

Medical communications

A risk evaluation and mitigation strategy (REMS) rescue

Accelerating launch readiness through phased, compliant delivery

Background

A commercial-stage biopharmaceutical company faced **significant launch risks** when they experienced a change in their inaugural risk evaluation and mitigation strategies (REMS) implementation plan with its original vendor. With **regulatory milestones approaching**, the organization needed a **compliant solution deployed within an accelerated timeline** while reducing operational complexity and stakeholder burden. The goal was to enable **immediate launch readiness** and establish a **scalable foundation for future growth**.

Considerations



External vendor delivery setback: No viable technology path under the pre-existing vendor plan



Complex workflow: Complex REMS Dispense Authorization (RDA) workflow requiring auditability and accuracy



Compressed timeline: Compressed timeline with multiple stakeholders and vendor dependencies



Stakeholder burden: Need to minimize stakeholder burden while maintaining compliance

Strategy

The PPD™ clinical research business of Thermo Fisher Scientific stepped in to rapidly align stakeholders around a **risk-based REMS**, providing **regulatory guidance, operational planning, and governance expertise** to support the client's **first REMS implementation** while simplifying the experience for health care stakeholders. By integrating **REMS leadership, platform delivery, and contact center operations**, we accelerated implementation while supporting long-term program evolution.

- Established an agile **roadmap and governance framework** that accelerated decision making, aligned stakeholders, and maintained regulatory compliance throughout project execution.
- Delivered a **launch-ready initial release** aligned to launch-critical requirements.
- Implemented a **validated 21 CFR Part 11-compliant platform** with integrated controls and **audit-ready traceability**.
- Designed **streamlined authorization workflows** with defined **quality controls** and **escalation pathways**.

Results

We preserved **launch readiness** through an **accelerated, compliance-first implementation** that reduced complexity and improved operational efficiency. The solution strengthened **inspection readiness** while creating a scalable path toward greater automation and self-service.

- Accelerated our go-to-market product timeline by 75% due to our **specialized REMS project managers** and **scalable knowledge repository**.
- Alleviated significant stakeholder burden by 60% using **optimized workflow solutions**.
- Enabled transition from **support-intensive workflows to self-service processes for routine activities**.
- Created a **comprehensive noncompliance plan and audit framework**, including end-to-end investigation process and stakeholder communication.
- Enhanced **inspection readiness** through disciplined governance, documentation, and compliance controls.

Launch readiness was protected with our compliance-first execution, simplified design, and strategic governance, which delivers a scalable REMS foundation for immediate access and long-term success.