health hazard assessments of your facility and compounded preparations to have scientific evidence in your defense.
- Public relations/communication plan to help manage or control reputational impact.
- FDA consultant to provide you with insight and forecast FDA's next move
- Attorneys to plan and execute a legal strategy.

# How to Position Your Business to be Prepared for FDA Action

## Take immediate steps to get out in front of possible FDA action.

- Aggressively address the observations in the 483 and communicate those actions to FDA.
- Begin implementing your “what if” strategy.
- Determine under what scenarios you would agree to an FDA “recommended” recall and under what scenarios you would not.
- Ready the processes and resources you would need to conduct a recall.

# How to Position Your Business to be Prepared for FDA Action

## Be prepared to react to FDA's recommended recall within a 24-hour period.

- Determine the impact on your business of complying with FDA's request and decide if you will be initiating the recall as recommended.
- If the decision is not to comply with FDA's request, execute on pre-planned actions like filing legal complaints, issuing press release/customer communications, etc.
- If the decision is to comply with FDA's request, immediately begin the process of initiating the recall.

# Questions?

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