

## OBJECTIVES

A pharmaceutical company was nearing completion of a multi-site, multinational registration trial. They had outsourced clinical development and regulatory submission, while a core team of experts maintained oversight. To strengthen operations, they brought in industry experts to bolster their QA team.

As the submission deadline approached, challenges intensified. The company needed to significantly increase QA oversight, but the CRO they used for development was too close to the project to provide impartial QA services. In-house QA soon identified multiple quality issues within a short period.

Compounding the situation, a local inspectorate's routine GCP inspection at a clinical site revealed significant non-compliances, including unacceptable practices by the investigator. This triggered "for-cause" inspections at other clinical sites across two different regions. Sponsor monitor inspections were anticipated at both the sponsor's facilities and the CRO, creating further pressure.

# CASE STUDY INSPECTION READINESS

RiverArk's strategy tackling sponsor's challenges

## AT A GLANCE

### Challenges

- CRO's QA services lacked objectivity.
- In-house QA found multiple issues.
- Local inspection revealed non-compliances.
- "For-cause" inspections announced regionally.
- Sponsor and CRO inspections expected.

### Benefits

- Head count savings
- Inspection Readiness training
- Whole project completed in 7 weeks

## SOLUTIONS

RiverArk tackled the sponsor's challenges with a robust three-pronged strategy:

- Comprehensive Quality Review and Reporting:
  - Oversight Summary: Assessed CRO and sponsor.
  - Issues Report: Analysed and categorised all identified and overlooked quality issues against compliance standards.
  - Regulatory Communication Strategy: Developed a transparent fact sheet for regulators and a detailed communication plan.
  - Risk Exposure Status: Prepared reports for the sponsor's management and advisory boards, guiding strategic decisions on the registration pathway.
- Targeted Quality Assurance Audits:
  - Risk-Based Audits: Planned and executed audits of vendors, key investigator sites, and regulatory processes related to submission documentation, ensuring all critical areas were scrutinised.
- Inspection Readiness Program:
  - Program Development: Created detailed processes, documentation templates, communication plans, escalation trees, and decision matrices.
  - Training: Provided comprehensive inspection readiness training for sponsor teams, CROs, and key investigator sites.
  - Mock Inspections: Conducted realistic mock inspections at high-risk sites based on a risk assessment model.

## OUTCOME

RiverArk's team, included GCP audit experts and inspection veterans.



NO HEAD COUNT HAD TO BE INCREASED FOR THE SPONSOR TO SUPPORT THESE CRITICAL QA ACTIVITIES



THE RISK EVALUATION PERFORMED ON THE VARIOUS ELEMENTS OF THE PROJECT WAS ADEQUATE & ACCEPTABLE TO THE REGULATORS.



THE OUTCOME OF THE INSPECTIONS WAS IN FAVOUR OF THE SPONSORS