APCER LIFE SCIENCES
Together for better health

CASE STUDY

Inspection Readiness: Supporting the pharma company in ensuring regulatory compliance with highest standards

Therapeutic area: Multiple therapies

Product type: Drugs

Geography: US, EU

Product life cycle stage: For all products through the product lifecycle

About the Client

The client is a global pharma company with a global presence in 40 countries and has experience across major therapeutic segments of cardiovascular (CV), central nervous system (CNS), gastrointestinal system, diabetology, pediatrics, and complex areas such as oncology with an advanced research and development (R&D) capability. It also had several innovative products addressing the needs of growing therapeutic areas such as gastroenterology, cardiology, diabetology, psychiatry, neurology, anti-bacterial, anti-infectives, and pain management.

Business Challenge

The pharma company was notified of a pharmacovigilance inspection by FDA Inspectors, 3 days prior to their arrival.

There were several challenges such as:

- limited time for inspection preparedness,
- lack of clarity on inspection readiness and know-how, and
- limited resources at the inspection site, cluttered documentation, and segregated data sources.

Overview - Inspection Readiness

Pharmaceutical, medical device, and biotech companies are constantly required to be ready for the Food and Drug Administration (FDA) and European Union (EU) Authority inspections. While some inspections are usually pre-determined (e.g., Medicines and Healthcare products Regulatory Agency [MHRA]), others are mostly unannounced (e.g., FDA). It is, therefore, critical to have a team and a system in place to ensure that all inspections are carried out effectively with minimum additional preparation. The FDA's safety-related inspections grew 66% during the period from 2011 to 2016. Further, the FDA is planning to double their foreign inspections annually over the next 5 years, as mandated by the US Food Safety and Drug Modernization Act, 2011. Pharma companies continually strive to improve processes and systems through a well-implemented quality management system (QMS) for demonstrating regulatory compliance. A trained and experienced quality assurance (QA) team with domain expertise in Good Clinical Practice and Good Pharmacovigilance Practice (GCP/GVP) and an effective QMS is, therefore, a mandate for any pharma company. A QMS ensures that the company is keeping up with changes controls, deviations, corrective actions preventive actions (CAPAs), and any outstanding action items from previous audits. The company must ensure that organizational charts, metrics, and training requirements are in place.

Solution

The pharma company approached the APCER QA team. The team, based on its rich experience for hosting FDA and MHRA Inspections, acted swiftly to:

- Gather all the preliminary information and immediately conduct a gap analysis of existing systems within 3 days and identify key areas for inspection preparation.
- Ensure the inspection preparedness of the personnel at the client site by:
  - conducting trainings,
  - conducting mock interviews,
  - conducting war room readiness workshop,
  - documenting request management trackers,
  - advising how to attend interviews with the inspector, particularly in difficult situations throughout the inspection, and
  - covering all information technology (IT) and administrative aspects, and
- Communicate a clear plan for successful inspection preparedness that was documented for the team to provide continuous inspection support.

Outcome

- The pharma company successfully hosted the FDA inspection with no form 483s (Notice of Inspectional Observations).
- The site personnel were well appreciated by the inspectors for apt responses and for providing the required documents in a timely manner.
- The inspected processes demonstrated high standards of regulatory compliance.

Our Quality Assurance Capabilities

Well-trained and experienced QA team with domain experience of more than 500+ GVP and GCP audits within the QA team.

Experience in conducting audits in multiple countries, including USA, EU, and Asia, in various therapeutic areas on 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.

Partnering of and support to 100+ regulatory inspections.

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APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2013, and ISO 27701:2019 certified company.

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