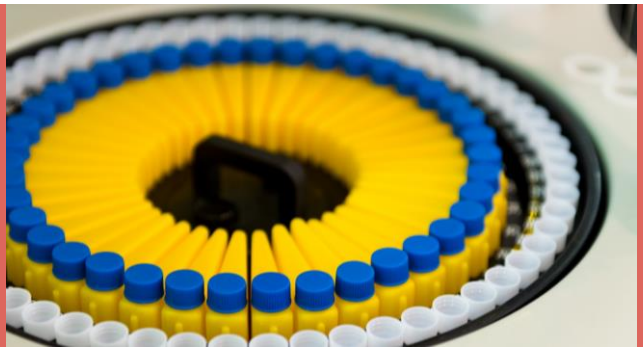

Global Pharmaceutical Company

Pharmaceutical Company Reduces Quality Risks and Streamlines Processes for Regulatory Requirements

In the pharmaceutical industry, effective risk management is critical to meeting a company's patient safety and regulatory compliance objectives. That's why one of the world's largest pharmaceutical companies, with clinical research conducted in more than 50 countries and manufacturing plants in over 12 countries, is focused on continuous process improvement for their quality risk management.

In 2009, this company identified an opportunity to improve current processes with the goal of reducing product defects across its worldwide operations. Realizing that they would benefit from a proven external partner, the company engaged with Sphera to implement a centralized risk management solution. The company adopted Sphera's Stature® as a consistent means of conducting Risk Assessments. "This company recognized that they had an opportunity to grow into optimizing their solution – not to become more efficient only, but gain further visibility than they had in the past." said the Sphera Consulting Manager.

The Business Case for a Centralized Risk Assessment Solution

In recent years, changes in the pharmaceutical industry have seen many companies evolve from a conventional pharma focus into biopharma drug production. This has led to additional complexities in terms of managing drug device combinations. It also means that companies need to meet requirements of both ISO14971 in terms of medical device risk management standards as well as ICH requirements in terms of drug production. An important element of these guidelines calls for requirements and risk traceability to ensure impact and coverage analyses. Prior to the implementation of Stature, the global teams at this pharmaceutical company lacked a centralized tool to capture requirements or to conduct risk assessments for hundreds of their products within many product families. As a result, in order to meet regulatory guidelines, the company maintained multiple spreadsheets as well as Process Flow Documents which were over 100-pages long for each product family! This created a very complex and cumbersome process. In addition, since the information was contained in multiple sources, there were no linkages between the requirements and controls, and the content was difficult to search and query. It also meant reliance on a few experts who could assess the relationships between all these elements.

CHALLENGE

- Consolidate disparate risk assessment processes into a centralized system for improved knowledge-sharing and visibility
- Decrease employee time spent on a manual risk assessment process and reporting
- Establish a more effective process for complaints analysis
- Reduce product defects and minimize the impact of potentially costly recalls

SOLUTION

Quality Risk Management

- Design FMEAs
- Process FMEAs
- Application FMEAs

RESULTS

- Reduced time spent on risk assessments and ensured consistency of data
- Decreased time spent on reporting from weeks to minutes
- Saved millions of dollars by streamlining the process for complaint investigation

The introduction of Stature as a centralized risk management tool has enabled the company to create an end-to-end process which includes multiple interacting templates that connect the requirements to the PHAs, DFMEAs, PFMEAs, AFMEAS and related control strategies. Now the process is optimized, so for every requirement they can readily identify all the related controls and this in turn has brought many benefits, including improved visibility and the ability to easily answer questions such as 'What are the controls around a Specific requirement?' or 'Which requirements are impacted at each manufacturing step?'. It also allows improved traceability since the relationships are built between elements in the system.

"They can now clearly see an 'orphan' requirement – this alerts them that this requirement is not met by the proper controls and risk mitigation measures which is extremely important from a regulatory perspective", stated the Sphera Consulting Manager. This in fact closed a gap they had identified during a Six Sigma initiative. Another advantage to the system is that the company can share common designs while maintaining the flexibility in recording differences between manufacturing processes which may vary across facilities.

This new standardized risk process has also helped with change management. "Previously, they maintained three to five different spreadsheets for one product. In the case of a change, they had to make sure that the change was reflected in all the spreadsheets. Now it's all connected, and the change automatically cascades to all the related templates in Stature. That has presented a significant time savings for them and also ensures consistency of the risk data."

Enhancing Communication and Streamlining Investigations

Now that data is organized in a central risk database the company can also benefit by sharing knowledge across teams. This helps continuously improve control strategies so that a failure at one facility or with a particular product is not repeated elsewhere. In addition, it results in the creation of a knowledge repository for failure causes, effects, and preventative measures which can be leveraged as new products are developed – in a nutshell they can now capture the experience of lessons learned and increase the efficiency of the overall process.

Another area where the company is leveraging Stature is on complaint investigations. In the past, because the Process Flow Document didn't clearly demonstrate the linkage between process elements, the cycle time for investigating and processing a complaint was lengthy. The company often had to assume that an event was a higher severity level than it actually was, which required a much more rigorous investigative study and unnecessary overhead. Now with the implementation of Stature, it has become much easier to see actual severity of harm. This provides a framework to analyze deviations with a consistent and repeatable process. In this way the company can now better categorize the severity level of each complaint and then apply the appropriate manpower expertise where it is most vital. Based on the large scope of the company's products and the number of complaints it investigates annually, the cost savings in terms of a streamlined investigative process can quickly add up to a few million dollars. More importantly, the new process also helps to quantify the riskiest parts of the manufacturing process and potential impacts to patient safety.

Gaining Insight through Improved Reporting

As new standards make Risk Management a TOP Management function, communicating performance and risks to senior executives has become very critical. In the past, the process of pulling data from disparate spreadsheets was extremely slow. In some instances, it took months to compile data that is now available within minutes in Stature. Reporting is also a key part of showing that the company is meeting regulatory requirements. "They have now been able to replace many, many hours of manual work, pulling information together for some of their compliance reporting and submissions. Having this information in Stature accessible for their FDA audits, has made the process significantly more efficient" according to the Sphera consulting manager. "In the future they plan to bring their risk information together with their complaints, look at their top risks and potential failures identified in FMEAs and those identified through complaints across products, this will lead to a whole new level of insight".

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>
> Sphera Consulting Manager

Today, more than 500 users in five countries take advantage of a centralized risk management process to ensure quality in design and manufacturing; share best practices and lessons learned and sync quality throughout the product lifecycle. Based on a positive experience over the past few years, the company plans to continue to expand usage of Stature into more countries and sites to continuously improve their quality processes.