

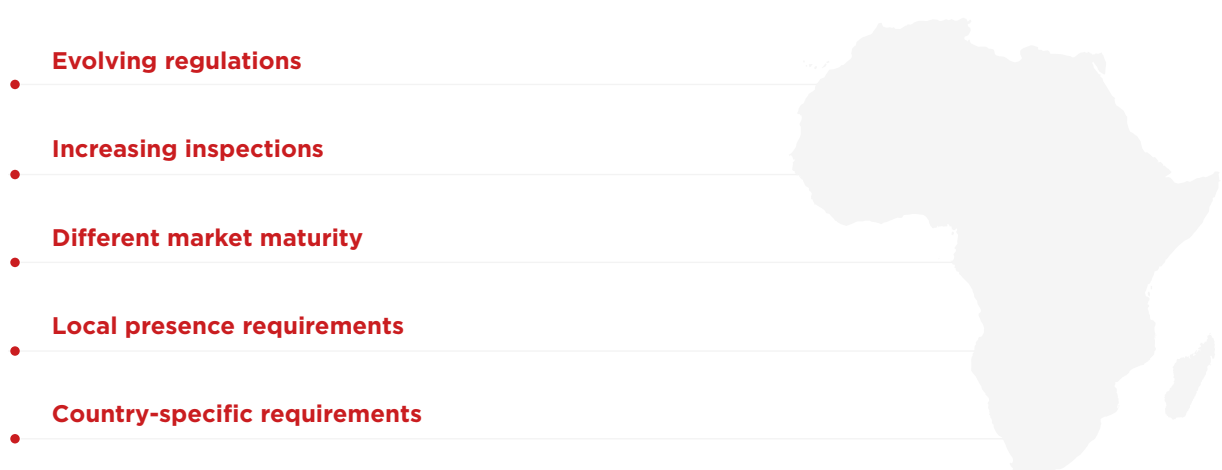
Case study

Turning Africa's PV Complexity into a Scalable Compliance Model

OUTCOME



OVERVIEW | One Region. Diverse Regulatory Requirements.



FROM FRAGMENTED COMPLEXITY TO A SCALABLE OPERATING MODEL

Fragmented — country-by-country, ad hoc

Scalable — governed, repeatable, inspection-ready

A standardized global approach is rarely sufficient; successful expansion depends on a flexible model that can adapt to diverse national requirements while maintaining consistent governance and oversight.

CHALLENGE | COUNTRY-SPECIFIC REQUIREMENTS MAKE PV COMPLIANCE ACROSS AFRICA INCREASINGLY COMPLEX

A global pharmaceutical company sought to establish and maintain compliant local pharmacovigilance oversight across multiple African countries. The operating environment presented several interconnected challenges:

1

TALENT SCARCITY

Limited availability of experienced Local QPPVs and PV specialists.

2

EVOLVING REGULATIONS

Increasingly stringent and differing country requirements.

3

INCREASING INSPECTIONS

Greater regulatory scrutiny requires continuous readiness.

4

OUTSOURCING RESTRICTIONS

Some markets require alternative locally compliant operating models.

5

LOCAL PRESENCE REQUIREMENTS

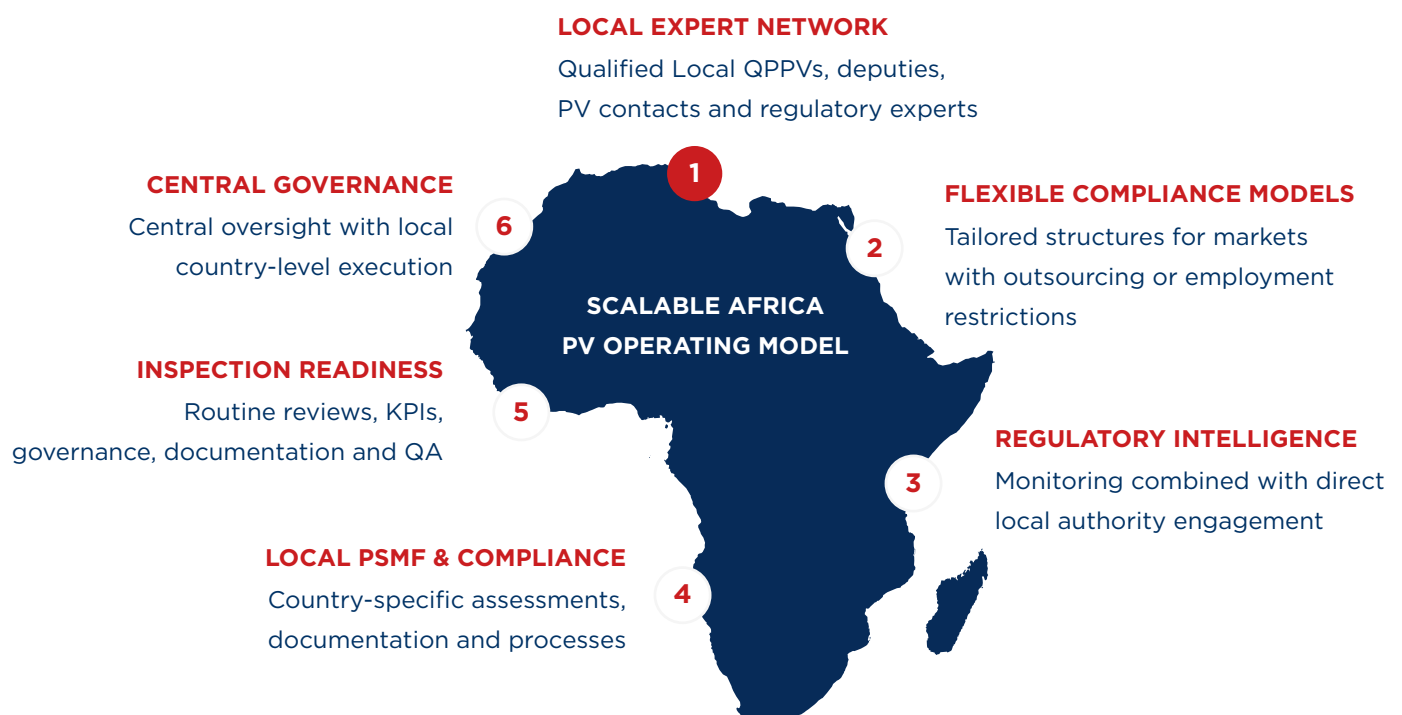
Residency, employment, registration and language obligations.

6

LIMITED REGULATORY INTELLIGENCE

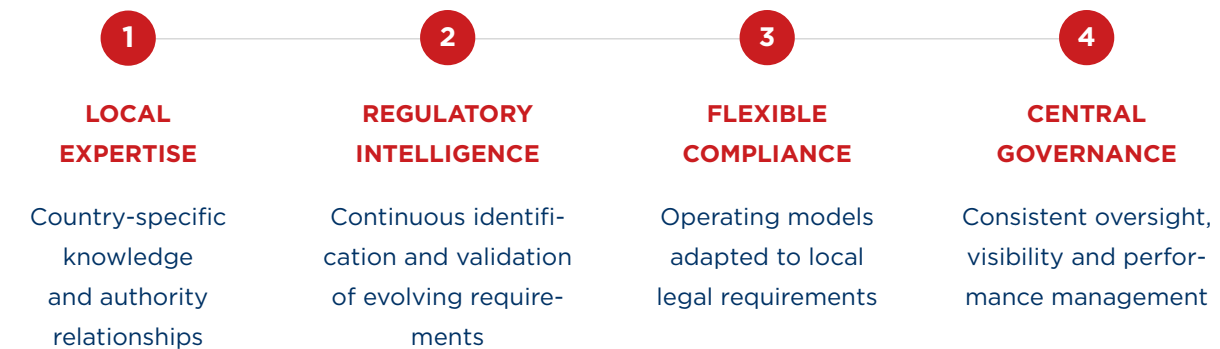
Local requirements are not always easily or consistently accessible.

A FLEXIBLE OPERATING MODEL COMBINES LOCAL EXPERTISE WITH CENTRALIZED OVERSIGHT



WHAT MAKES THE MODEL WORK

Africa's pharmacovigilance landscape is maturing rapidly but unevenly, creating a complex environment in which talent scarcity, regulatory fragmentation, residency obligations, outsourcing restrictions, rising inspection activity, and limited access to regulatory intelligence often interact. For pharmaceutical companies, this makes compliance a dynamic and country-specific challenge rather than a fixed regional standard.



Local expertise where it matters. Central oversight where it counts.

A scalable PV model that helps pharmaceutical companies navigate regulatory complexity and expand across African markets with confidence.

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

info@primevigilance.com
primevigilance.com

