Managing an FDA Pre-Approval Inspection (PAI)

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Agenda

- Introduction
- What to Expect
- Managing the Audit Room
- Managing the Staging Room
- Managing Area Tours
- Interacting Effectively and Appropriately with the FDA: Do’s and Don’ts

Introduction

The purpose of a pre-approval inspection (PAI) is to ensure that your facility is in compliance with FDA rules and regulations.

Inspectors want to know that product development was done appropriately and the current good manufacturing practices (cGMP) are up to FDA standards.

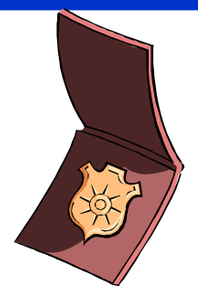
Introduction

One of the primary goals is to **MANAGE** the inspection from start to finish by:

- Understanding the FDA's expectations
- Preparing your site
- Generating documented evidence of compliance with FDA regulations
- Managing the inspection
- Interacting appropriately with FDA inspectors

What to Expect

- Inspectors will show up at front desk/lobby
  - Receptionist verifies inspectors credentials and obtains Form 482, *Notice of Inspection*, from inspectors
  - Receptionist contacts appropriate personnel (Compliance, Quality, etc) of arrival



What to Expect

- Notification of arrival will be communicated to management and appropriate individuals

- Escort (inspection coordinator) greets inspectors and brings them to the Audit Room

Managing the Audit Room

- Inform the inspector to direct all questions to the Escort
  - Escort should…
    - Be trained and experienced in…
      - FDA inspections,
      - company quality systems,
      - product being inspected,
      - compliance issues that may already be known
    - Be familiar with company inspection policy
    - Accompany the inspector at all times
    - Request support from Subject Matter Experts (SME)
    - Provide support to interviewees (SME)

Managing the Audit Room

- Inspectors will request to speak to the individuals responsible for making decisions
  - Subject Matter Experts (SME) should…
    - Be knowledgeable in product being inspected
    - Answer only questions being asked
    - Request support from Escort or additional SME's as needed

Managing the Audit Room

- Maintain notes of all discussions that take place in the audit room (scribe notes)
  - Scribe should…
    - Be able to keep detailed notes (typed or handwritten)
    - Keep staging room informed of all inspector requests
      - May have a separate person (Runner) performing this task
    - Maintain a list of everything viewed or taken by inspector
      - Samples, copies of documents, and copies of records taken by inspector
    - Remain QUIET!!!

Managing the Staging Room

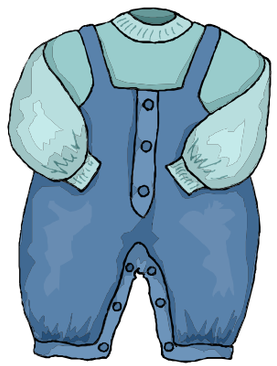
- Pre-stage documents that FDA will likely want to see
  - Records of products for inspection
  - Quality System documents (Management Controls, CAPA, Complaints, Design Controls, etc)
- Ensure timely fulfillment of inspector requests

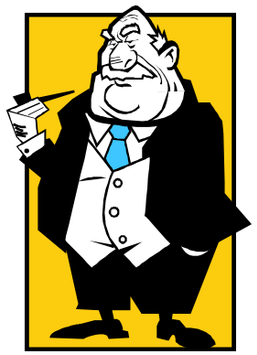
Managing the Staging Room

- Keep reference copies of all documentation and records requested by the inspector
- Keep records of all requests, if possible keep tabs on when the request took place (day/time)
- Contact Subject Matter Experts to be interviewed by inspector

Managing an Area Tour

- Escort the inspector at all times during the inspection
  - Ensure proper gowning procedures are performed
- Ensure appropriate area management is available
  - Ensure area personnel are aware of potential tours to their area ahead of schedule





Managing an Area Tour

- Ensure areas are clean and presentable
  - Remove any obsolete or unnecessary procedures
  - Remove any extraneous or unnecessary postings
  - Empty trash cans
  - Clean work areas

Interacting with the FDA

- Your cooperation with FDA inspectors is vital to the success of your inspection. Maintain a good level of communication with the inspectors and make certain the conduct and manner of the inspection is reasonable.

- Proper training of all employees is key. Focus specialized training to Subject Matter Experts (SME's)

- Review Inspection Do's and Don'ts

Inspection Do’s

- Escort the inspector at all times
- Act in a courteous and professional manner
- Require that all requests from the inspector go through your inspection team
- Answer inspectors questions honestly and directly

Inspection Do’s

- Provide documents in an accurate and timely manner
- Handle document requests with care
- Limit the inspector’s access to the records, facilities and materials that are subject to inspection

Inspection Do’s

- Attempt to clarify or correct misunderstandings or assumptions
- Ask for explanations or interpretations of what you do not understand, even sections of the regulations
- Try to encourage FDA inspectors to discuss their observations at the actual time they are observed

Inspection Don’ts

- Leave inspectors alone while they are in your plant
- Volunteer information. You want to provide full and complete answers, but you don’t have to go beyond that point.
- Guess
- Provide any misinformation

Inspection Don’ts

- Tell inspectors that records are unavailable. You can say that you cannot locate the record
- Tell inspectors they are being unreasonable (even when they are)
- Ask questions such as, “Where does it say we have to do that?” Their response will likely be “Where does it say that you don’t?”

Inspection Don’ts

- Attempt to answer “What if?” questions or hypothetical questions
- Engage in arguments with inspectors and engage in arguments with peers in the presence of inspectors
- Admit to an inspectional finding or corrective action. Let management do that later

Inspection Don’ts

- Allow FDA inspectors to go through your files on their own. Ask them what they want and provide it for them.
- Refuse appropriate requests from inspectors, but try to narrow the scope of the request when possible
- Sign any statements or affidavits

Conclusion

- Be prepared to MANAGE the inspection
  - Establish roles and responsibilities before the inspection
  - Have the necessary resources to accommodate the number of inspectors

References

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  - FDA Compliance Program Guidance Manual (CPGM) 7346.832, Chapter 46 – New Drug Evaluation
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