Unannounced FDA Inspections Without Borders

Unannounced inspections are expanding globally. Here's how to build continuous inspection readiness within your firm to stay compliant.

The Inspection Landscape Has Changed

Beginning as early as August 2025, foreign sites are subject to the same unannounced FDA inspections and public scrutiny as U.S. facilities, following the US Executive Order made in May 2025.

What's Changing:

- Manufacturing sites
- Packaging & labeling
- Testing labs
- Warehouse & distribution

What It Means For Your Organization:

- Global sites now face **US-level regulatory pressure**
- Sponsors remain accountable **for the performance and compliance of their external partners**
- Inspection readiness **must be proactive and continuous**, not reactive

New in 2025

The FDA will publish inspection data by country and manufacturer.

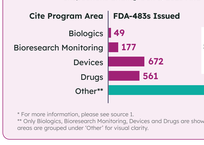
Compliance By The Numbers

Each **FDA Form 483** signals non-compliance with regulatory standards, with Warning Letters and Consent Decrees indicating more serious issues.

In FY2024 alone, **more than 4,000 observations were recorded**, hundreds of which were in **biologics**, **bioresearch monitoring**, **devices** and **drug** manufacturing environments.

Number Of 483s Issued From FDA Inspection Database

Inspections Ending Oct. 1, 2023 And Sept. 30, 2024



4,104
Sum product area 483s posted on FDA website*

* For more information, please see source 1.
** Only Biologics, Bioresearch Monitoring, Devices and Drugs are shown in detail. All other FDA-regulated areas are grouped under "Other" for visual clarity.

These aren't outliers — even experienced facilities face compliance challenges.

FDA's FY2024 Top Citation Hot-spots — Drug Manufacturing

- Stability program deficiencies
- Missing or outdated procedures
- Inadequate deviation investigations
- Insufficient lab/equipment validation
- Contamination control gaps
- Data integrity issues

What The FDA Is Really Looking For

It's not just about paperwork. It's about proof that your systems work — every single day. Inspections aren't static reviews. They're real-time evaluations of how your systems perform when no one is watching.

Consistency + Control + Credibility → **Demonstrates compliance via:**

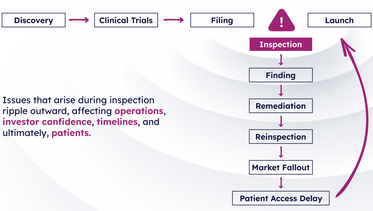
While FDA inspectors follow structured *Compliance Program Guidance Manuals*, their on-site approach isn't rigid — they **assess systems in real-time to identify embedded compliance and potential risks.**

The Non-Readiness Ripple Effect

A single failed inspection can undo years of **investment**, **planning**, and **trust**.

When systems break down under inspection, the consequences can be far-reaching:

The Price Of Non-Readiness



Issues that arise during inspection ripple outward, affecting **operations**, **investor confidence**, **timelines**, and ultimately, **patients**.

Did You Know?

Inspection findings often stem from systems that look compliant on paper but break down in practice.

At **ProPharma**, we help teams embed readiness into daily operations — so confidence isn't staged, it's sustained.

Real-Time Readiness Starts With The Right Partner

Organizations need systems that can withstand scrutiny to navigate unannounced inspections. That assurance comes from making readiness a routine activity, not a reactive task.

ProPharma's Impact At A Glance

- **100% success rate** on Pre-Approval Inspection (PAI) readiness projects to date
- Support across **all industries** and **regulatory environments**
- Trusted by the industry for seamless **inspection strategy**, **management**, and **execution**

How ProPharma Can Help

ProPharma brings decades of global regulatory experience to help clients do exactly that. By embedding readiness into real-world processes, we support organizations in building *Quality Systems* that hold up under pressure and deliver consistent results when it matters most.

This infographic is brought to you by:

ProPharma

For the last 25 years, ProPharma has improved the health and wellness of patients by providing advice and expertise that empowers biotech, med device, and pharmaceutical organizations of all sizes to confidently advance scientific breakthroughs and introduce new therapies. With deep domain expertise in regulatory sciences, clinical research solutions, quality and compliance, pharmacovigilance, medical information, FSP Solutions, and digital transformation, ProPharma offers an end-to-end suite of fully customizable consulting solutions that de-risk and accelerate our partners' most high-profile drug and device programs. For more information about ProPharma, please visit propharmagroup.com.

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Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more.

Sources:

1. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations
2. https://www.propharmagroup.com/services/quality-and-compliance/inspection-readiness