



CASE STUDY

PV QA AUDIT PROGRAMME

AT A GLANCE

CHALLENGES

- Compliance challenges
- Numerous auditing parties
- Complex management hurdles
- Diverse business partners
- Intensive, risk-based audits
- Internal system complexities
- Inter-departmental audits

BENEFITS

- Rigorous audit execution
- Exceeded audit objectives
- KPI-aligned department performance
- High-quality processes standards
- SOP compliance improved

OBJECTIVES

A mid-sized European company specialising in pharmaceuticals, biopharmaceuticals, OTC, and cosmetic products faced significant compliance challenges in its global auditing program. With operations spanning multiple countries and involving diverse business and licensing partners, the company required a rigorous, risk-based audit approach to meet regulatory demands.

Managing these complexities while ensuring the integrity of its pharmacovigilance project was a major hurdle. Additionally, internal system audits were needed to address interdepartmental and cross-departmental processes, ensuring smooth and compliant operations. Strengthening oversight and enhancing audit execution were crucial to upholding quality standards and minimising risks.

This case study explores how the company tackled these challenges with input from RiverArk, refined its audit strategies, and reinforced its compliance framework, highlighting its dedication to quality, innovation, and regulatory excellence as a leader in the pharmaceutical and cosmetics industries.

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RiverArk's three-pronged strategy to address the company's compliance and audit challenges:

- **Rigorous Audit Adherence:** Enforced strict compliance with the established audit program, ensuring all activities were meticulously aligned with predefined audit plan and associated schedule.
- **Pharmacovigilance Expertise:** Our team deployed auditors with deep expertise in GVP, ensuring that audits were conducted with a high level of precision and in accordance with the latest regulatory guidelines. Our industry knowledge was crucial for identifying and mitigating potential compliance risks.
- **Strategic Expectation Management:** We meticulously planned and structured audit scopes, agendas, and methodologies to align with stakeholder agreements, facilitating detailed cross departmental audits.

Additionally, targeted ad hoc audits on other GxP requirements were conducted by experts with deep regulatory insight, ensuring proactive issue identification and continuous improvement. This approach strengthened the company's compliance framework, driving excellence in QA and regulatory conformance.

OUTCOMES



8 AUDITS CONDUCTED RIGOROUSLY WITHIN 16 WEEKS AS PER DEFINED SCOPE AND AGENDA.



ALL ESSENTIAL REPORTS DELIVERED WITHIN THE SET TIMEFRAME.



PERFORMANCE MET ALL CLIENTS' KPIS FOR TIMELY DELIVERY.



TEAM RIGOROUSLY TRAINED TO UPHOLD AND EXCEED SOPS AND COMPLIANCE EXPECTATIONS.



4 ADDITIONAL AUDITS SCHEDULED FOR YEAR-END TO EXCEED OBJECTIVES.

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