FDA Inspection: After the Inspection Tip Sheet

FDA: "We are leaving."
You: "Now what do I do?"

1. Notify the IRB of record and the sponsor (if applicable) that the inspection has ended and provide a copy of the FDA 483 (if issued) and the inspection report once available (if requested). Provide a copy of the 483 and inspection report (when received) to the FDA program.

2. **If an FDA 483 is not issued,** the observations made by the inspector should still be reviewed to see what can be corrected and prevented for the future. The FDA program can help with identifying what can be corrected or to prevent something from being repeated.

3. **If an FDA 483 is issued** the site should respond within 15 business days. The FDA program will assist in drafting responses and will review the final response letter prior to being submitted to the FDA. Responses to an FDA 483 can make the difference in determining whether the FDA issues a warning letter. Make sure to:

   - Cite the observation listed in the FDA 483
   - CAPA plan to address the observation, and if already corrected
   - If the CAPA is not immediate, a timeline for the correction and implementation of preventive action

   Please note, responses to an FDA warning letter are ***mandatory*** and should follow the same format as the above.

4. It is important to review these observations and implement potential CAPAs across other studies or department processes that may have the same observations seen.

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!

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