Case Study: Top Pharma

A global Pharmaceutical company with more than 50,000 employees across the world has been using Orbit for five years for RMP and REMS tracking.

The Problem

Hundreds of Risk Management Plans, no way to track them

Our client found that controlled strategic planning and operational tracking of patient risk management was not being conducted in a proactive, cohesive, and transparent manner across all global functions and markets. It was difficult to scale because their existing techniques for tracking their Risk Management Plans were local and often ad hoc. While the process in place functioned, it was manual and came with considerable overhead. Since it was not centralized, it was time-consuming and resource intensive for Global Safety Officers to get the complete picture of their processes.

Their heavy reliance on disconnected and passive applications to store compliance data and track it, including spreadsheets, emailed documents, and scanned and rescanned paper forms, meant that there was a risk that they couldn't demonstrate robust risk management to regulatory authorities.

Additional Challenges

Missed Deadlines
Manual tracking processes made it difficult to obtain information necessary to meet deadlines.

No Audit Trail
"Data tracking" meant following the email chain of spreadsheets; ineffective and time-consuming.

Critical Inspection Findings
Absent a system for globally tracking RMPs, the chance of inspection findings are higher.

Unharmonized Data
Numerous versions of tracking documents created a major disconnect with data accuracy.

No Single Source of Truth
With no centralized repository, finding current information on-demand was nearly impossible.

Market Access Restrictions
Inadequate auditing of RMP activities and their statuses carry increased risk to the bottom line.

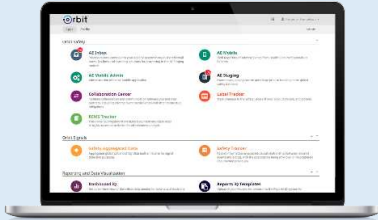*Lack of Global Oversight*
Proper oversight was often sacrificed to save the resources needed to create reporting.

Wasted Resources
Safety resources were spending enormous amounts of valuable time amassing information.

Patient Risk
Product updates took time to solidify and then get to doctors, leading to health risks for

The Orbit Solution:

Software providing one global, completely validated, single source of truth for RMPs & USREMS

The Project

The client determined Orbit to be the only truly end-to-end solution for Risk Management Plan and Additional Risk Minimization Measure tracking. After a discovery phase to establish which naming conventions and processes the client needed, the Orbit team configured the off-the-shelf solution to the client's specific products and RMP terminology. After this short configuration phase, the software went through the necessary stages of User Acceptance Testing, Installation Qualification, Operational Qualification, and final Validation.

The RMP lifecycle at Top 10 Pharma today

The Orbit platform allowed the client to achieve measurably higher compliance levels with significantly fewer errors, and fewer missed due dates and Risk Management Activity milestones.

Roughly a year following go-live, they were inspected by a major regulatory body and found that their new system made the process go much more smoothly than in the past. The ability to instantly show the global end-to-end RMP process with a click of a button, complete with an Audit Trail of every RMP change and ARMM activity for all products, was a marked improvement from past inspection processes.

Users found that the system made it easier for them to keep on top of their responsibilities with the automatic deadline reminders and notifications helping to keep them aware of what they owed and to whom. RMP officers found that they could now manage the entire scope of RMPs and their associated activities.

"Orbit is a straightforward and dependable way to manage what are often complicated logistics around compliance obligations." - Top 10 Pharma Client