

Case Study

Inspection Readiness and Mock Audit Support



UMSai LLC

Unique Medium for Solutions
and Innovations

WWW.UMSaiLLC.com



(423) 758-6724



info@umsaillc.com

Client Profile

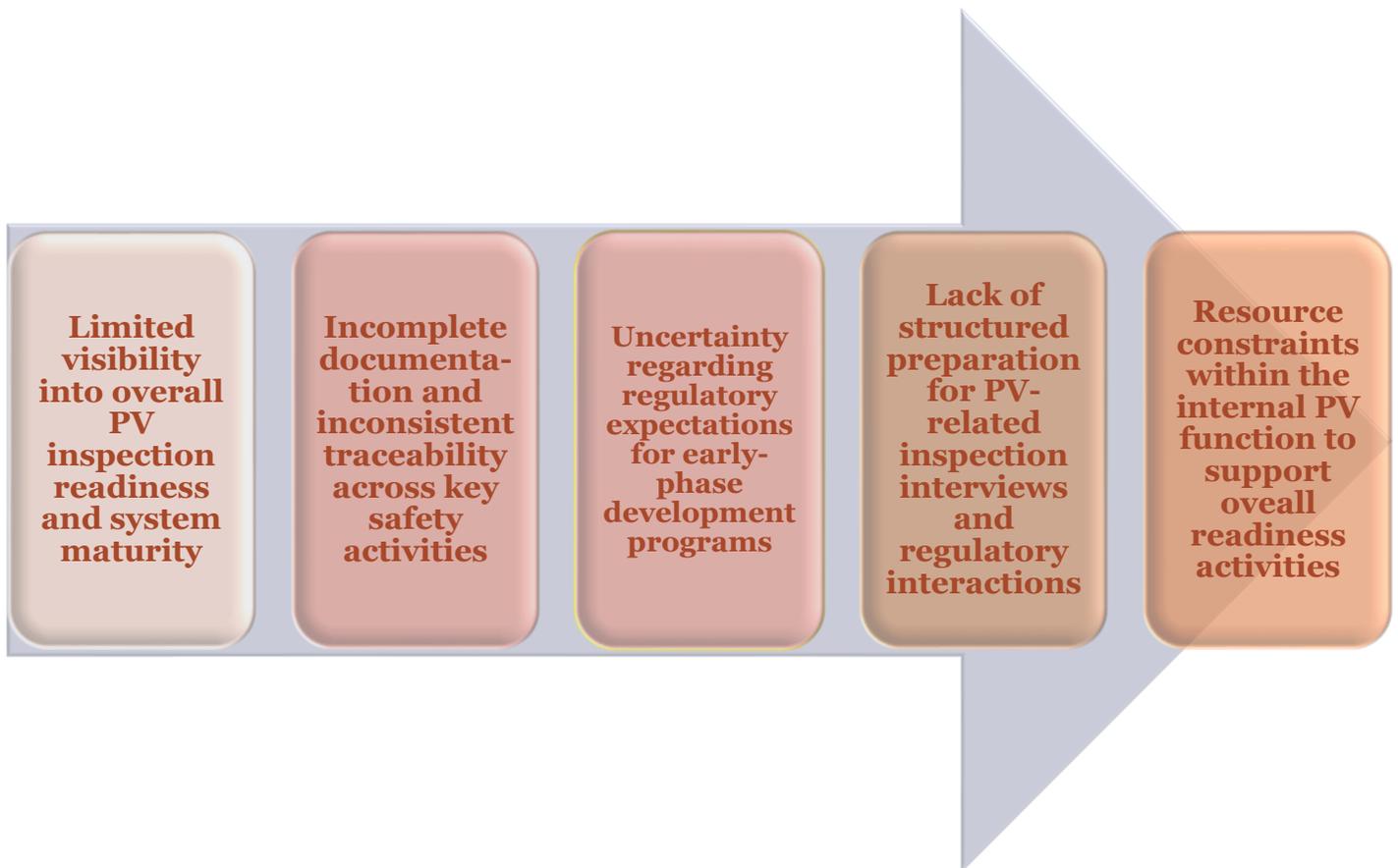
A clinical-stage, innovation-focused biotechnology company advancing a growing pipeline of investigational therapies across multiple therapeutic areas, including oncology, rare diseases, immunology, neurology, and metabolic disorders. The organization was conducting early-phase clinical trials (Phase I–II) across the United States, Europe, and select international regions as part of its global development strategy.

As the development portfolio expanded and regulatory interactions increased, the company was transitioning from a start-up operational model to a more structured and scalable global framework. Pharmacovigilance activities were managed through a lean internal safety function supported by multiple external vendors, requiring strong oversight, clear governance, and consistent processes.

In preparation for anticipated inspections by the FDA and EMA, the organization sought to proactively assess the maturity of its Pharmacovigilance (PV) system and strengthen operational readiness to ensure alignment with global regulatory expectations and support future clinical and organizational growth.

Business Challenge

As the organization prepared for potential health authority inspections, several risks and operational gaps were identified:



These challenges created a need for a structured, risk-based approach to assess readiness and address potential compliance gaps ahead of regulatory review.

Solution

Inspection Readiness Assessment

- * Conducted a detailed review of key PV operational and quality elements, including:
- * Case processing and expedited reporting compliance
- * Signal management documentation and decision traceability
- * DSUR preparation, content quality, and supporting data reconciliation
- * Safety governance, oversight, and escalation processes
- * Vendor oversight, performance monitoring, and quality controls

Mock Audit Execution

- * Performed a simulated PV audit modeled on FDA and EMA inspection approaches
- * Evaluated document availability, consistency, and inspection traceability
- * Assessed system readiness through targeted document requests and scenario-based questioning.

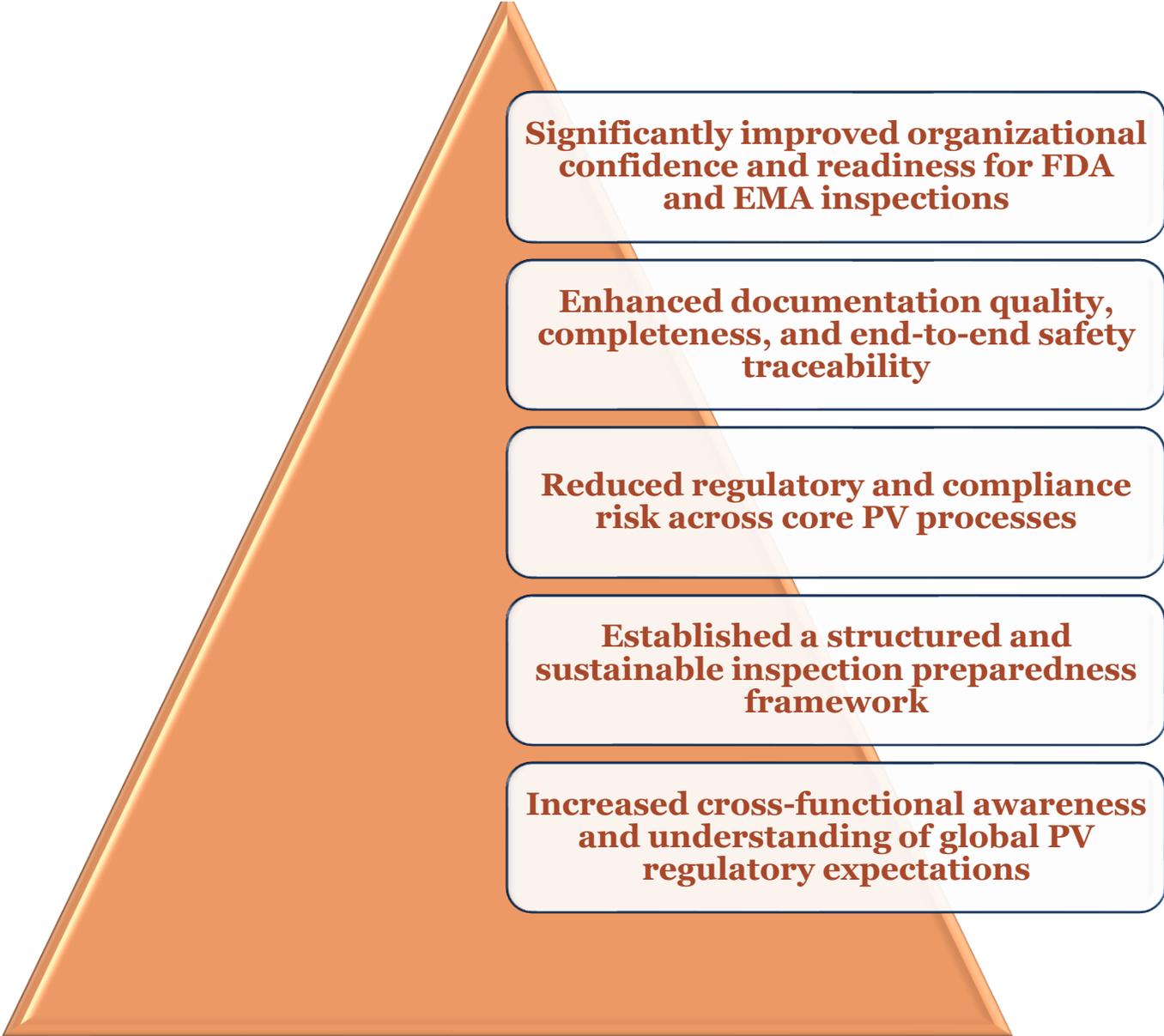
Risk Identification & Remediation Planning

- * Identified critical and moderate risk areas
- * Developed a prioritized, risk-based remediation roadmap
- * Supported closure of high-risk gaps within defined timelines

Inspection Preparedness Tools & Training

- * Developed an inspection response playbook and document readiness checklist
- * Created traceability maps linking key safety processes, decisions, and outputs
- * Provided interview coaching and inspection readiness training for PV and cross-functional stakeholders

Outcome



Significantly improved organizational confidence and readiness for FDA and EMA inspections

Enhanced documentation quality, completeness, and end-to-end safety traceability

Reduced regulatory and compliance risk across core PV processes

Established a structured and sustainable inspection preparedness framework

Increased cross-functional awareness and understanding of global PV regulatory expectations

Contact

Monica Singh

Regulatory and Pharmacovigilance Consultant

Phone: (617) 775-7630

Email: monica@Umsailllc.com



UMSai LLC

**Unique Medium for Solutions
and Innovations**

WWW.UMSaiLLC.com



[423] 758-6724



info@umsaillc.com