

# Enhancing GCP Compliance Through Risk-Based Auditing at Biotech Company



## Client background

- Pioneering Biotech Company
- Development of novel gene therapies
- Phase II and Phase III trials underway
- Facing increased complexity in managing GCP compliance
- Struggle to keep pace



## Challenge

- **Reactive Auditing:**

The companies audit schedule was largely reactive, addressing issues as they arose rather than proactively identifying potential risk.

- **Resource Constraints:**

The QA department lacked the resources to conduct comprehensive risk assessments and develop a strategic audit plan.

- **Inconsistent Vendor Oversight:**

Monitoring of third-party vendors was inconsistent, leading to potential compliance gaps.

- **Rising Non-Compliance Findings:**

An increasing number of non-compliance findings were recorded during routine audits, indicating systemic issues.

- **Difficulty in Prioritizing Audits:**

with multiple ongoing clinical trials, it was difficult to determine which audits should be prioritized.

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These challenges threatened the quality and reliability of their clinical trial data, potentially delaying regulatory submissions and impacting patient safety.



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## Company Overview

Biotech company engaged RiverArk, a specialized quality consulting firm with extensive experience in GCP auditing and risk management. RiverArk conducted a thorough assessment of Biotech's clinical development program, including:

## Assessment

- **Review of Existing Audit Processes:** An analysis of the company's current audit procedures, documentation, and reporting.
- **Analysis of Non-Compliance Data:** Review of past audit findings and CAPA (Corrective and Preventive Action) effectiveness.
- **Evaluation of Vendor Management:** Assessment of vendor selection, qualification, and monitoring processes.
- **Clinical Program Risk Assessment:** A comprehensive risk assessment of ongoing clinical trials, considering factors such as trial phase, complexity, patient population, and geographic location.
- **Process mapping:** Mapping critical processes to identify potential compliance gaps.

## High-Risk Areas Identified

- Inadequate documentation of investigational product handling.
- Inconsistent monitoring of investigator sites.
- Lack of robust vendor oversight for specialized services.
- Potential for data integrity issues due to software validation gaps.



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## RiverArk Solution

Implementation of a multi-faceted solution to address biotech's challenges

### Risk-Based Audit Schedule Development:

- Conducted a detailed risk assessment of the clinical development program, identifying high-risk trials and processes.
- Developed an annual audit schedule that prioritized high-risk areas, including investigator sites, vendors, and internal processes.
- Implemented a risk-scoring system to objectively assess and rank audit priorities.

### Internal Process Audit Enhancement:

- Developed a comprehensive list of internal process audits, including data management, pharmacovigilance, and quality control.
- Created standardized audit checklists and templates to ensure consistency and efficiency.

### Vendor Qualification and Monitoring:

- Assessed the qualification and performance of critical vendors, such as central laboratories and CROs.
- Developed a vendor oversight plan that included regular audits and performance reviews.
- Developed a vendor risk assessment to identify high-risk vendors that required additional auditing.

### Training and Capacity Building:

- Provided training to Biotech's QA staff on risk-based auditing principles and best practices.
- Assisted in developing and implementing standard operating procedures (SOPs) for audit management and CAPA.



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## Results and Outcomes

The implementation of RiverArk's recommendations resulted in significant improvements for Biotech company:

- **Improved GCP Compliance:** A reduction in non-compliance findings during audits, demonstrating enhanced adherence to GCP guidelines.

- **Proactive Risk Management:** A shift from reactive to proactive auditing, enabling the company to identify and mitigate risks before they impact trial quality.

- **Increased Audit Efficiency:** Optimized audit schedules and standardized processes led to more efficient use of resources.

- **Enhanced Vendor Oversight:** Improved monitoring of third-party vendors, ensuring consistent quality and compliance.

- **Strengthened Data Integrity:** Increased confidence in the reliability and accuracy of clinical trial data, facilitating regulatory submissions.

- **Improved regulatory readiness:** the company was better prepared for regulatory inspections.

- **Increased QA department efficiency:** The QA department was able to focus their resources on the highest risk areas.

Biotech company successfully navigated the complexities of its expanding clinical development program, ensuring the integrity of its clinical data and safeguarding patient safety. The collaboration with RiverArk resulted in a robust and sustainable GCP compliance program, providing a solid foundation for future growth and regulatory success.



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