Turning Risk Into Readiness: Regulatory Inspection Insights You Can Use

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SPEAKERS

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Overview

- Legal Provisions for GCP Inspections
- GCP Purpose
- Types of GCP Inspections
- Typical Timelines
- Practical Considerations Before, During, and After Inspections
- Common Findings
- Response Expectations
- Regulatory Actions/Sanctions

Legal Provisions for GCP Inspections

Section 704 of the FD&C Act [21 U.S.C. 374] and specifically, 704(a)(5) of the FD&C Act [21 U.S.C. 374(a)(5)].

Sections 505(k)(2) and 520(g)(2)(B)(ii) of the FDCA provided for maintaining clinical trial records for FDA Inspection,

Reference, FDA's Compliance Program Guidance Manual for clinical investigators and sponsor-investigators (CPGM 7348.811, July 22, 2020)

Reference FDA's BIMO Compliance Program Guidance Manual for sponsors and contract research organizations (CPGM 7348.810, September 15, 2021)

Reference, FDA's Investigations Operations Manual, 2025, Chapter 3 (Regulatory) and Chapter 5 (Inspections.)

Reference, FDA's Regulatory Procedures Manual, July 2024

Types of FDA GCP Inspections

- **On-Site Inspections**

  Surveillance, For Cause, Application-based, Follow-up

- **Data Audits**
- **Remote Regulatory Assessments**
- **PADE**

  Post marketing adverse drug experience reporting

- **REMS**

  Risk Evaluation Mitigation and Reporting






GCP Purpose

The Bioresearch Monitoring (BIMO) Program was established by the Food and Drug Administration (FDA) in 1977 to strengthen oversight of FDA-regulated research and ensure the integrity of clinical and nonclinical studies.

To protect and ensure the rights, safety, and welfare of research participants involved in FDA-regulated clinical trials;

To verify the accuracy and reliability of study data submitted to FDA in support of research or marketing applications;

Timelines of GCP Inspections

5 DAYS

Pre-announcement / Rescheduling / Unannounced

Generally provided no less than five (5) calendar days in advance of an inspection, unless special circumstances apply. Sponsors, CROs, and investigators should be prepared for the possibility of shorter notice or unannounced.

0 DAYS

Foreign BIMO Inspections

These have potential to be conducted without advance notice.

Clinical sites outside the United States should maintain readiness at all times, as FDA investigators may arrive unannounced to review data integrity, subject protection, and regulatory compliance.

15 DAYS

Reportable Observations

A written response must be provided within 15 business days of the end date of the inspection. The response should address each observation, outline corrective and preventive actions, and include supporting documentation to demonstrate compliance efforts.

30 DAYS

Notice of Initiation of Disqualification Proceedings and Opportunity to Explain (NIDPOE)

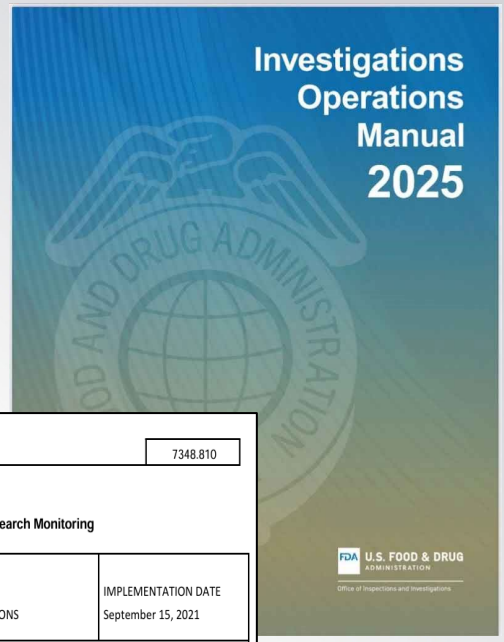
Clinical Investigator writes or calls, within 15 working days, to arrange for an informal conference or to indicate intent to respond to allegations in writing. If submitting written response, must respond within 30 working days of receipt of the NIDPOE.

Practical Considerations

Before: Get to know the Investigations Operations Manual (IOM), Regulatory Procedures Manual (RPM), and Compliance Program Guidance Manual's (CPGM) applicable sections. Get prepared through Inspection Readiness activities (Training & MOCK Inspections).

During: Work collaboratively with your study partners (sponsor for clinical investigators and CROs) during an inspection. Follow the "Do and Do Not" list provided during Inspection Readiness Training. Answer the question asked and wait for the follow up questions from the FDA Investigator.

After: Partner with Sponsor to collaborate on drafting a voluntary 483 response and Warning Letter (WL) response to US FDA within applicable time frames. Although voluntary, responses to 483's and WLs are viewed as highly favorable by the Agency within 15 business days, excluding holidays.



FOOD AND DRUG ADMINISTRATION
COMPLIANCE PROGRAM 7348.810

CHAPTER 48 – Bioresearch Monitoring

SUBJECT: SPONSORS AND CONTRACT RESEARCH ORGANIZATIONS	IMPLEMENTATION DATE September 15, 2021
DATA REPORTING	
PRODUCT CODES: Bioresearch Monitoring inspections do not require product codes	
PROGRAM ASSIGNMENT CODES	
09810 Foods, Food Additives and Color Additives	
41810 Biologics (Human Cellular, Tissue and Gene Therapies)	
42810 Biologics (Blood and Blood Products)	
45810 Biologics (Vaccines and Allergenic Products)	
48810 Human Drugs and Therapeutic Biologics	
68810 Animal Products (Animal Drugs and Food Additives)	
83810 Medical Devices	
98810 Tobacco Products	

Common US FDA Findings - Clinical Inspections

Inspection Themes Identified in FY 2023

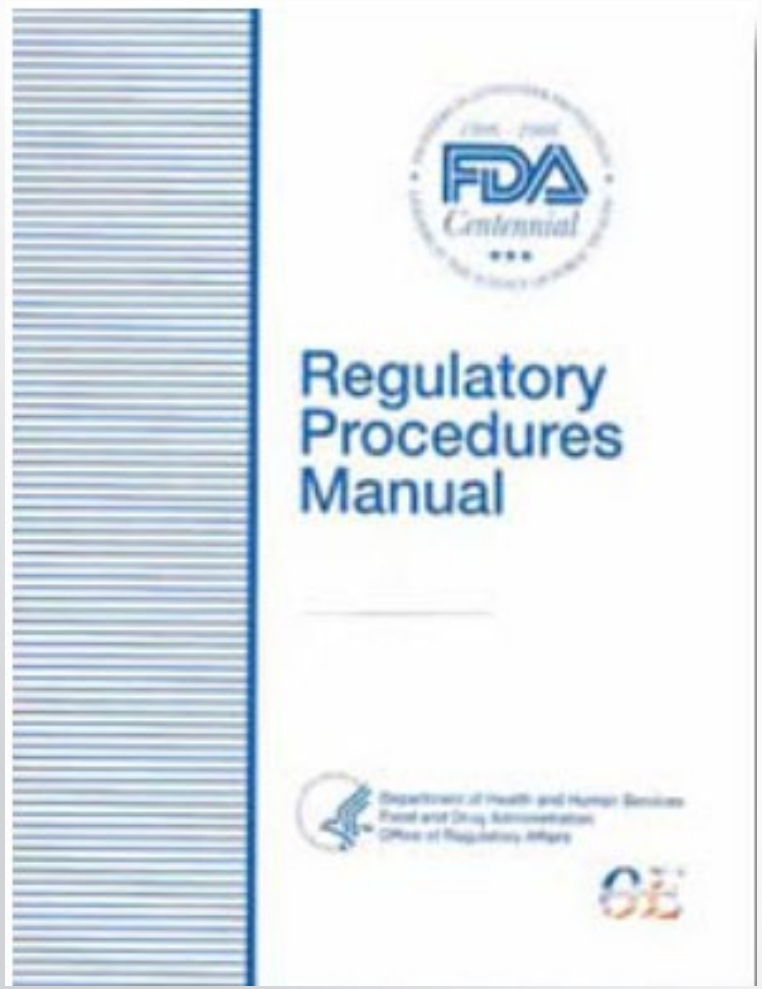
Compliance	Reporting	IRB	Records
Protocol Compliance (312.60 / 812.100 & 812.110) Accurate/Adequate Case Histories (312.62(b) / 812.140(a)(3))	Failure to Report Adverse Events to Sponsor Promptly (312.64(d))	Institutional Review Board (312.66) (812.150(a)(3))	IP Accountability Records (312.62(a) / 812.140(a)(2))

Common Findings - Sponsor Inspections

Inspection Themes Identified in FY 2023

Lack of IRB Approval	Missing ICF Elements	Failure to Secure Compliance	Annual Report	Failure to submit IND to FDA
312.66; 56.104(c)	50.25(a)(1); 50.25(a)(4); 50.25(a)(4)	812.28(a)(1); 312.56(b); 812.46(a)	812.150(b)(5); 312.56(c)	312.20(a); 312.20(b)

Response Expectations



A comprehensive, well-documented, and timely (within 15 business days) voluntary response to an FDA Form 483 is expected to include the following:

- A detailed root cause analysis for each observation;
- Specific corrective and preventive actions (CAPA);
- An implementation timeline, a plan for follow-up and monitoring, and supporting evidence for completed actions

The response should also address systemic issues beyond individual findings, demonstrate senior management's commitment, and be prepared for future re-inspections

Regulatory Actions/Sanctions

Regulatory Actions	Sanctions	Other Consequences
FDA Inspections	Data Rejection	Reputational Damage
Form FDA 483s	Study Suspension/Termination	Legal Liability
Warning Letters	Clinical Investigator Disqualification	Breach of Contract
Notices of Noncompliance (ClinicalTrials.gov)	Civil Monetary Penalties	
Clinical Holds	Injunctions and Criminal Prosecution	
	Grant Funding Actions	

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