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CASE STUDY

Evaluating GLP compliance ahead of a regulatory submission

BACKGROUND

The client (a small-sized, UK based, pharmaceutical company) was developing a new product and was preparing to submit a Clinical Trial Authorization (CTA) application to the Medicine and Healthcare products Regulatory Agency (MHRA) ahead of initiating clinical trials.

The pre-clinical trials were being conducted at third-party vendors. These contract research organisations (CROs) were full-service animal facilities and were conducting the in-life phases and laboratory analysis.

Given the criticality of GLP, RiverArk were engaged to audit these CROs ahead of the CTA application. It was key that any gaps in compliance were identified and the audits needed to be conducted in a timely manner. RiverArk were engaged late in the process and needed to be flexible to fulfil the deadline of the client.

OBJECTIVE

Perform two audits of compliance, one of each CRO, to assess compliance to GLP and the study plans.

The audits included general review of the GLP systems, including facilities, equipment, personnel, and procedures. As well as comprehensive review of the study management and data.

- Conduct each audit independently of each other while keeping the requirements of client in scope. One CRO was a large-scale, global organisation and the other was a single facility organisation.

Review of specific issues identified by the client including deviations to study plans/Standard Operating Procedures (SOPs) and Corrective and Preventative Actions (CAPAs).

Expedited reporting of the outcome of the audits in order to allow the sufficient time for follow-up of the resolution of issues identified.

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SOLUTION

Experienced GLP auditors well-versed in the laboratory analysis that was being performed, conducted comprehensive onsite audits of both CROs focusing on critical areas such as:

- Facilities, design and maintenance
- Animal husbandry and care
- Laboratory areas and operations
- Test item handling and administration
- Data collection, recording, and archiving
- Equipment calibration and maintenance
- Quality assurance unit (QAU) operations
- Adherence to standard operating procedures (SOPs)
- Study Director (SD) oversight of client studies
- Raw study data including paper and electronic data

Adopting a risk-based strategy, the auditors prioritised areas that had the potential to have the highest impact to the study integrity.

The outcome of the audit was reported via an audit debrief meeting with the client a few days following the end of onsite audit. Additionally, two audit reports were prepared for each audit. An observation only report was prepared to be shared with the auditee for their response. A full narrative audit report, detailing the conduct of the audit including all personnel interviewed, all areas visited, all documentation reviewed, and all equipment inspected.

Responses from the auditee were evaluated, including Corrective and Preventative Actions (CAPA) that the CROs implemented. At the client's request, feedback was discussed via video call if further action is required.

OUTCOMES

The client were able to work with the CROs to address the identified process gaps and non-compliances.

The GLP compliance of the client's studies was assured. Successful audits of the CROs assured them and the client of the process and study conduct, strengthening their working relationship. This gave the client confidence in their CTA submission to the MHRA.

Partnering with Riverark ensures a thorough GLP compliance assessment, minimizing risk and streamlining your regulatory submission. Our experts identify gaps, mitigate issues, and provide tailored solutions for a smooth approval process. Trust Riverark for precision, expertise, and reliability.

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