Human Genome Sciences Implemented TrackWise to Manage Quality

Company

The mission of Human Genome Sciences (HGS) is to discover, develop, manufacture and market innovative drugs that serve patients with unmet medical needs, with a primary focus on protein and antibody drugs. The company is making rapid progress toward the commercialization of cutting-edge products for the treatment of viral and autoimmune diseases. HGS has developed the capability to manufacture its own drugs for clinical and commercial use.

The Impetus for TrackWise

As a rising company with a pipeline of new products, HGS found itself outgrowing its manual systems for tracking deviations, corrective actions, and out of specifications (OOS). The use of spreadsheets and departmental databases created the potential for lost records, overdue investigations, and duplicate documents, and presented the risk of not meeting compliance regulations. Realizing its paper systems and databases would no longer be sufficient, the quality and IT organizations set out to find a management solution to replace the paper processes and electronic database silos.

The HGS quality organization required a user-friendly, web-based system that would enforce its workflows and employ a powerful audit trail to increase accountability and compliance. Management also wanted the ability to retrieve accurate and reliable information quickly through a fully integrated reporting system. This would increase visibility and enable the organization to make more timely decisions to improve closure time of open issues.

"After evaluating various QMS systems on the market, we selected TrackWise. A key reason for our decision to use TrackWise was not just its ability to address all of HGS's requirements, but also its ability to do much more," stated Ken Koeser, HGS Sr. Developer/Analyst. "While we initially intended to purchase a system to manage our quality records, once we took a closer look at TrackWise, we realized that it could address a number of other processes that were currently paper-based. What we did not realize then, was just how many applications would end up in TrackWise."

A member of Sparta Systems' professional services organization joined the HGS team for the initial TrackWise implementation to assist with needs assessment and configuration. HGS's IT department embraced the tool immediately, and was able to utilize the initial knowledge transfer and training to complete the configuration process on its own.

Company Overview:

Name: *Human Genome Sciences*

Industry: *Biopharmaceutical*

Revenue: *$131 million (as of 2011)*

Employees: *1,000*

Solution: *TrackWise*

The Initial Deployment: Deviation, Corrective Action, and OOS Record Types

HGS initially implemented TrackWise to manage all aspects of its deviation, corrective action, and OOS processes. HGS used automatic email notifications to designated HGS employees to provide critical information throughout the process based on real-time updates to the system. In addition, managers began receiving proactive alerts to notify them of records that were not progressing on a timely basis. This enabled them to address the most urgent issues and avoid late investigations.

HGS also found that it could improve visibility by making use of built-in AutoReports™ that provide up-to-date status of investigations, as well as measure performance against past metrics. Items are color-coded in the report based on the age of the quality record, bringing attention to the most urgent items. Previously, it had taken HGS employees several hours of work each week to compile these reports, and the risk of inaccurate information still existed due to the manual entry involved in the process. Now, TrackWise automatically emails these reports without any manual intervention. Additionally, information in the reports is reliable and accurate, as TrackWise validates all data upon entry and eliminates data duplication and procedural errors that were previously a possibility in HGS' legacy systems.

"As a result of these process improvements, the TrackWise system decreased deviation and corrective action closure time by over 50%," **stated Regina Grochowski, Sr. Manager, QA Compliance, Human Genome Sciences, Inc.**

Beyond CAPA... TrackWise Takes Off at HGS

The success of the TrackWise system quickly became visible throughout the organization. It was not long before the HGS quality team was flooded with requests to implement other processes in TrackWise. The requests came from all areas and included GLP, GMP and GCP applications. In less than one year, HGS began to deploy additional processes based on business criticality, and had expanded its use of TrackWise from a deviation and CAPA system to an integrated quality and compliance management system that now manages over 23 cGxP tracking areas.

"The flexible and configurable nature of the system, and the fact that it does not require us to purchase additional software modules to implement new processes, enables us to quickly roll out additional tracking areas in a matter of a few weeks," commented Grochowski. "This has allowed us to implement solutions quickly using internal resources." Some of the additional processes HGS has expanded TrackWise to manage include:

- Change Control (GMP and Clinical)
- Out of Trend
- Materials Review Board
- Supplier Corrective Action
- Alarm Notification
- Critical Utility Event Notification
- Internal Audit/Audit Finding Response
- Environmental Monitoring Alert/Water Alert
- Cleaning Validation Alert
- Metrology Discrepancy/Metrology Standard Recall/Out of Process
- Tolerance (GMP and GCP/GLP)

Empowering TrackWise Users

The Dashboard is another TrackWise tool that has helped HGS monitor status and key performance indicators. The Dashboard provides the quality organization with up-to-date metrics and allows it to measure how well the organization is performing against various goals. Management has instant access to the status of any and all Material Review Board items and CAPAs, and can instantly see how many quality records are currently outstanding based on different levels of criticality. Data on specific criteria, including recurring open items, can be accessed in various report forms directly from the Dashboard. Reports generated in TrackWise have become an essential component of status meetings. To aid in user training, HGS has published workflows and instructions on the QA corporate intranet.

At any time, users can view steps in workflow processes, based on the specific group to which they belong. They can also find detailed instructions for tasks within specific processes. The QA web site has reduced technical support calls and has increased users' self-sufficiency.

Related Processes with a Common Goal

HGS believes an integral part of its success can be attributed to TrackWise's ability to relate record types. "We evaluate new process requests to ensure they fit the overall goal of tracking and trending GMP information. That's why we added processes like alarm notifications, which might require a deviation investigation to determine if there was product impact," said Koeser. In addition, the approach for adding new processes relies on reusing the fields, states, activities, and notifications already in the system and configuring them for the new application. This has streamlined both development and validation efforts, and makes new processes more familiar to end users.

Conclusion

As a growing organization, HGS initially implemented TrackWise to manage its deviations, OOS investigation tasks and related CAPAs. The successful improvement of root cause analysis and CAPA processes, combined with significant decreases in closure time, created a momentum that resulted in a continually evolving, comprehensive quality system that emphasizes automation and accountability.

"Human Genome Sciences is continually modernizing and adapting its cGxP compliance processes. TrackWise provides our organization with a compliant and effective tool to interrelate our quality systems. The ability to quickly configure workflows and reports to meet new requirements has drastically increased our agility as a competitive, quality-driven biopharmaceutical organization."

---Regina Grochowski, Sr. Manager, QA Compliance, Human Genome Sciences, Inc.

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