Processes and Practices Applicable to Bioresearch Monitoring Inspections

Guidance for Industry

DRAFT GUIDANCE

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For questions or information regarding this guidance, contact the Office of Regulatory Affairs (ORA), Office of Policy, Compliance, and Enforcement (OPCE), Food and Drug Administration at ORAPolicyStaffs@fda.hhs.gov.

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June 2024

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Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

FDA is issuing this guidance to comply with section 3612(b)(2) of the Food and Drug Omnibus Reform Act of 2022 (FDORA), enacted as part of the Consolidated Appropriations Act, 2023.[2] FDORA directs FDA to issue guidance describing the processes and practices applicable to inspections of sites and facilities described in section 704(a)(5)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[3] to the extent not specified in existing publicly available FDA guides and manuals for such inspections. These establishments[4] are inspected under FDA's Bioresearch Monitoring (BIMO) program in accordance with section 704(a)(5) of the FD&C Act. Specifically, this guidance addresses the following (to the extent not publicly available in FDA guides and manuals): the types of records and information required to be provided, best practices for communication between FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct.[5]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only

[1] This guidance has been prepared by the Office of Regulatory Affairs (ORA) in cooperation with the Office of Clinical Policy (OCLiP), the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Food Safety and Applied Nutrition (CFSAN), the Center for Tobacco Products (CTP), the Center for Devices and Radiological Health (CDRH), and the Center for Veterinary Medicine (CVM) at the Food and Drug Administration.

[2] FDORA was enacted as title III of Division FF of Public Law No. 117-328 (2022).

[3] Section 704(a)(5) of the FD&C Act clarified FDA's authority with respect to bioresearch related inspections.

[4] In this guidance, the term "establishment" includes any entity, person, site, or facility, whether foreign or domestic, within the scope of section 704(a)(5)(C) of the FD&C Act.

[5] The following two guidances will be withdrawn upon finalization of this guidance (as their substance is superseded by this draft guidance and other guidances and related documents described in this draft guidance): "Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Inspections of Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-inspections-clinical-investigators, and "Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors: FDA Institutional Review Board Inspections," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-institutional-review-board-inspections.

as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

FDA's BIMO program is a comprehensive portfolio of programs designed to assess and monitor all aspects of the conduct and reporting of FDA-regulated research as well as certain postmarketing activities through on-site inspections, investigations,[6] and Remote Regulatory Assessments (RRAs). The BIMO program was established to assess the quality and integrity of data submitted to the Agency in support of regulatory decision-making, as well as to provide for protection of the rights, safety, and welfare of human trial participants[7] and animal subjects involved in FDA-regulated research.[8] The program assesses compliance with statutory requirements and FDA's regulations governing the conduct of nonclinical and clinical studies, and applicable postmarketing activities (e.g., in REMS and PADE).[9]

FDA is authorized at reasonable times to access, inspect, and copy records and other information as described in section 704(a) of the FD&C Act (21 U.S.C. 374(a)). The general authority for establishment inspections is found in section 704(a)(1) of the FD&C Act (21 U.S.C. 374(a)(1)). Section 704(a)(5) of the FD&C Act (21 U.S.C. 374(a)(5)), as added by FDORA, clarified[10] and detailed the Agency's authority for conducting BIMO inspections. Specifically, in clarifying the Agency's BIMO inspection authority, section 704(a)(5) includes, among other things, the following:

- the establishments subject to BIMO inspection, e.g., those used by sponsors in connection with developing an application or other submission to FDA for marketing authorization, or those conducting a study related to such an application or submission; and
- the records and other information that may be inspected, e.g., information related to the conduct, results, and analyses of studies, including those involving human trial participants or animal subjects.

It also underscores that those subject to BIMO inspection must provide FDA with access to the information to be inspected (including access to all paper and electronic records and access to electronic information systems used to hold, analyze, process, or transfer that information), and

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[6] See "Bioresearch Monitoring Investigations" under section 8.6 of the "Investigations Operations Manual," available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual.

[7] In this document, the term "trial participant" is used and covers both human trial participants and animal subjects.

[8] The terms "research," "trial," and "study," are deemed to be synonymous for purposes of this guidance and include both clinical research (also referred to as "clinical study," "clinical trial," and "clinical investigation") and nonclinical research (also referred to as "nonclinical trial" and "nonclinical laboratory study").

[9] "REMS" refers to Risk Evaluation and Mitigation Strategies, see section 505-1 of the FD&C Act (21 U.S.C. 355-1). "PADE" refers to Postmarketing Adverse Drug Experience, see e.g. 21 CFR 310.305 , 21 CFR 314.80, 21 CFR 329.100 , 21 CFR 600.80 , and 21 CFR parts 803 and 806.

[10] See section 704(a)(5)(F) of the FD&C Act.

permit FDA to inspect relevant facilities and equipment used in generating that information.[11] At the same time, section 704(a)(5) makes clear that existing safeguards[12] against disclosure of confidential commercial information and trade secrets continue to apply, and that BIMO inspections – like inspections generally – are to be conducted at reasonable times, within reasonable limits, and in a reasonable manner.[13]

Generally, an inspection, such as described in section 704(a) of the FD&C Act, involves duly designated officers or employees of FDA physically entering establishments subject to regulation under the FD&C Act to determine compliance with applicable FDA requirements. FDA also uses other oversight tools when appropriate, such as RRAs. An RRA is an examination of an FDA-regulated establishment and/or its records, conducted entirely remotely, to evaluate compliance with applicable FDA requirements. RRAs under the BIMO Program may consist of: (1) Remote Interactive Evaluations[14] and (2) requests for records or other information under section 704(a)(4) of the FD&C Act from sites and facilities subject to inspection under section 704(a)(5)(C)(i) (i.e., establishments subject to BIMO inspections) in advance of or in lieu of such inspections.[15]

[11] See section 704(a)(5)(D)(i) of the FD&C Act.

[12] See section 704(a)(5)(D)(ii) of the FD&C Act.

[13] See section 704(a)(5)(D)(iii) of the FD&C Act. Also see Department of Health and Human Services' website for information on permissible disclosures of protected health information to public health authorities (including FDA), available at https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html.

[14] For more information on Remote Interactive Evaluations, see "Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities Guidance for Industry" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[15] For more information on RRAs generally, including their applicability to BIMO sites and facilities, communications between FDA and industry regarding requests for records or other information, and the distinction between an RRA and inspections under sections 704(a)(1) and 704(a)(5) of the FD&C Act, see "Conducting Remote Regulatory Assessments Questions and Answers Draft Guidance for Industry" (hereafter, the "Draft RRA Guidance"), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-remote-regulatory-assessments-questions-and-answers. Although an RRA is not an inspection and the Draft RRA Guidance notes that the Agency does not intend to conduct an RRA at the same time as an inspection, the Draft RRA Guidance provides information about communications between industry and FDA during an RRA that may be relevant for communications during an inspection. Specifically, see the Draft RRA Guidance's discussion of records security, file format (e.g., Portable Document Formats), and language translation. When finalized, that guidance will represent the Agency's current thinking on how RRAs apply generally to all FDA-regulated products. For additional translation guidance, see the draft "Translation of GLP Study Reports: Questions and Answers" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/translation-good-laboratory-practice-study-reports-questions-and-answers.

III. PROCESSES AND PRACTICES APPLICABLE TO BIORESEARCH MONITORING INSPECTIONS

A. BIMO Processes and Practices

The Agency's processes and practices applicable to BIMO inspections are detailed in its Investigations Operations Manual (IOM), compliance programs, and the Regulatory Procedures Manual (RPM). In general, for all domestic and foreign BIMO inspections, FDA follows the same processes and practices before and during the inspection, except as noted in this guidance.

FDA's IOM[16] is the primary operational reference for FDA investigators and other FDA personnel to perform investigational activities in support of the Agency's public health mission across all program areas. The BIMO compliance programs were developed to provide uniform and specific instructions for FDA personnel. They describe the inspection focus and types of records and information FDA personnel evaluate to assess compliance with the relevant FDA regulations and statutory requirements for each regulated entity or program.[17]

These compliance programs include:

- In Vivo Bioavailability-Bioequivalence Studies - Clinical
- In Vivo Bioavailability-Bioequivalence Studies - Analytical
- Inspection of Nonclinical Laboratories Conducting Animal Rule-Specific Studies
- Good Laboratory Practice (Nonclinical Laboratories)
- Good Laboratory Practice Program (Nonclinical Laboratories) EPA Data Audit Inspections
- Institutional Review Boards
- Radioactive Drug Research Committees
- Sponsors and Contract Research Organizations
- Clinical Investigators and Sponsor-Investigators
- Postmarketing Adverse Drug Experience (PADE) Reporting Inspections
- Risk Evaluation and Mitigation Strategies (REMS) Reporting Inspections

[16] See "Investigations Operations Manual," available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual. The IOM is reference material for investigators and other FDA personnel. The document does not bind FDA and does not confer any rights, privileges, benefits, or immunities for or on any person(s).

[17] See "Bioresearch Monitoring Program (BIMO) Compliance Programs," available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-program-manual/bioresearch-monitoring-program-bimo-compliance-programs. Compliance programs do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used as long as the approach satisfies the requirements of the applicable statutes and regulations.

FDA's centers (CBER, CDER, CDRH, CFSAN, CTP, and CVM) and the Office of Bioresearch Monitoring Operations (OBIMO), within the Office of Regulatory Affairs (ORA), administer the applicable BIMO compliance programs.

For regulatory and enforcement matters, the RPM[18] is a reference manual that provides internal procedures and related information for FDA employees to administer these matters in support of the Agency's public health mission. The RPM includes information detailing administrative actions such as clinical investigator disqualifications and related procedures such as a Notice of Opportunity for Hearing (NOOH).

Although the IOM, compliance programs, and RPM are primarily used by FDA staff, all are available publicly so regulated industry and other interested parties can better understand FDA operations. We note that FDA regularly reviews its processes and practices described in the IOM, compliance programs, and RPM that are applicable to establishment inspections to evaluate whether any updates are needed.[19]

See the Resource Guide, below, for further details on the IOM, compliance programs, and RPM as well as additional resources on BIMO inspections and RRAs.

B. Types of Inspections

FDA personnel conduct inspections to determine an establishment's compliance with applicable FDA statutory and regulatory requirements (e.g. with respect to bioresearch inspections – to help ensure trial participant safety, and to evaluate data reliability). FDA BIMO inspections generally include: inspections conducted in support of FDA's review of specific submissions or marketing applications; periodic inspections of establishments with on-going activities, such as nonclinical laboratories or institutional review boards; or inspections conducted to evaluate potential noncompliance or safety issues raised in a complaint or required report (e.g., from IRBs or sponsors) pertaining to a study or establishment. Inspections may be comprehensive, covering all operations of the establishment, or directed, covering a subset of operations. As explained in Part IV below, FDA conducts both announced and unannounced BIMO inspections.

C. International Inspections

Product development and marketing are often global pursuits and therefore FDA's BIMO inspections are not limited to the United States. International inspections may be conducted when appropriate (e.g., when studies conducted outside the United States are in support of, or

[18] See "Regulatory Procedures Manual," available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual. The RPM does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

[19] In accordance with section 3612(b)(1) of FDORA, as part of developing this guidance, the Agency reviewed "processes and practices in effect as of the date of enactment of this Act [i.e., FDORA] applicable to inspections of foreign and domestic sites and facilities described" in section 704(a)(5)(C)(i) of the FD&C Act "to evaluate whether any updates are needed to facilitate the consistency of such processes and practices". FDA makes needed updates on a routine basis, as part of our regular review of processes and practices, as noted above.

otherwise related to, a marketing application submitted to FDA and provide data critical to regulatory decision making). For domestic inspections, a notice of inspection (e.g., Form FDA 482[20]) is issued at the time of inspection. During foreign inspections, FDA credentials are presented to the top management official (or onsite designee) but FDA does not issue a notice of inspection.[21] With the exception of this difference and those related to pre-announcement procedures described below[22] inspections of foreign and domestic establishments are generally the same in terms of processes and practices.

FDA has issued guidance[23] relevant to the conduct of clinical studies, including guidance on issues specific to studies conducted internationally.[24] FDA also collaborates with certain international regulatory partner agencies to conduct joint inspections, observe inspections, share inspection information and develop policy.[25] This collaboration is important to the BIMO program.

IV. BEST PRACTICES FOR COMMUNICATION BETWEEN THE FDA AND INDUSTRY IN ADVANCE OF, DURING, OR AFTER AN INSPECTION

A. Pre-announcement Notice and Communication

The Agency's primary purpose for pre-announcing an inspection is to ensure the appropriate records and establishment personnel will be available during the inspection. FDA may communicate a general idea of the records that may be requested during the inspection (e.g., regarding certain establishment procedures and any associated records).

Pre-announcement practices depend on the type of inspectional activity being conducted and are explained in each compliance program.[26] During pre-announcement of FDA inspections, FDA intends to make reasonable efforts to contact the establishment, including to discuss inspection plans, and the inspection start date and time. Pre-announcement communications also include discussions with the establishment to ensure the availability of relevant establishment staff and

[20] See section 5.5 of the IOM.

[21] For additional information on FDA notice of inspection (e.g., Form FDA 482), see "Authority to Inspect" under section 2.2 of the IOM. See also the Bioresearch Monitoring Program compliance programs.

[22] See Part IV. A Pre-announcement Notice and Communication.

[23] See "Search for FDA Guidance Documents," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[24] FDA BIMO inspections include, but are not limited to, studies that are conducted under an FDA investigational new drug application (IND), as well as studies at non-U.S. establishments that are not conducted under an IND, an investigational new animal drug (INAD) exemption, or under an investigational device exemption (IDE). See, for example, the "Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions Statement of Investigator (Form FDA 1572)," discussing foreign clinical studies conducted under an IND or as non-IND studies.

[25] FDA may enter into cooperative arrangements and confidentiality commitments to facilitate international partnerships with counterpart foreign government agencies. See "International Arrangements," available at https://www.fda.gov/international-programs/international-arrangements.

[26] See footnote 17 for more on compliance programs. Also see Part III of this guidance and "Pre-Announcements" under section 5.2 of the IOM.

the associated records and specific operations for review during the inspection, as applicable. Establishments using electronic information systems to hold, analyze, process, or transfer pertinent information should be prepared to provide access to FDA personnel upon their arrival.[27]

FDA investigators routinely share their names, titles, contact information, and, when appropriate, reasons for conducting the inspection. There may be instances in which FDA investigators may not disclose specific reasons for conducting the inspection during pre-announcement. In such cases, if appropriate, FDA investigators may inform the establishment representative that additional details will be shared during the opening meeting of the inspection.

Establishment staff should also confirm arrival details with FDA investigators and provide a contact phone number. FDA believes that an establishment's failure to acknowledge the pre-announcement notification should not be a reason to delay the start of an inspection. This pre-announcement notification should be provided within a reasonable time before the inspection is scheduled to occur. FDA generally pre-announces both foreign and domestic inspections, but pre-announcement for foreign inspections is generally further in advance of the inspection due to country clearance requirements. In general, pre-announcements for domestic inspections will be given via phone while for foreign inspections pre-announcements may be by phone and/or email.

Inspections, whether pre-announced or unannounced, are conducted consistent with our compliance programs, the IOM, and applicable statutory authority. The Agency may determine to not pre-announce an inspection (foreign or domestic) if prior notification may impact the inspection.

B. Inspection Timeframe and Duration

During the pre-announcement, FDA investigators intend to communicate with the establishment the planned timeframe and duration of the inspection, including appropriate working hours during which the inspection is likely to take place. Inspection duration is impacted by a myriad of factors, such as the complexities of the operations, availability of knowledgeable staff, the nature of any observations, and if FDA needs to follow-up on complaints received by the Agency.

C. Communication During An Inspection

When FDA personnel request records or other information as part of an inspection,[28] the Agency will typically provide an opportunity to discuss the nature, process, and timeline of the request. The establishment may ask clarifying questions and should be prepared to provide the records in a timely manner during the inspection. Details of the establishment's electronic information

[27] See Part II. Background for additional detail. Access may be read-only. See "Read-Only Access to Electronic Databases During Bioresearch Monitoring Inspection Assignments" under section 5.14 of the IOM.

[28] Such requests are distinct from requests for records or other information in advance of, or in lieu of, an inspection under section 704(a)(4) of the FD&C Act.

systems, including the technical capabilities for providing FDA access to electronic records, should also be discussed.

FDA personnel can view electronic records via read-only access or other methods. Regardless of the method(s) used to view records, establishments should be prepared to provide requested copies from electronic systems to FDA[29] either electronically, via electronic storage media or as paper copies.

When time and circumstances permit, FDA personnel should discuss observations with the staff in charge of the establishment as they are observed, or on a daily basis. These discussions may address findings not documented on the FDA "Inspectional Observations" (Form FDA 483) for which FDA seeks clarification during the inspection.[30]

D. Communication After An Inspection

At the end of an inspection, the FDA investigator conducts a closeout of the inspection with the establishment representative that includes discussing the findings from the inspection[31] and, if appropriate, issuing a written Form FDA 483 to the establishment. The Form FDA 483 is intended for use in notifying the inspected establishment's top management in writing of "observations of objectionable conditions and practices"[32] identified during an inspection in order to "assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration."[33]

If the establishment chooses to respond to the Form FDA 483 observations orally during the closeout of the inspection, those responses may be incorporated into the inspection report.[34] However, there may not be complete information about corrective and preventative actions at the time of closeout. Although there is no regulatory requirement for the inspected establishment to respond to a Form FDA 483, a timely written response to the Form FDA 483 that includes appropriate corrective and preventive actions could impact FDA's determination of the need for subsequent Agency action. FDA encourages establishments to provide written responses to the observations within fifteen (15) U.S. business days after the end date of the inspection. Responses submitted to FDA during that timeframe addressing the issues identified during the inspection generally will be considered before further Agency action or decision.

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[29] See section 704(a)(5)(D) of the FD&C Act.

[30] For additional detail on Form FDA 483, see Chapter 5 of the IOM. See also the Bioresearch Monitoring Program compliance programs.

[31] Once the inspection is closed by the Agency, the inspected establishment will be provided a copy of the Establishment Inspection Report. See "FMD-145 - Release of the Establishment Inspection Report (EIR)" available at https://www.fda.gov/media/83055/download.

[32] See "Reports of Observations" and "General Discussion with Management" under sections 5.5 and 5.7 of the IOM for more on discussing the objectionable conditions observed and the potential legal sanctions available to FDA after further review by the Agency.

[33] Language on back of FDA Form 483. There may be other objectionable conditions that exist at the establishment that are not cited on the Form FDA 483. Also see the Bioresearch Monitoring Program compliance programs.

[34] See "General Discussion with Management" under section 5.7 of the IOM.

For domestic inspections, if the establishment chooses to respond in writing to the observations discussed or listed on the Form FDA 483, the response should be addressed to the FDA OBIMO division contact which is listed on the Form FDA 483. Hard copy responses may be mailed to the address listed on the Form FDA 483 or emailed, with email being the preferred approach.[35] It is recommended that the respondent include the FDA Establishment Identification (FEI) of the inspected location in its correspondence.[36] For foreign inspections, if the establishment chooses to respond in writing to the observations discussed or listed on the Form FDA 483, the response should be addressed to the FDA center point of contact (POC) provided by the investigator.

There are several best practices for responding in writing to a Form FDA 483. A response should demonstrate the establishment's acknowledgment and understanding of FDA's observations. It should also demonstrate the establishment's commitment to address the observations, including a commitment from senior leadership.

Responses should be well-organized and structured to:

- Address each observation separately
- Note whether the establishment agree(s) or disagree(s), 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
- Submit documentation (e.g., training, Standard Operating Procedures (SOPs), corrective action plans, records, etc.)

E. Who to Contact at FDA for More Information?

If an inspected establishment has any questions that the FDA personnel conducting the inspection has not answered, the establishment may contact the ORA OBIMO management staff. The FDA investigator who conducted the inspection should be able to provide the name and telephone number of OBIMO division management to the establishment.[37] Questions about the inspection classification[38] can be directed to the FDA center POC identified in the post-inspection correspondence or in the relevant compliance program. Alternatively, the ORA

[35] Email appropriate division contacts depending on the location of establishment. See "Office of Bioresearch Monitoring Operations Map" available at https://www.fda.gov/media/104799/download?attachment for more on district abbreviations and contact information.

[36] For more on the FDA Establishment Identification, see "FEI Search Portal," available at https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login.

[37] FDA intends to provide an inspectional handout with contact information to the establishment during the inspection.

[38] Following an inspection, the Agency evaluates the inspection findings to determine if the establishment is in compliance with applicable statutes and regulations and classifies the inspection according to three classifications (No Action Indicated, Voluntary Action Indicated, Official Action Indicated). See "Inspection classifications" available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-basics/inspection-classifications and Chapter 4 of the RPM, available at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual#_top.

Ombudsman Program is a communication resource for stakeholders facing unresolved concerns, providing a confidential and impartial avenue to address and resolve their issues effectively.[39]

[39] Contact information can be found on the ORA Ombudsman webpage available at https://www.fda.gov/about-fda/contact-ora/ora-ombudsman.

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RESOURCE GUIDE

BIMO Inspection and Program Resources	Summary of Resource	Where can I find this information?[40]
BIMO Program Information	The webpage provides an overview of the program mission and vision. Other select resources are covered, including: Application Integrity Policy, Compliance Lists, Compliance Policy Guides, etc.	FDA Bioresearch Monitoring Information
Compliance Programs (CPs)	The CPs provide uniform and specific instructions to ORA OBIMO and FDA center employees for conducting inspections and for gathering and preparing the evidence to support recommendations as part of the regulatory decision-making process. The CPs detail inspection operational procedures, types of interviews performed, and records requested.	Bioresearch Monitoring Compliance Programs
Investigations Operations Manual (IOM)	The primary operational reference for FDA employees who perform field investigational activities. The IOM includes a discussion on statutory authority and establishment inspections.	Investigations Operations Manual
BIMO Inspection Metric Reports	The webpage provides annual bioresearch monitoring inspection metrics by fiscal year. The webpage also covers compliance trends and "Inspectional Observations" (Form FDA 483) findings.	BIMO Inspection Metrics
FDA Guidance Documents	Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do	Search for FDA Guidance Documents (Browse by

[40] Links in this column were last accessed: May 28, 2024.

	not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. Guidance documents describe FDA's interpretation of or policy on a regulatory issue (21 CFR 10.115(b)).	topic, e.g., "Clinical Trials" or "Remote Regulatory Assessments")
Regulatory Procedures Manual (RPM)	A reference manual for FDA employees. It provides employees with information on internal procedures to be used in processing regulatory and enforcement matters.	Regulatory Procedures Manual

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