



Advanced Risk Assessment for Quality Risk Management

Ensure compliance. Promote standardization. Improve efficiency and reporting.

Product deficiencies can threaten human health and safety. Furthermore, recalls of drugs, medical devices, manufactured products or foods are hugely expensive and can severely damage the company’s reputation. Getting things right the first time is not just desired, it is a requirement. Managing quality risk is mandatory in highly regulated industries such as the life sciences, but also in all food production and manufacturing industries, including semiconductors and consumer packaged goods. Such diverse enterprises all share the need to perform comprehensive risk assessments.

With Sphera’s Advanced Risk Assessment for Quality Risk Management, companies can ensure that the proper controls are in place to deliver high quality, reliable products faster, safer and more efficiently. Sphera’s solution offers a best-practices framework for various risk assessment methodologies and capabilities for risk data management. These help organizations comply with international and local quality standards, such as requirements published by the International Organization for Standardization (ISO) and the International Council for Harmonisation (ICH), or based on the Advanced Product Quality Planning (APQP) framework, among others.

Moving beyond compliance starts with standardization. Advanced Risk Assessment enables companies to implement a quality risk management program across the organization. Key components of such a program include establishing corporate standards, enabling knowledge-sharing and ensuring a common risk language.



Central Repository of Risk
Drives data consistency, data security and accessibility.



Role-Based Multiuser Collaboration via the Web
Allows teams to determine traceability and control reliability.



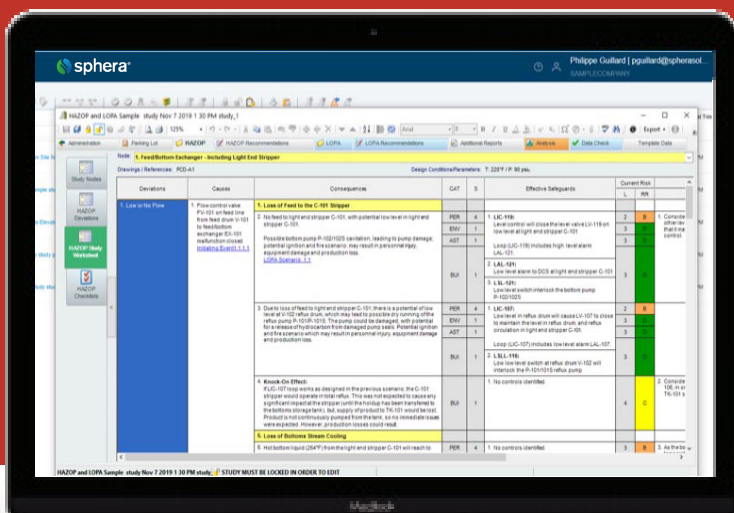
Knowledge Repositories for Continuous Improvement
Enable knowledge-sharing for continuous improvement.



Workflows for Recommendation and Approval Management
Track control measures to completion.



Real-time Risk Distribution / Risk Reports and Dashboards
Allow reporting on performance.



Make Your Risk Data Work for You.

Sphera offers various out-of-the-box risk templates—based on best practices—on a centralized Advanced Risk Assessment platform for Quality Risk Management. With configurable methodologies and advanced risk assessment workflows, companies not only standardize their risk management practices across the company, but they also realize efficiency gains and report effectiveness in their overall risk management program – a true shift from “compliance” to “risk-based decision-making.”

A Comprehensive, Data-Driven Approach for Risk Assessments and Quality Management.

In highly regulated industries such as the life sciences, quality risk management practices must be embedded in a cohesive risk management framework. With Advanced Risk Assessment for Quality Risk Management, companies can identify and assess risk more effectively, assign controls, develop risk mitigation plans and continually review and monitor potential risks using methodologies such as Failure Modes and Effects Analysis (FMEA) or Process Hazard Analysis (PHA).

Eighty percent of quality issues are repeated events. So, it is vital that organizations are able to convert raw risk data into readily sharable communication and understand critical quality attributes (CQAs) and critical process parameters (CPPs). Advanced Risk Assessment for Quality Risk Management allows companies to be proactive in their quality risk management while empowering them to make risk-based decisions.



Enable continuous improvement across the organization.

Sphera's risk templates promote standardization through a common risk language. Companies can perform quality risk assessments, accelerate productivity and ensure data integrity.



Ensure product quality for your customers.

Quality issues are expensive and can endanger lives. Sphera's quality risk management links critical quality metrics data across design, manufacturing and supply chain processes.



Empower risk-based decisions.

Improved visibility enables proactive risk mitigation by providing the information needed for sound risk-based decisions and improved safety performance.

Confident, Proactive Quality Risk Assessment and Management.

Organizations immediately benefit from using a shared quality risk management solution. On average, companies report between 40% and 60% in time savings by leveraging corporate risk templates, using predefined knowledge repositories and avoiding duplication of risk data creation. Advanced visualization tools help monitor the effectiveness of controls and facilitate reporting on performance across the company.

Build stronger risk assessment processes. Improve your quality programs in the life sciences or in other highly regulated manufacturing industries. Be confident that your processes and products are compliant with stringent standards such as ICH requirements and U.S. Food and Drug Administration regulations.

Is your organization ready to boost quality, meet regulatory requirements and better allocate time and resources toward managing risk where it matters most?

**Contact us to learn more about
Sphera's Advanced Risk Assessment for Quality Risk Management.**

[sphera.com/contact-us](https://www.sphera.com/contact-us)

ABOUT SPHERA

Sphera is the leading provider of environmental, social and governance (ESG) performance and risk management software, data and consulting services focusing on Environment, Health, Safety & Sustainability (EHS&S), Operational Risk Management (ORM), Product Stewardship and Supply Chain Risk Management (SCRM).

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