FDA Inspection: During the Inspection Tip Sheet

FDA: “We are here!”
You: “Now what do I do?”

1. Accompany the FDA inspector to the reserved conference room that will be utilized for the duration of the audit. The PI and lead representative (i.e., coordinator) must be present for the opening meeting which will include presenting credentials, discussing the process, and issuing a FDA 482 to the PI. In the event the PI is unable to attend, their supervisor or chair should be available to receive the 482.

2. After the opening meeting, the inspector will begin reviewing the study documentation and other requested documentation as it is provided to them. Any requested documentation should take no longer than 2 hour to be provided. For any institutional documentation needed, the OVPRI FDA program will assist in providing these to the study team.

3. The lead representative for the site will act as the liaison for the FDA. The lead representative will take notes, provide documentation and copies, arrange facility tours and meetings with those requested by the inspector.

   Please note, IDS pharmacy does allow the FDA to tour the pharmacy.

4. At the end of each day, the inspector will discuss observations and any additional items they made need for the next day. The lead representative and PI should be present and provide a summary of requested items and discussions with the inspector to the FDA program.

5. The FDA inspector will conduct a close out meeting at the end of the inspection with the PI and lead representative. The inspector will review overall findings and will notify the site **IF** they are issuing an FDA 483 and what classification they are recommending the inspection be given.

Additional information about how to prepare for an inspection, what to expect during and after the inspection can be found in the FDA program’s manual.

Additional questions? Contact us at indide@vcu.edu. We are here to help!

Version 1 dated 03/172025