

Case study

From Regulatory Gaps to Inspection-Ready Operations Across 56 Countries

OUTCOME



56 COUNTRIES

Compliance framework
established



COMPLIANT L-PSMFs

Country-specific
requirements addressed



INSPECTION-READY

Enhanced readiness
across affected markets



NO MAJOR OR CRITICAL FINDINGS

Regulatory inspections
successfully completed

A FRAGMENTED PV FRAMEWORK CREATED COMPLIANCE RISK ACROSS MULTIPLE MARKETS

A global pharmaceutical company inherited **a fragmented pharmacovigilance framework** across Africa and Asia. Local Pharmacovigilance System Master Files (L-PSMFs) were either missing or not aligned with country-specific requirements, creating **significant compliance risks** across numerous markets.

1

Missing
L-PSMFs

2

Country-specific requirements
not consistently addressed

3

Significant compliance
exposure

A COORDINATED COMPLIANCE PROGRAM COMBINED GLOBAL OVERSIGHT WITH LOCAL EXPERTISE

PrimeVigilance mobilized Regulatory Intelligence, Local QPPV, and Project Management expertise to assess local requirements, develop country-specific L-PSMFs, and implement a coordinated compliance program across all affected markets. A structured governance framework **ensured consistent execution and oversight.**

- **Regulatory Intelligence**
- **Local Requirements Assessment**
- **Country-Specific L-PSMFs**
- **Local QPPV Expertise**
- **Central Governance & Oversight**

WHAT MADE IT SUCCESSFUL

Maintaining compliance across dozens of jurisdictions requires more than documentation. It demands a scalable framework that combines global oversight with local expertise.



**GLOBAL
OVERSIGHT**

+



**LOCAL
EXPERTISE**

**= scalable compliance across complex
regulatory environments.**

**Ready to Partner?
Contact Us Today!**

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