

Quality Risk Management

Pharmaceutical Industry



AS CUSTOMER EXPECTATIONS AND REGULATORY SCRUTINY CONTINUE TO RISE, THE NEED TO IMPROVE PRODUCT AND QUALITY PROCESSES HAS BECOME CRITICAL



BENEFITS

- Enable critical expert knowledge retention & sharing
- Link risk analysis across lifecycle stages from clinical hazard analysis to PFMEAs to Control Plans
- Provide enterprise visibility to critical risks to enable informed decisions
- Allow harmonized processes and measurement of all product quality risks
- Facilitate traceability for ease of compliance management

A lapse in quality means not only financial impact; also it means placing patients at risk. The result of a major quality issue can have devastating effects, leading to costly and highly visible product recalls, which can destroy the trust of customers, shareholders and regulatory authorities alike.

The Sphera Quality Risk Management Solution connects your organizational knowledge, integrates your processes and empowers your people to meet customer demands for product quality excellence.

A harmonized process is essential to manage inherent risks in the development and manufacturing of pharmaceuticals. Leading companies are embracing a Quality by Design approach, while others have adopted standards such as ICH9 and ICH10 to improve quality. However many continue to struggle with:

- Documenting linkages between Target Product Profile (TPP), Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)
- Facilitating efficient and complete Risk Assessments and mitigation throughout the product realization process
- Ensuring a closed-loop process, where controls are identified and monitored through validation work flows, ensuring existence and effectiveness
- Seamless transfer of risk information and identified controls from design and development phases to production sites during the technology transfer phase
- Creating a repository of knowledge to leverage lessons learned across product teams and the entire organization
- Making risk profiles and metrics visible across the enterprise

What software and technologies support your Management System?

Our solution, with its proven enterprise software, content and domain expertise, helps companies strengthen and improve their quality risk processes. It does this by enabling rigorous and proactive risk assessment methodologies such as Failure Modes and Effects Analysis (FMEA) to identify and then design out potential failures and avoid costly recalls.

RESULTS

“The Sphera solution provides us with visibility into risks across all divisions and sites, enabling management to easily understand top risks and control the associated prevention strategies”

- Global Pharmaceutical Company

“With the Sphera solution data is centralized in one location and relationships are built between data elements to achieve traceability required by regulatory agencies... It helps to quantify the most risky parts of the manufacturing process and potential impact to patient safety.”

-Global Pharmaceutical Company

With the Sphera Quality Risk Management Solution you can...

Link Critical Quality Information Across the Lifecycle

- Ensure shared risk assessments are linked appropriately at each step of the product lifecycle so that data is entered once and synchronized across stages.
- Centralize risk information and build required relationships to achieve traceability required by regulatory agencies for compliance requirements and audits.
- Obtain electronic approvals in accordance to 21CFR Part 11 on specific revisions of the risk assessment.

Create the Capacity for Knowledge Retention & Sharing

- Ensure that critical expert knowledge is captured and retained.
- Create a comprehensive knowledge-base of experiences, built on a consistent vocabulary of failure modes, causes and other quality characteristics. This library of lessons learned is then accessible in subsequent development cycles to improve the quality of designs.

Improve Product Quality

- Assign ownership for controls and monitor the effectiveness and existence of those controls through automated workflows.
- Improve flexibility in applying generic product manufacturing standards and controls to various production sites and tailor those as necessary while maintaining full visibility of differences in application of the standards.

Gain Consistency and Visibility

- Improve the consistency of risk ranking by having standardized definitions and applications of severity, occurrence and detection across products and teams.
- Increase visibility and produce quality risk management reports and dashboards to surface risk information previously unseen to help prioritize corrective action and drive ownership.

Increase Efficiency

- Shorten time to conduct risk assessments, increase productivity and facilitate technology transfer by providing the ability to share knowledge and automate processes across departments and teams.
- Consolidate and streamline quality risk data that may currently be dispersed over numerous spreadsheets across your organization so that they are turned into collaborative specifications that enable continuous improvement.

Leverage a Community of Best Practices

- Gain access to a community of industry-leading peers, as well as Sphera domain experts. The combination of which have created content and best practices that accelerates your time to value and helps you attain your next round of continuous improvements.

www.sphera.com

For more information contact us at: sphera.com/contact-us/

ABOUT Sphera Solutions

For more than 30 years, Sphera has been committed to creating a safer, more sustainable and productive world by advancing operational excellence. Sphera is the largest global provider of Operational Excellence software and information services with a focus on Environmental Health & Safety (EH&S), Operational Risk and Product Stewardship. The Chicago-based company serves more than 2,500 customers and over 1 million individual users across 70 countries. Sphera is a portfolio company of Genstar Capital, a leading middle-market private equity firm focused on the software, industrial technology, financial services and healthcare industries.