

GCP Audits in EU requiring local language competency for a biopharma company



Therapeutic area : Neurology



Product type : Drugs



Geography : USA, EU, Australia



Product lifecycle stage : Clinical trial phase III



About the client

The client is an advanced clinical-stage drug development company creating the next generation of therapeutics to treat neurological and other neuroinflammation-related disorders.



Business challenge

The company wanted preparedness for regulatory inspections. They had an urgent need for trained and experienced auditors with proficiency in local norms and language expertise in target European Union countries. The local regulatory authorities wanted all the documents to be compliant with local norms. They were evaluating options for building in-house capabilities versus engaging with established service providers who provide quality auditing services.



Overview

- ◆ International Council of Harmonisation (ICH) E6(R2) mandates health authority inspectors to emphasize strongly on source data documentation and verification, its audit trail, data integrity, risk-based trial management, and investigator oversight. Auditing of clinical trials is necessary to assure that the rights and safety of patients are protected; reported trial data are accurate, complete, and verifiable from source documents; and that the conduct of the trial is in compliance with the protocol, good clinical practice (GCP), and applicable regulatory requirements. The sponsor of a clinical trial is responsible for implementing quality systems, including the development of an audit plan for the trials they manage. Audits are designed to assess and assure the reliability and integrity of the sponsor's trial systems per the local regulatory requirements. Independent assessment of all clinical trial-related activities, processes, and protocol compliance are essential to any pharma company concerned with quality management. Independent GCP audits provide insight into the quality of the trial conduct as well assure compliance to standard operating procedures (SOPs) and protocols. Audits should be conducted to identify process gaps, to rectify and improve the system, and to prevent reoccurrence of any non-compliance.



Solution

The biopharma company engaged with APCER Life Sciences, who already has an established quality assurance (QA) services portfolio and a team of trained and experienced auditors across geographic locations per client specifications.

- ◆ With in-depth understanding of the company requirements, APCER formed a cross-functional team of auditors and physicians with 15+ years of GCP audit experience and proficiency in 5+ local languages in the EU region.
- ◆ APCER's team of experts helped the company to review all the documents in the local language and ensured oversight of the study.



Outcome

- ◆ The APCER team has been contracted for a series of GCP audits. The initial assignment has been, subsequently, deployed on a long-term basis.
- ◆ Assured compliance for clinical trial study on a real-time basis through high quality and local language GCP Audits.
- ◆ Increased total cost of ownership (TCO) savings when compared to in-house build option.

Quality Assurance Capabilities

- ◆ Well-trained and experienced QA team with domain experience of more than 500+ GVP and GCP audits.
- ◆ Experience in conducting audits in multiple countries, including USA, EU, and Asia, in various therapeutic areas over a wide range of products, including Biologics.
- ◆ Hands-on experience in end-to-end quality management system (QMS) services, e.g., Corrective Action Preventive Action (CAPA), deviations, and standard operating procedure(SOP) management by dedicated resources.
- ◆ Participation and support for over 50 global PV inspections of clients since 2017.

Together for better health

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.

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