

Reduce Quality Risk and Streamline Regulatory Processes

OVERVIEW

For one of the world's largest pharmaceutical companies, patient safety and regulatory compliance are top priorities.

Amid the evolution from conventional to biopharma drug production, this company identified an opportunity to improve quality risk management and reduce product defects. Biopharmaceutical products must meet both medical device and drug requirements, meaning compliance was growing more complex and traceability was key. But the company was using spreadsheets and massive process flow documents to conduct risk assessments for hundreds of products. The process was complex, cumbersome and difficult to query. Process elements weren't clearly linked, so investigating complaints was onerous and costly.

To streamline data capture and risk assessment across its portfolio, the company engaged Sphera's centralized risk management solution.

Global Pharmaceutical Company



Pharmaceutical



Global

\$22.3 billion
Revenue

33,000+
Employees

CHALLENGES



Disparate risk assessment processes
across 62+ countries



Time-intensive, manual reporting tools



Ineffective complaints analysis process



Increasingly complex product requirements

SOLUTION

SPHERA'S ADVANCED RISK ASSESSMENT SOFTWARE

The global pharmaceutical company introduced Sphera's Advanced Risk Assessment (ARA) solution as a centralized risk management tool. The solution helped the company create an end-to-end process, including multiple interacting templates, that connected requirements to PHAs, FMEAs and related control strategies.

The initial rollout began with over 500 users in five countries, who used the newly centralized risk management process to ensure quality and share best practices throughout the product lifecycle. The company also began using ARA to evaluate complaint severity and allocate resources accordingly.

Based on its positive experience, the company plans to continue to expand usage of ARA into more countries and sites to continuously improve their quality processes.



"They have been able to replace many, many hours of manual work, pulling information together for some of their regulatory compliance reporting and submissions."

— Sphera Consulting Manager

RESULTS

With Sphera's Advanced Risk Assessment solution, the pharmaceutical company can share knowledge enterprise-wide, so failures don't multiply. Streamlined data capture has led to better complaint analysis and resource deployment. In addition, compliance reports and executive communications can be generated in a matter of minutes, rather than months. The company plans to expand the solution to more sites.



Consistent, centralized risk data



Significant time-savings
with digital risk reporting tools



Saved millions of dollars
streamlining the complaint investigation process



Reduction in product defects and costly recalls

Is your organization ready to understand critical dependencies, control effectiveness and better allocate time and resources toward managing risk where it matters most?

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