APCER LIFE SCIENCES
Together for better health

CASE STUDY

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

Therapeutic area: Neurology

Product type: Drugs

Geography: US, EU, Australia

Product life cycle stage: Clinical trial phase 3

About the Client

The client is an advanced clinical stage drug development company creating the next generation of therapeutics to treat neurological and other neuro-inflammation 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 - GCP Audits

International Council of Harmonisation (ICH) E6(R2) mandates health authority inspectors to emphasize strongly on source data documentation and verifcation, 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 verfiable from source documents.

The conduct of the trial should be 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.

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

APCER LIFE SCIENCES | Together for better health
Part of APC Group

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.

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) 11 4650 0802

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