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Alert | Health Care & FDA Practice

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FDA Draft Guidance for Bioresearch Monitoring Program Contains General Best Practices for FDA Inspections

Go-To Guide:

- Prior to an inspection, FDA may inform establishment staff of which documents must be made available for viewing and/or copying while FDA is on site.
- If establishment staff orally respond to FDA's observations during the inspection, FDA may include those responses in its inspection report.
- Providing a thorough and timely written response to a Form FDA 483 can help minimize subsequent enforcement risks.

On June 4, 2024, the U.S. Food and Drug Administration released draft guidance titled *Processes and Practices Applicable to Bioresearch Monitoring Inspections* (Draft Guidance) that describes FDA's approach to conducting inspections of sites and facilities engaging in bioresearch activities subject to FDA regulation under its Bioresearch Monitoring (BIMO) program. While some of FDA's recommendations in the Draft Guidance are specific to the BIMO program, much of the commentary on how to prepare for and what to expect before, during, and after a BIMO inspection is broadly applicable to nearly all types of FDA inspections.

Types of FDA Inspections

FDA's BIMO program encompasses several programs for assessing and monitoring all aspects of the conduct and reporting of FDA-regulated research, plus certain post-marketing activities via on-site inspections, investigations, and Remote Regulatory Assessments. Regarding on-site inspections, FDA conducts such inspections, both in the United States and abroad, for a variety of different purposes, including the following:

- Inspections conducted to support FDA's review of an application (e.g., new drug application, biologics license application, 510(k) premarket submission, etc.) submitted by the sponsor;
- Periodic inspections of registered establishments with ongoing activities, such as nonclinical laboratories and institutional review boards; and
- Inspections conducted to evaluate potential noncompliance or safety issues identified in an adverse event report or other complaint.

Before FDA Inspections

Any FDA inspection of a registered establishment will be preceded by a "pre-announcement notice" via phone call. FDA's primary purpose in providing this notice is to communicate the general category of records that FDA will inspect to ensure the appropriate personnel will be present at the inspection and that any relevant records will be readily available for inspection, copying, or transfer upon request. This pre-inspection conversation with FDA can help internal teams prepare to interact with FDA during the inspection, ensure all areas of the facility that will be inspected are fully accessible to FDA staff, and proactively organize clinical study records (both electronic and paper) that may be inspected.

During FDA Inspections

During the inspections, FDA investigators will request records or other information that establishment staff must provide in a timely manner. Establishment staff may ask clarifying questions as necessary to better understand the nature, process, and timeline of requests for records or information. FDA investigators may also discuss their observations with establishment staff either as they are being observed during the inspection or at the end of the day. Establishment staff may proactively inquire about any observations FDA investigators make at the daily wrap-up meeting and document those discussions.

After FDA Inspections

At the conclusion of an inspection, the FDA investigator will discuss his or her findings with establishment staff and, depending on those findings, may issue a written Form FDA 483 to notify the establishment of any observations of "objectional conditions and practices." If the establishment staff decide to respond orally during the inspection closeout meeting, FDA notes that those responses may be incorporated into the inspection report. While FDA acknowledges that responding in writing to a Form FDA 483 is not required, the establishment should consider providing a thorough and timely written response, ideally within 15 business days, to minimize subsequent enforcement risks. According to the Draft Guidance, the written response should:

- Address each observation separately;
- Note whether the establishment agrees or disagrees with each observation and why;
- Provide both corrective and preventive actions and timelines for completion;

- Provide both completed and planned actions and related timelines;
- Provide a method of verifying or monitoring the effectiveness of the actions; and
- Submit documentation (e.g., training, Standard Operating Procedures (SOPs), corrective action plans, records).

Comments on the Draft Guidance must be submitted by Aug. 5, 2024.

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