RiverArk®
Quality Delivered

CASE STUDY

OPTIMIZING PV COMPLIANCE

Navigating the Complexity of Pharmacovigilance Compliance

OBJECTIVES

For a medium-sized pharmaceutical client, the objective was to enhance the effectiveness and authority of the Qualified Person for Pharmacovigilance (QPPV) in influencing the performance of the Pharmacovigilance (PV) system. This involved ensuring that the QPPV's role, influence, and autonomy were clearly defined and documented within the client's internal procedures.

An analysis of the organisational structure was required to align with best practices seen in companies with similar frameworks, ensuring a robust governance model.

Additionally, evaluating the independence of the QA function was critical, particularly given the multiple roles within organisation, to prevent conflicts of interest and maintain a high standard of regulatory compliance and oversight within the PV system.

SOLUTION

- Strengthened QPPV Authority: Enhanced the QPPV's capacity to effectively impact PV system performance through clear governance frameworks. The QPPV's authority was solidified in SOPs, ensuring a clear mandate for independent decision-making and escalation of PV concerns.
- Process Mapping: Detailed process mapping for QPPV responsibilities was performed that helped to identify the procedural gaps which were not aligned with actual practices.
- Clarified QPPV Role: Revised their documentation to explicitly describe the QPPV's influence and autonomy, ensuring alignment with regulatory expectations. and responsibilities. This includes recommendations for updates in applicable procedural documents.
- Organisational Alignment: Conducted a thorough analysis of client's organisational structure, aligning it with industry standards to optimise PV system oversight. Defined roles and responsibilities across departments clearly depicting QPPV authority and reducing decision-making time on safety issues by 25%.
- Ensured QA Independence: Established robust boundaries and processes to safeguard the independence of the QA function, mitigating ambiguity in procedural documents.

AT A GLANCE

CHALLENGES

- Alignment with regulations
- Ensuring QA independence
- Ensuring QPPV influence is evident from processes
- SOPs alignment with practices

BENEFITS

- Rigorous audit execution
- Regulatory compliant documentation
- Improved effectiveness of QPPV
- Organisational credibility

MILIND NADGOUDA

Co-founder & Director of Operations

"Pharmacovigilance compliance isn't just about meeting regulatory requirements—it's about building a culture of quality that ensures patient safety and business resilience. At RiverArk, we turn compliance into a strategic advantage, helping our partners stay inspection-ready and ahead of evolving regulations."

Navigating the Complexity of Pharmacovigilance Compliance

OUTCOMES

- 5 SME INTERVIEWS WERE PERFORMED AS PER DEFINED SCOPE AND AGENDA.
- 50% INCREASE IN SPECIFIC DETAILS FOR REQUIRED UPDATES IN SOP
- 8 KEY DOCUMENTS WERE RECOMENDED FOR REVISION TO REDUCE AMBIGUITY
- INCREASED QA ACCOUNTABILITY AND REDUCED SAFETY DECISION-MAKING TIMEFRAMES
- GUIDED SOP UPDATES TO ENSURE QA INDEPENDENCE AND ASSESSMENT OBJECTIVITY

WHY PARTNER WITH RIVERARK?

At RiverArk, we transform compliance from a regulatory obligation into a competitive advantage. Our team of GxP, QA, and PV specialists help companies navigate complex regulations and build resilient, efficient pharmacovigilance systems through:

- **End-to-End Compliance Support** – We ensure full adherence to ICH E2E, GVP Modules, and global safety reporting guidelines.
- **Robust Data Governance** – Implementing ALCOA+ principles to strengthen data integrity and audit readiness.
- **Risk-Based Approach** – Leveraging predictive analytics to enhance signal detection and mitigate compliance risks.
- **Process Optimisation** – Automating workflows to improve case processing efficiency and reporting accuracy.
- **Regulatory Inspection Readiness** – Conducting mock audits and GVP compliance assessments to ensure seamless regulatory interactions.

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.

THE IMPACT: COMPLIANCE, EFFICIENCY & MARKET CONFIDENCE

CONTACT US

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WE DELIVER QUALITY RESULTS