APCER LIFE SCIENCES

CASE STUDY

# Inspection Hosting Excellence: APCER's Success in Hosting a Flawless US FDA Inspection for a Leading Pharmaceutical Company

**Therapeutic area:** Multiple therapeutic areas

**Product type:** Drug

**Geography:** United States, European Union, and Rest of the World

**Product lifecycle stage:** Postmarketing

## Overview

Pharmaceutical, medical device, and biotechnology companies must maintain continuous readiness for global inspections by the United States (US) Food and Drug Administration (FDA), the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA), the European Union (EU) regulatory authorities, and other relevant bodies. Although some inspections, such as those by the MHRA and the European Medicines Agency (EMA), are pre scheduled, others, like FDA inspections, often occur without prior notice. This makes it crucial for organisations to maintain a robust Quality Management System (QMS) and to always have a well-trained inspection team ready. In addition, evolving regulatory frameworks and risk-based approaches have strengthened oversight of global drug manufacturing. More recent trends indicate a continued recovery and rise in inspection activity following pandemic-related disruptions, with a substantial proportion of inspections conducted at foreign sites highlighting a faster, globally focused inspection landscape. To meet these demands, organisations must implement a robust QMS, supported by an experienced Quality Assurance (QA) team with expertise in Good Clinical Practice (GCP) and Good Pharmacovigilance Practice (GVP). A robust QMS ensures effective management of change controls, deviations, corrective action and preventive action (CAPA), and audit findings, while maintaining clear organisational structures, performance metrics, and training programmes aligned with regulatory expectations.

## About the Client

The client is one of India's leading pharmaceutical companies, operating in multiple countries including the US, the UK, Germany, Canada, and Russia, with experience across major therapeutic areas such as cardiovascular, central nervous system, gastrointestinal system, and anti-diabetic segments. With a strong presence in both domestic and international markets, the company focuses on innovation and strategic global expansion to drive sustainable growth.

## Business Challenge

The pharmaceutical company received an FDA notification for a pharmacovigilance inspection on a Thursday evening, allowing them only 3 days to prepare before the inspectors' arrival at their US office. The company faced several challenges during the inspection preparation, including

1. Inadequate resources at the inspection site
2. Limited time and lack of clear guidance for inspection preparation
3. Inadequate inspection readiness and shortage of subject-matter expertise
4. Disorganised documentation and segregated data sources
5. Absence of a well-defined inspection management plan

## Solution

The company, an existing client of APCER, approached the APCER QA team for urgent inspection readiness support. Leveraging its extensive experience in successfully managing various regulatory inspections, such as those by the FDA, the EMA, the Federal Institute for Drugs and Medical Devices (BfArM), and the MHRA, APCER promptly initiated a structured, end-to-end approach to ensure seamless execution. Despite the short notice, the APCER team

- Conducted an immediate Inspection Readiness Meeting to coordinate the next steps and gather all preliminary information
- Performed a comprehensive gap analysis of the client's existing systems
- Identified key areas requiring immediate attention for inspection preparation
- Established a Core Inspection Management Team to oversee the inspection process, including key stakeholders from both APCER and the client. The team comprised 13 key stakeholders - 7 from the client (2 onsite and 5 offsite) and 6 from APCER (1 onsite and 5 offsite)
- Ensured in-person presence of the APCER Functional Head and the Subject Matter Expert (SME) at the client's US office to manage on-site inspection activities
- APCER ensured readiness through strategic, high-impact initiatives:
  - Conducted inspection hosting trainings
  - Organised mock interview sessions
  - Set up a 'war room' and conducted a Readiness Workshop
  - Identified a critical list of 22 anticipated inspection documents and managed the end-to-end collation of these materials in partnership with the client
  - Implemented a Document Request Management Tracker and a Document Sharing Platform with requisite access control in place
  - Managed all logistics, IT, and administrative requirements, ensuring a seamless environment for the inspection team
- APCER successfully hosted the entire inspection over 4 days, with the client's local team participating from APCER's office, while the SME from APCER hosted the inspection along with other client team members at the client's US site. All interview sessions, document requests, and logistical arrangements were seamlessly managed by the APCER QA team, with support from the functional team and Qualified Person for Pharmacovigilance (QPPV).

This engagement demonstrated APCER's expertise, agility, and commitment to excellence, ensuring full inspection readiness within a tight timeframe.

## Outcome

- Full **inspection readiness** was achieved within 3 days, resulting in a seamless end-to-end hosting experience.
- The FDA inspection concluded with **no Form 483 observations** *(Notice of Inspectional Observations).*
- **The inspectors commended the team's professionalism,** emphasising the smooth conduct of sessions, concise and accurate responses throughout, and prompt document provision.
- **Both the inspectors and the client recognised** the APCER team's commitment, responsiveness, and excellence throughout the engagement. The client expressed high satisfaction with the outcome and APCER's overall inspection management.

## APCER's QA Capabilities

**Well-trained and experienced QA team,** with domain experience of 500+ GVP/GCP audits within the QA team.

**Experience in conducting audits in multiple regions**, including the US, the EU, the UK, and Asia, in various therapeutic areas over a wide range of products, including biologics.

**Hands-on experience in end-to-end QMS services**, e.g., CAPA, deviations, and standard operation procedure (SOP) management by dedicated resources.

**Actively supported and participated in over 100+ regulatory inspections,** , including the US FDA, the UK MHRA, and the EMA.


## Executive Summary

A leading Indian pharmaceutical company faced an unexpected FDA pharmacovigilance inspection with only 3 days to prepare. The company engaged the APCER QA team, whose proven expertise in the FDA and MHRA inspections ensured rapid, end-to-end readiness. Through structured planning, expert gap analysis, and on-site management, APCER delivered flawless inspection hosting. The inspection concluded successfully, with no Form 483 observations. APCER earned a recommendation from the FDA inspectors and high appreciation from the client for their professionalism and excellence.


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Learn more at www.apcerls.com or contact us at one of our global offices:
Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120
UK: (+44) 208 326 3220 • Asia: (+91) 79 6677 8600

For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com