CASE STUDY:
Transitioning an Enterprise Literature Monitoring Program with EVERSANA ORCHESTRATE™ PV

One of our enterprise clients approached us with a critical challenge: their existing literature monitoring vendor lacked transparency, creating regulatory exposure and limiting their ability to prepare confidently for inspections. They needed a partner who could restore structure, visibility, and compliance —and complete the transition within an aggressive timeline.

KEY CHALLENGES

- Ensuring a seamless transition from the incumbent vendor without interrupting ongoing safety surveillance
- Limited visibility into processes and gaps in compliance documentation
- Managing a portfolio of ~600 generic products requiring high-volume global surveillance
- Meeting a strict 2-day turnaround requirement
- Rapidly onboarding, training, and calibrating teams while maintaining quality standards

OUR APPROACH

To stabilize operations and bring transparency back to the process, we anchored the transition on our ORCHESTRATE PV Literature Monitoring platform. This provided a structured foundation for search-strategy validation, workflow traceability, and compliance oversight.

- **Portfolio Management at Scale**
  Structured surveillance for ~600 products, supported by fully documented monitoring logic
- **Verified Search Strategies**
  Precision/recall validation completed prior to go-live to ensure scientific and regulatory alignment
- **High-Volume Processing**
  Annual management of ~150,000 literature items, including 60% full-text articles
- **Consistent Turnaround Times**
  A 2-calendar-day TAT enabled by standardized, quality-controlled workflows
- **Controlled 1.5-Month Transition**
  Complete knowledge transfer, onboarding, and workflow stabilization without operational downtime

OUTCOMES & IMPACT

- 100% compliance and quality KPIs achieved from the first surveillance cycle
- Zero disruption to ongoing global safety monitoring
- Strengthened audit readiness through fully traceable workflows, with U.S. FDA system and process inspections completed with no Form 483 observations or follow-up regulatory actions related to literature monitoring
- Reduced downstream review workload thanks to improved accuracy in identifying valid literature
- Increased confidence in global surveillance operations

As confidence in the process grew, the client significantly expanded the engagement. Within eight months of go-live, they outsourced over 600 additional nutraceutical products, and the complete literature monitoring process for these products was fully set up, with the expanded portfolio.

CLOSING PERSPECTIVE

Transitions of this scale are ultimately trust-building moments. By combining disciplined execution with the automation capabilities of ORCHESTRATE PV, we delivered what mattered most: clarity, reliability, and compliance the client could confidently stand behind.

ABOUT EVERSANA

EVERSANA is a leading provider of global life sciences services, supporting pharmaceutical, biotech, and medical device organizations across the product lifecycle. Our pharmacovigilance solutions combine operational expertise with intelligent automation to deliver scalable, compliant, and audit-ready safety operations for clients worldwide.

Visit our website to learn more about EVERSANA ORCHESTRATE™ PV