

# Monitors vs Auditors vs FDA...Quality Perspective Focus

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## SIMILARITIES IN ROLES

- **Compliance & Regulation Enforcement** – Monitors, Auditors and the FDA ensure that organizations comply with established laws, regulations, and standards.
- **Risk Assessment** – These professionals evaluate risks associated with non-compliance and help organizations mitigate potential legal, financial, or health risks.
- **Process & Documentation Review** – Monitors, Auditors and the FDA review procedures, policies, and records to verify that companies follow established guidelines and maintain proper documentation.
- **On-Site and Remote Inspections** – All on-site and remote visits are conducted to examine operations, check for discrepancies, and ensure that procedures are being followed correctly.
- **Objective & Independent Analysis** – They all function as independent evaluators, assessing compliance objectively without direct involvement in the company's daily operations.
- **Interviews & Evidence Collection** – Monitors, Auditors and the FDA personnel interview, gather evidence, and analyze data to support their findings and conclusions.
- **Reporting & Recommendations** – After a monitor visit, an audit or inspection, all provide reports detailing their findings, highlighting areas of non-compliance, and suggesting corrective actions.
- **Follow-Ups & Continuous Monitoring** – They all may conduct follow-up or request corrective action plans to ensure that previous issues have been resolved, and compliance is maintained.
- **Legal & Ethical Considerations** – All roles are led by ethical guidelines and legal frameworks to ensure impartiality and accuracy in their evaluations.
- **Training & Industry Knowledge** – All require ongoing education and expertise in their respective fields to stay updated on evolving regulations, best practices, and technological advancements.

## DIFFERENCES IN ROLES

- **Authority & Role**
  - **Monitors:** Hired on behalf of the Sponsor as a representative to assess compliance with the protocol, regulations and standards for the clinical trial.
  - **Auditors:** Typically work for private companies, consulting firms, or internal teams within an organization. Their role is to assess compliance with internal policies, industry standards (e.g., ISO, GMP, ICH), and regulatory requirements.
  - **FDA Inspectors:** Government officials from the U.S. FDA who enforce federal laws and regulations. They have legal authority to conduct inspections and issue warnings or penalties.
- **Purpose**
  - **Monitors:** Conduct monitoring visits to ensure protection of the human subject and verify trial data is accurate.
  - **Auditors:** Conduct audits to help companies improve processes, maintain certifications, and ensure quality and compliance with industry standards.
  - **FDA Inspectors:** Conduct inspections to enforce regulations and ensure public health and safety by checking compliance with FDA laws (e.g., Food, Drug, and Cosmetic Act).
- **Scope of Work**
  - **Monitors:** Alignment of the protocol, regulatory expectations and real-world site activities.
  - **Auditors:** Focus on quality systems, documentation, risk management, and operational efficiency. They provide feedback and recommendations for improvement.
  - **FDA Inspectors:** Focus on legal compliance. They review records, interview employees, collect samples, and can issue regulatory actions like Warning Letters or product recalls.
- **Consequences of Findings**
  - **Monitors:** Report protocol deviations, essential documents, query resolution through monitoring reports. Issues found may lead to corrective actions but typically do not result in legal penalties.
  - **Auditors:** Report findings internally or to clients. Issues found may lead to corrective actions but typically do not result in legal penalties.
  - **FDA Inspectors:** Can take legal actions, such as issuing Form 483 observations, Warning Letters, import alerts, product seizures, or facility shutdowns.
- **Frequency & Type**
  - **Monitors:** Scheduled based on fixed or adaptive risk-based plans; onsite and remote.
  - **Auditors:** May be scheduled regularly (e.g., annual audits) or on an as-needed basis.
  - **FDA Inspectors:** Conduct unannounced inspections (especially for high-risk facilities) or scheduled inspections based on regulatory risk assessments.
- **Follow-up Actions**
  - **Monitors:** Monitor queries, staff training, CAPA closure, safety reporting.
  - **Auditors:** Provide recommendations; companies voluntarily address findings.
  - **FDA Inspectors:** If non-compliance is found, companies must respond officially, and failure to comply can lead to enforcement actions.

## PERSPECTIVE

A review of Monitoring, Auditing and an FDA Inspection/Investigation activities were evaluated for assessment processes, reflecting how they differ in purpose, authority, and execution.

Aspect	Monitoring	Auditing	FDA Inspection
Definition	Personnel who work with sponsored clinical trials required by the FDA to ensure compliance with protocols, guidelines, regulations primarily protecting participant safety and data integrity	A systematic, independent review of processes, documents, or products to ensure compliance with regulations or internal standards	A formal examination conducted by the FDA to ensure compliance with federal regulations related to public health and safety
Conducted By	Clinical Research Associate (CRA) onsite monitor, field-based CRA, centralized monitor (CM), in-house CRA	Internal auditor, third-party auditor, or regulatory bodies.	FDA Consumer Safety Officer (CSO) Inspector or Investigator
Purpose	To ensure the protection of human subject rights, verify trial data is accurate, complete, and verifiable, and confirm the study adheres to the approved protocol, guidelines, and regulatory requirements	To verify compliance with internal policies, industry standards (e.g., GMP, ISO), or regulatory requirements	To ensure compliance with FDA regulations, such as GCP (Good Clinical Practices), FSMA (Food Safety Modernization Act), or other federal laws
Scope	Mitigate risks to both study participants and integrity of the clinical trial data	Can be broad (covering multiple areas) or focused on specific processes. Usually scheduled	Specific to FDA-regulated products and facilities. Can be routine, for-cause, or pre-approval inspections
Authority	No legal enforcement power; findings may lead to protocol deviations or corrective actions	No legal enforcement power; findings may lead to recommendations or corrective actions	The FDA has legal authority to issue warning letters, citations (Form 483), or take enforcement actions (e.g., product recalls, facility shutdowns)
Frequency	Conduct regularly scheduled visits or follow adaptive monitoring based on identified risks	Conducted as scheduled per company policy or industry standards	Occurs periodically, randomly, or triggered by complaints, product issues, or premarket approval needs
Outcome	Ongoing quality control recorded in interim monitoring reports	Report documented areas of review with findings, recommendations, and corrective actions	Can result in Form 483 observations, FDA warning letters, import bans, recalls, or legal actions if violations are found
Plan	Clinical Monitoring Plan (CMP); Fixed and Adaptive Site Monitoring Schedules	Clinical Site Audit Plan; Vendor/CRO Audit Plan; System Audit Plan, Mock BIMO Inspection, Internal (Process) Audit Plan/Calendar, Triggered (For-Cause) Audit Plan	Inspection Plan; Compliance Program Guidance Manual

## KEY DIFFERENCES

**Monitor Visits and Audits** are often **internal or third-party** reviews, while **FDA Inspections/Investigations** are **official government investigations**.

**Monitors and Auditors** help **prepare** for inspections but have **no legal consequences**. FDA inspections/investigations can result in **regulatory action**.

FDA Inspections/ Investigations focus on **public health and regulatory compliance**, while Monitor visits and Audits may also include **business efficiency, risk management, and quality improvement**.

## SUMMARY

In summary, **Monitors and Auditors** focus on **quality improvement and compliance verification**, while **FDA Inspectors/ Investigators** have the power to **enforce laws and take legal action** if regulations are not met.

## CONTACT

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