HURON

Biopharmaceutical Firm Increases Efficiency and Global Compliance with a Centralized Risk Management System

A global biopharmaceutical organization moved from manual, spreadsheet based risk management tracking to a centralized cloud-based digital system. The successful implementation of the new platform has expedited risk management processes across the business, shielded the organization from compliance issues and improved collaboration across its global and local teams.

Challenge

Today many pharmaceutical companies rely on Excel spreadsheets or SharePoint basedapplications to track critical regulatory, safety-related commitments across each local market where a drug is licensed. This manual approach often results in data silos and version control issues, as well as doubts around the accuracy or timeliness of information — putting organizations at risk of negative audit findings and fines. Often companies have difficulties demonstrating that commitments were implemented consistently and, during audits from health authorities, have been warned that regulators are looking for companies to adopt validated tracking systems.

One global biopharmaceutical organization markets four innovative medicines used to treat rare diseases. Due to precautions that need to be taken when using these medicines, the firm developed risk management plans (RMPs) for each drug, committed to providing healthcare professionals and patients with educational materials.

These medicines are marketed worldwide under different local regulatory environments, complicating the process of implementing RMPs and tracking that all local commitments are delivered in a compliant way. The organization wanted a way to manage plans and commitments and track their progress in a way that provided robust global and local oversight.

Approach

Huron worked closely with the client and software firm Feith Systems to implement Feith's Orbit system, a centralized, validated tool developed specifically for pharmacovigilance and drug safety commitment tracking purposes. Within Orbit, activities are linked to timetables so that it is easy to identify if programs are complete, on track, delayed or late. This system allows the tracking of:

- Core, European and local risk management plans (RMPs).
- Core versions of additional risk minimization materials (aRMMs).

- The dissemination of plans, aRMM templates and other compliance-related documents, or activities to local markets.
- Implementation of tasks by local teams to agreed timelines.
- Progress of plans from development to final implementation worldwide.

It was essential that the system was mapped as closely as possible to the organization's established operating procedures, was simple to use and collected the right information to demonstrate compliance.

Huron's process redesign and risk management experts began by reviewing the client's current RMP procedures to better understand:

- Resources responsible for different process deliverables.
- Process step owners.
- How risk management decisions are made and communicated.
- How success of the implementation would be measured.

These considerations were used to establish how different items would be tracked across the organization, and to identify gaps or ambiguities in task ownership that could be clarified. This information was also used to create user groups within the system and define their permissions profiles, especially for third-party companies involved in local risk minimization and pharmacovigilance activities.

Once the people and processes involved in the implementation of risk management and risk minimization commitments were understood, it was possible to determine:

- How global or regional RMPs are created and approved internally and by health authorities.
- How different versions of RMPs are related.
- How plans are disseminated and who needs to review and act on them.
- The process for creating core aRMMs.
- How core aRMMs are distributed to local markets and what needs to be tracked to confirm local implementation.
- Where exceptions exist and how they might be managed (e.g., rules for allowing different safety language in some local markets, which do not need to be applied globally).

The analysis of the process and role assessments was reviewed at a discovery workshop and used to select the correct trackers for the client's system along with the data each would need to capture.

Throughout the deployment, Huron was responsible for managing the user groups and training the organization's superusers on how to leverage the system. Issues or bugs identified during testing were used to develop requirements for enhancing the Orbit system, with a number of these now implemented and available to all clients using the product.

Once the system had been configured, validated and user-tested, the system went live. Users then created all the global and local trackers related to the activities for the four drugs. As new features become available in Orbit, Huron will work with the client to ensure its system remains current and validated.

Results

At the end of configuration, the organization had a set of accessible trackers tailored to its unique needs. With Orbit as the core repository for RMP tracking, the client can:

Ensure compliance with regulatory commitments worldwide. Currently the system holds over 500 trackers, including RMP versions (core, EU-RMP or| local), core RMMs and local RMMs that are in development, in progress or due to be worked on. An audit trail identifies what changes have been made, when and by whom.

Increase employee efficiency: The amount of information and oversight provided by the system far exceeds what could be managed using spreadsheets. Users of the system are better able to plan work, disseminate tasks and complete those tasks in a timely manner. For example, when there is a change to a core aRMM, a global team can disseminate tasks related to its local adaptation, approval and implementation to all affected countries in a region via a single step. The local markets can work on these tasks as per agreed timelines, providing instant status reports thatmanagement can monitor through a dashboard.

Improve internal transparency: Managers can investigate all activities related to a product or a country/region and see which are due to start, are in progress, are on track or are late. This information is useful in preparation for regional or local audits. By examining activity statuses, managers can measure the resource impact of tasks, identify how long tasks take to complete and be confident that the company is able to prove to health authorities that they are audit-ready.

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