



Independent Pharmacovigilance Due Diligence Audit to Enable Global PV System Integration Following Acquisition

Fidelity Health Services

EXECUTIVE SUMMARY

This case study outlines an independent **Pharmacovigilance (PV)** due diligence audit conducted by **Fidelity Health Services (FHS)** following the acquisition of a specialty biopharmaceutical company by a global pharmaceutical organization.

The engagement focused on evaluating the readiness of the acquired company's PV system for integration into

the parent organization's global PV framework. The audit enabled identification of **compliance gaps**, risk mitigation strategies, and provided a structured roadmap for regulatory-compliant PV system integration.

BACKGROUND



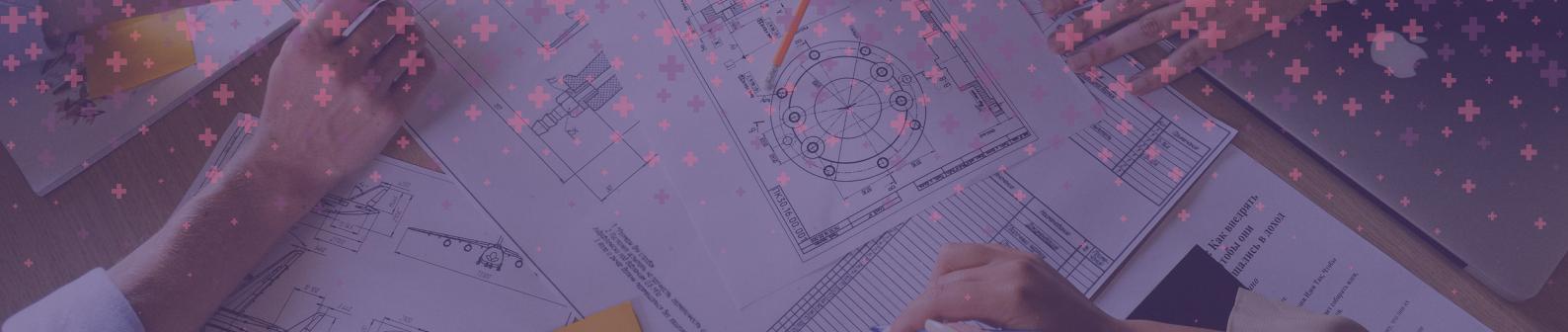
The client, **Global Pharma Group (Client A)**, is a leading Indian multinational pharmaceutical company with a diversified portfolio spanning prescription medicines and consumer healthcare products.

The organization operates across more than **30 countries**, including **Latin America, Southeast Asia, Africa, and CIS regions**.

The company manufactures and markets over **100 approved products across 25+ countries**, complying with major global regulatory standards such as **US FDA, EU GMP, and ANVISA**.

It operates a mature, centralized Pharmacovigilance system aligned with international regulatory expectations.





PROBLEM STATEMENT

Following the acquisition of a specialty biopharmaceutical company (Company ABC), Global Pharma Group planned to integrate the acquired company's PV system into its centralized global PV framework. However, due to the regulatory sensitivity associated with PV system mergers. Given these needs, an independent PV due diligence audit was considered critical.

THE ORGANIZATION REQUIRED:

- 1 Independent assessment of the acquired company's PV system
- 2 Identification of regulatory, operational, and compliance gaps
- 3 Evaluation of readiness for system integration
- 4 Risk mitigation before management approval and system consolidation

GOALS

The key objectives of the engagement were to:

	Perform an independent PV system assessment of the acquired entity		Provide actionable recommendations for remediation
	Identify critical, major, and minor compliance gaps		Support informed decision-making for PV system integration
	Evaluate inspection readiness and regulatory exposure		Ensure continuity of patient safety and regulatory compliance

STRATEGIC IMPACT FOR THE CLIENT

Fidelity Health Services was engaged as an independent PV audit partner to conduct a comprehensive and objective assessment. The approach included:

	Establishing documented evidence of independent oversight		Evaluation of both operational and quality system elements
	Alignment with global GVP and regulatory expectations		Focus on inspection readiness and compliance sustainability

The audit was conducted by experienced PV Quality Assurance professionals and subject matter experts with global regulatory expertise.



EXECUTION

The engagement involved a comprehensive on-site Pharmacovigilance system audit covering:



PV governance and organizational structure



Safety data collection and case intake processes



ICSR processing, medical review, and regulatory submissions



Signal detection and risk management activities



Aggregate report preparation and oversight



Quality Management System (QMS) and SOP framework



Vendor management and PV agreements



Training, competency management, and documentation controls



Inspection readiness and regulatory compliance mechanisms

The audit was executed using a structured, evidence-based assessment approach aligned with international PV standards.

STRATEGIC IMPACT FOR THE CLIENT

THE AUDIT RESULTED IN:

- 1 Identification of critical gaps requiring immediate remediation
- 2 Documentation of major and minor observations aligned with regulatory expectations
- 3 Practical and prioritized corrective and preventive actions
- 4 Clear roadmap for harmonizing PV systems post-acquisition
- 5 Comprehensive audit report supporting management decision-making

The client gained full visibility into system maturity, risks, and compliance status.



KEY SUCCESS FACTORS / HIGHLIGHTS

- 1 Independent and objective PV due diligence
- 2 Strong alignment with global regulatory expectations
- 3 Risk-based audit methodology
- 4 Actionable, business-focused recommendations
- 5 Enhanced readiness for regulatory inspections
- 6 Support for smooth PV system integration
- 7 Strengthened governance and compliance oversight



CONCLUSION

This engagement demonstrates Fidelity Health Services' expertise in delivering high-impact pharmacovigilance audits for complex post-acquisition scenarios.

Through a structured, regulatory-aligned approach, FHS enabled the client to confidently proceed with PV system integration while minimizing compliance risks and strengthening inspection readiness.

The engagement reinforced the client's commitment to patient safety, regulatory compliance, and quality-driven operations.

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