



FDA Infusion Center Inspections

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This document is designed to assist pharmacists practicing within infusion centers prepare for an FDA Inspection. It begins with tips on how to prepare the visit, followed by a sample inspection template. An example visit is included as a reference at the end.

FDA Inspection Visit: Preparation Checklist

Before the Visit

- Write policies and procedures to address a visit
- Perform routine internal audits to find and correct problems
- Implement corrective and preventive actions
- Train each employee on his or her potential role in an inspection
- Prepare the facility
 - Remove clutter
 - Ensure all calibrations are up to date
 - Ensure all competencies are up to date

EMPHASIZE TO EVERYONE TO ANSWER ONLY THE QUESTIONS THAT ARE ASKED

During the Visit

- Provide honest answers
- Provide the documents requested by the inspector and make copies of all documents requested
- Only answer the questions that are in your expertise. Defer other questions to those who have expertise in that area
- Request a summary of each day's findings
- Be prepared to answer the following
 - Is the air in the negative pressure room vented to the outside?
 - What is the ISO classification of each room in the Clean Room Complex?
 - Are your gowns sterile or non-sterile? Do you use sterile sleeves?
 - Are the sterile 70% isopropyl alcohol bottles refilled?
 - Are the penicillins compounded in a dedicated area?
 - How often are you changing your sterile gloves?
 - How often are the hoods cleaned?
 - What agents are used to clean the hoods?
 - What is the spectrum of effectiveness of the cleaning agents?
 - Who inspects the pre-filters in the hoods? How often? When was the last Inspection?
 - When was your last smoke study? How often is one done?
 - Who reviewed the smoke study?
 - What is the maximum number of people allowed to mix at one time in each hood?
 - What are the pressures between the rooms?
 - Do you move carts from the pharmacy into the clean room complex?
 - How often do you clean the wheels on the carts in the clean room?
 - How often do you sanitize the bins that go into the clean room?
 - How often do you do surface sampling? How do you pick the sites?



What is your cleaning procedure for the hood? What products are you using?

Are you using dedicated scrubs and shoes?

Describe the gowning procedure.

Are you filtering add pools with a 0.22 micron filter?

Where are compounds labeled?

Describe the final check of compounded product.

Who does your hood/room certification? Are they CETA certified?

How do you monitor temperatures and humidity?

What is your emergency plan if your HVAC system fails?

What is your emergency plan if your refrigerator fails?

What is your emergency plan if your power fails?

If you have a generator, how do you test it?

How are media fill tests conducted?

Do you have a control for the media fill tests?

Where are your policies and procedures?

Who has access to the policies and procedures?

Where are your compounding records?

What % of your products are shipped out of state?

What products are compounded in syringes?

Have you have any positive results from environmental monitoring? Was it air or surface sampling?

How was this handled?

Do you perform end product sampling? Have you had any positive samples? How was this handled?

After the Visit

If you receive a 483, put together an action plan to determine the causes and make corrections.

Be sure to respond to your plan to correct nonconformities/quality issues in a timely and effective manner (You have 15 days to respond but you can submit updates at any time.)

Do a systematic review of your Quality System to find quality problems that are related to the inspector's findings.

Reply with supporting documentation that demonstrates the corrections you have implemented.



FDA Inspection: Visit Template

Policy Name: FDA Inspections

Date:

Review Date:

Approved by:

SCOPE

This Policy and Procedure applies to all employees, representatives and agents of (company name)

PURPOSE

The purpose of this policy is to provide guidelines for all (company) employees during an FDA Inspection

POLICY

1. (Company) employees shall immediately notify management when the FDA arrives at the facility.
2. FDA Inspectors will provide (Company) with identification as FDA employees.
3. (Company) employees will notify legal counsel when the FDA arrives.
4. FDA Inspectors will sign the visitor log on arrival and departure.
5. The Pharmacy Manager will act as the contact for the FDA inspectors.
6. Prior to providing any records, verify that the inspectors have paperwork for the inspection.
7. If a member of the State Board of Pharmacy accompanies the FDA, clarify their role and confirm their credentials.
8. All employees are to be respectful and cooperative.
9. During the first phase of the inspection the pharmacy manager should accompany the inspectors while they observe operations and determine if the operation is a 503A or 503B facility.
10. Phase 2 addresses the Nature of the operation: Documentation, product volume of compounds/day, market share, all states where the pharmacy is licensed, possible restrictions on compounding, types of products compounded, a review of complaints and all recalls and how they are handles. The Pharmacy Manager will designate the appropriate employee to work with the inspectors for each of these items.
11. Phase 3 addresses the sterile compounding process. They will probably ask for a sample of at least one compounded product to submit for independent sterility testing. They will want to know how BUD's are



decided and will verify that staff know the difference between sterility and stability. Ensure that all employees involved in the process understand all the requirements of USP <797>.

12. Phase 4 will address non-sterile to sterile compounding. If a branch is doing this type of compounding, it is imperative that all compounding staff be proficient in the proper procedures.
13. Notify all appropriate personnel when the closing conference is scheduled.
14. Once a 483 is received the branch staff will work with the appropriate personnel to respond. All 483 reports are posted on the FDA website and the response is the only way for the organizations to voice their responses.

FDA Inspection: Example Visit

Home Infusion Pharmacy – 503A Classification

Inspector was on-site for 4 days from 8:30am – 2pm and one more day for final observation and to administer the 483 to the location.

First, need to determine if the pharmacy is 503A or 503B

FDA Process includes the following steps:

- Phase 1 –
 - Phase 1a - observation, visual
 - Phase 1b – designate 503a vs 503b
- Phase 2 – Nature of Operation: Documentation, product volume of compounds/day, market share, all states pharmacy is licensed in, restrictions on compounding, what type of drug products are mixed at facility, review of complaints and all recalls (internal and manufacturer)
- Phase 3 – Sterile compounding – possibly take samples of mixed products; any container studies (will not be applicable for 503A); how is stability/sterility determined (we used our policy with BUD in USP 797);
- Phase 4 – Non-sterile to sterile compounding – possibly take samples of mixed products (Will not be applicable for 503A pharmacy)

On-Site Questions and Observations from Inspector:

1. How does the air from the chemo room get filtered? Does the air go outside or is it recycled?
2. Layout of the clean room- ante room, buffer room, compounding
 - a. ISO 5 versus ISO 7
3. What gowning materials are sterile vs non sterile
 - a. Lint free?
 - b. Non sterile gowns not meeting ISO 7 requirements
4. Are the sterile isopropyl alcohol 70% bottles refilled or purchased?
5. For penicillin/cephalosporin products, is there a dedicated area where they are prepared? What are the procedures? How do you avoid cross contamination?
6. How often do you change sterile gloves?
7. How many hoods are there?
8. How often are the hoods cleaned?
9. Who inspects the filters in the hoods? How often? When was the last inspection?

0. Cleaning? What is the procedure?
 - a. What is used?
 - b. Inspected the cleaning agents
 - c. Using SIPA only in ISO 5 designated area
 - d. Cleaning clothes- are they sterile?
1. Compounding techniques – watched techs for 3 hours.
0. Last smoke study? Passed?
 - a. How often is it done?
1. Maximum number of people in the compounding room?
2. How does the air return flow? Back and side walls?
3. Pressures different between these two areas in clean room/ante room?
0. Materials moved into ISO 7 must be sanitized
 - a. Have we tested carts, the stools?
 - b. How often are they cleaned?
 - c. Do we wipe the wheels on the carts?
1. Gloves- alcohol wiping is enough between ISO 7 and ISO 5? Have we done a study?
2. How do you monitor the hoods and the rooms?
3. Personnel monitoring between each batch?
4. Calculator/ phone in the clean room
 - a. Have there been tests?
5. What gets cleaned during monthly cleaning?
6. What are we using?
7. Does the agent have activity against Gram +?
8. Do we use a second set of gloves during compounding?
9. Do we use dedicated scrubs for clean room and shoes?
10. Where are the gowns, gloves etc. donned?
11. Spikes, are we filter with 0.2 filters? Using lyophilized products?
12. Compounding sheets and labeling within the clean room – is it done after compounding?
0. Do gloves touch the gown?
1. How are the refrigerators monitored?
 - a. Who has access?
 - b. What is the emergency plan?
 - c. Generator- how is it powered? How long does it work for? How long does it take to kick in?
2. Storage of gowns, masks, gloves outside of the clean room
3. Separate drugs- cep/pen vs other
 - a. Recovery studied to prove that there is no cross-contamination?
 - b. Per inspector - Alcohol cleaning isn't sufficient
4. Check of final compounded product
 - a. Inspector Checked 6 products
5. Process of final check?
 - a. Amount of time spent checking
 - b. Do you require eye exams for RPh that check?
 - c. How do you qualify checking RPhs?
 - i. Challenge sets?
 - ii. Awareness training?
6. How many orders per day are made?

- a. Provide past 90 days of drug orders
7. Review HEPA filters
 - a. If a leak was found, can it be repaired?
 - b. What is the procedure?
 - c. Do you have the company information? What are their qualifications and limits?
8. Smoke testing- video – Inspector looked and reviewed all smoke test videos.
 - a. What does certifier use to test?
9. Sterile products
 - a. How many variations of empty containers do you have?
 - b. Does the manufacturer state or certificate they are sterile? Is it stated on the receipt?
10. Review environmental monitoring and personnel information
 - a. 2 years of data
 - b. Reviewed Procedures
11. How are media fill tests conducted? How are the medias bought?
 - a. Who tests them? What are the limits?
12. Documentation asked for
 - a. Past 3 months of dispense list / list of drugs that are stocked
 - b. Production logs
 - c. Forms to document cleaning, media fills and related policies
 - d. Videos of smoke test
 - e. Garbing policy
13. Does the dynamic air roll off the person compounding and go back into hood?
14. Phone in TPN room
 - a. There are special cleanroom phones?
15. How are the manual TPN adds compounded? What happens in the little compounding space in the TPN hood?
16. Review of 3 months of prescription records. Every prescription that has been dispensed, needed to provide a report.
17. Review of complaint record/log for 2 years previous.
18. Review of all policies and procedures to do with pharmacy and sterile compounding.
19. Looked for bulk syringes vs. sterile syringes individually wrapped
20. Cleaning agents used in clean room areas – wanted activity for each agent and specification sheet for each one.
21. Company Overview requested
22. Top 5 medication compounding sheets requested
23. Reviewed and took a copy of 1 month of pressure readings for all rooms in clean room.
24. Any clean room growth found in reports – wanted explanation of how it was handled and why it was handled that way
25. What % of products shipped into state from out of state
26. What drugs are compounded in syringes, brand of syringe and example in original package was provided. Additional materials requested by inspector after he left the location:
27. Beta Lactam and Penicillin compounding examples from same day with another compound
28. Purchase order for non-sterile gowns, masks, booties, head covers and photos of item packages
29. Policy on reconstitution – agitation
30. Environmental Monitoring records from last 6 months with action levels and recovery
31. Labeling and Purchasing information on wipes to clean ISO 5 Area



32. Inspector took with him – jump drive with 7 days of patient prescriptions (FDA originally asked for 90 days and inspector convinced them 7 was adequate)

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