

# Accelerating QA Audit Compliance for a Mid-Sized Biopharma Company

## Background

### Client background

- Within Biopharmaceutical Industry
- Mid Sized Biopharma Company
- Specializing in Oncology Therapeutics
- Global Supply Chain
- Numerous vendors
- Derailed Audit Plan Due to Shifting Priorities
- Stalled Audit Programme Causing Audit Gaps



### Challenge

- **Zero Execution on the Annual Plan:**

Despite meticulous initial planning, no audits had been initiated. This left a backlog of over 30 planned audits across vendors, CROs, and investigator sites, risking non-compliance with internal policies and external regulations.

- **Irrelevant Site Selections:**

Investigator sites selected at the year's outset no longer aligned with current risk exposures. Clinical trial enrolment shifts and emerging data integrity concerns at certain sites rendered the original selections obsolete, potentially exposing the company to unaddressed vulnerabilities in trial conduct.

- **Inaccurate Risk Assessments:**

Vendor risk calculations, based on outdated data, had led to misreported risks. High-risk vendors were under-audited, while low-risk ones consumed disproportionate resources, skewing the overall program effectiveness.

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These issues compounded operational pressures, as the QA team—already stretched thin—lacked the bandwidth, expertise, and local presence to pivot quickly. Failure to complete the audits risked regulatory citations, delayed product launches, and strained relationships with key stakeholders.

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## RiverArk Solutions

RiverArk was engaged as a specialized QA consultancy to rescue the audit program, leveraging our expertise in risk-based auditing and global regulatory compliance. Our approach emphasized agility, documentation, and a multipronged execution strategy to deliver results within the compressed timeline.

- **Reassessment and Revision:**

We initiated a rapid risk reassessment using RA's proprietary quantitative framework, incorporating real-time data on vendor performance, trial metrics, and regulatory intelligence. This involved scoring over 50 entities on factors like data integrity, patient safety, and historical compliance. Risks were recalibrated, identifying 12 high-priority vendors previously underrated and deprioritizing 8 low-risk sites. Each revision was documented with clear impact analyses

- **Revised Audit Schedule:**

The original plan was overhauled into a dynamic 15-week schedule, prioritizing high-impact audits while balancing resource demands. We segmented the portfolio into three audit modalities for efficiency:

- **Desktop Audits:**

For low-to-medium risk vendors requiring document reviews only.

- **Remote Audits:**

For medium risk vendors, utilizing secure video platforms and shared digital repositories.

- **Onsite Audits:**

Reserved for critical high-risk entities needing physical verification including investigator sites.

**Multipronged Strategy with Local Resources:** A hybrid team consisting of 25 auditors, including local experts in key regions was deployed helping to minimize travel disruptions. Enabling the completion of the full annual plan: 5 desktop audits (focusing on low risk service providers), 12 remote audits (targeting CROs, IXR's service provider, ePRO service provider and mid-tier vendors), and 16 onsite audits (covering high-risk investigator sites and key suppliers such as CDMOs). Audits were staggered across weeks 1-15.

**Operational Excellence:** Dedicated project managers oversaw the program, treating each audit as a mini project with Gantt charts for milestones. Meticulous planning included site-specific checklists, pre-audit questionnaires, and contingency protocols for delays. A clear audit strategy was co-developed with the client's QA leads, emphasizing standardized reporting templates to streamline CAPA (Corrective and Preventive Actions) integration.

**This structured intervention transformed a stalled initiative into a high-velocity operation, all while maintaining GxP and ISO-compliant documentation.**



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### Outcome

RA's intervention not only salvaged the audit year but exceeded the client's expectations, delivering 100% completion of the revised plan within the 15-week window—two weeks ahead of schedule. Key achievements included:

**Full Compliance Achievement:** All 33 audits (5 desktop, 12 remote, 16 onsite) were executed flawlessly. All CAPAs resulting from these audits were entered into the Quality System of the company. This fortified the company's risk profile, reducing overall exposure by 35% as validated by post-audit metrics.

**Long-Term Partnership:** The success has now fostered a multi-year engagement with RA, including ongoing risk monitoring tools. The company avoided potential FDA observations during a subsequent inspection and accelerated a Phase III trial submission by three months.

**Enhanced Risk Intelligence:** The reassessed risks provided a refreshed baseline for the next annual plan, with documented decision impacts enabling the QA team to justify shifts to leadership and regulators. Vendor relationships improved, with two high-risk partners entering remediation partnerships.

**Operational Efficiencies Gained:** By tracking audits as individual mini projects via a centralized dashboard, RA reduced planning time by 40% compared to historical benchmarks. The client's QA team reported a 25% bandwidth recovery, allowing refocus on strategic initiatives like new trial launches.

RA helped turn QA crises into compliance triumphs, empowering mid-sized Biopharmas to navigate regulatory complexities with confidence and precision.



# WHY PARTNER WITH RIVERARK?

At RiverArk, we position quality as a cornerstone of compliance and operational integrity within Medical Affairs and Scientific Communications. Our QA and life sciences experts provide comprehensive support to ensure that scientific exchange, publications, and medical information activities meet the highest standards of regulatory and ethical governance through:

**Comprehensive Quality Oversight** – Supporting adherence to Good Publication Practice (GPP), EFPIA/PhRMA/ABPI codes, and organizational SOPs governing medical affairs outputs.

**Data Integrity and Governance** – Embedding ALCOA+ principles across medical information systems, publication management, and scientific communications to ensure accuracy, traceability, and audit readiness.

**Risk-Based Quality Management** – Applying structured QA methodologies to proactively identify compliance risks, mitigate reputational and regulatory exposure, and reinforce the reliability of scientific materials.

**Process Harmonisation and Optimisation** – Enhancing review, approval, and dissemination frameworks to align with regulatory expectations while improving efficiency and consistency of deliverables.

**Audit and Inspection Preparedness** – Conducting independent quality assessments, mock audits, and targeted training to prepare Medical Affairs and Communications teams for internal QA reviews, regulatory inspections, and external partner evaluations.

**THE IMPACT: COMPLIANCE, EFFICIENCY & MARKET CONFIDENCE**

## 1. Reduced Compliance Risks

Minimise the likelihood of regulatory findings and costly remediation efforts.

## 2. Increased Operational Efficiency

Cut reporting delays and streamline adverse event case management.

## 3. Enhanced Market Reputation

Build regulatory trust and stakeholder confidence with a gold-standard PV framework.

