

Case study

Restoring PSUR & RMP Compliance Across High-Risk Markets

OUTCOME



COMPLIANCE RESTORED
Across multiple regions



HARMONIZED SUBMISSIONS
One coordinated management process



SUSTAINABLE GOVERNANCE
PSUR/RMP oversight established



NO MAJOR FINDINGS
During regulatory inspections

OVERVIEW | MISSING PSUR SUBMISSIONS AND LIMITED LOCAL VISIBILITY CREATED SIGNIFICANT COMPLIANCE RISK

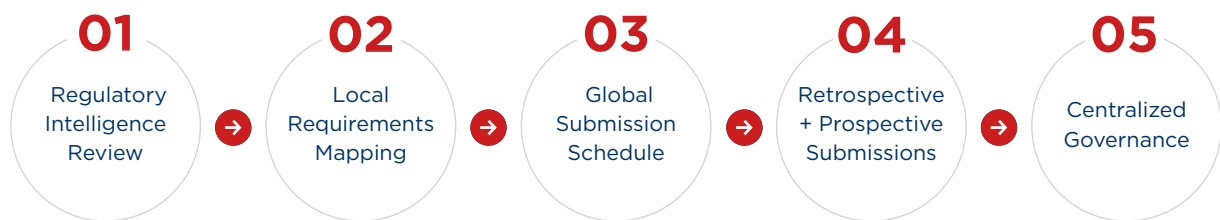
A pharmaceutical company discovered that **required PSURs** had not been submitted in multiple countries and lacked visibility of local reporting obligations across Africa and Asia. The risk of regulatory non-compliance was **substantial**.

Missing required PSUR submissions

Limited visibility of local reporting obligations

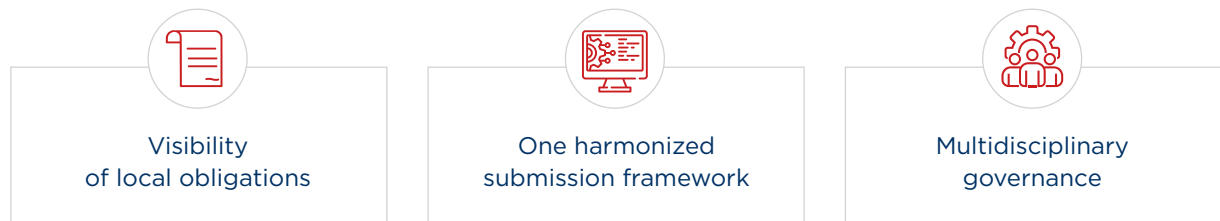
OUR APPROACH | A HARMONIZED GLOBAL SUBMISSION MODEL RESTORED CONTROL AND REGULATORY VISIBILITY

PrimeVigilance conducted a comprehensive Regulatory Intelligence review, mapped local requirements, created a harmonized global submission schedule, and coordinated retrospective and prospective submissions. Regulatory Intelligence, Medical Writing, Local QPPVs, and Project Management worked within **a single governance model**.



Regulatory Intelligence | Medical Writing | Local QPPVs | Project Management

WHAT MADE IT SUCCESSFUL



Regulatory reporting is not merely a submission activity. It is a strategic **compliance function that protects** products, patients, and business continuity.

