Fact Sheet

SmartSolve® Risk Management

Reduce product risk to improve patient safety

Technology solution for streamlined risk procedures

IQVIA SmartSolve® Risk Management enables medical device manufacturers to streamline their product risk management process with a compliant, policy-driven workflow, based on ISO 14971, that reduces the challenges of audits and inspections by consolidating all your risk information in a single space. Risk Management will help improve patient safety by reducing risk to the lowest levels possible without negatively impacting the benefit-risk ratio.

This streamlined approach shortens cycle times

Single source of truth for product risk management

Eliminate risk-related data silos

Organizations can suffer from storing multiple layers of data in multiple locations, resulting in bottlenecks that cause delays, errors, and ultimately inconsistent risk assessments. Without a single source of truth for product risk, consolidating data and documentation for impending audits is a challenge, resulting in longer inspections and potentially more findings.

Risk Management consolidates all your product risk content, such as the risk plan, analysis, evaluation, controls, residual risk and periodic reviews, as well as the ability to open risk assessments against Product Families and Product Lines, into a single location. Maintaining all risk-related documentation and data in one system reduces costly and time-consuming errors that can arise when it's siloed and eases the burden of performing product risk assessments. This streamlined approach shortens cycle times for risk assessments and simplifies maintenance of the Product Risk File.

Control, identify and mitigate risk

Risk Management allows you to effectively and efficiently define risk policies and thresholds to successfully document and assess product risk. Changes to product, process or defect history are immediately available in your product risk view to enable quick identification and complete mitigation of potential risks and new risks.

Perform the right tasks at the right time

Risk Management allows you to manage your product risk assessment steps with a policy-driven workflow designed for ISO 14971:2019 compliance. You can expect to work in a consistent process that allows the right people to focus on the most significant risk assessments at the right time. Working efficiently through your product risk assessments by following a best-practice workflow allows for shortened cycle times and reduced burden during audits.

Boost quality with closed-loop integration

Closed-loop integration with the SmartSolve ecosystem drives continuous improvement and increases overall quality system effectiveness. Quality records from internal and external activities are automatically pulled into periodic and ad hoc risk assessments. This synchronized information retrieval enables you to update your Product Risk File when risk, harms or failure mode severities are higher than anticipated. The framework for managing product risk provides the data needed to improve device quality and patient safety.

Reduce audit findings

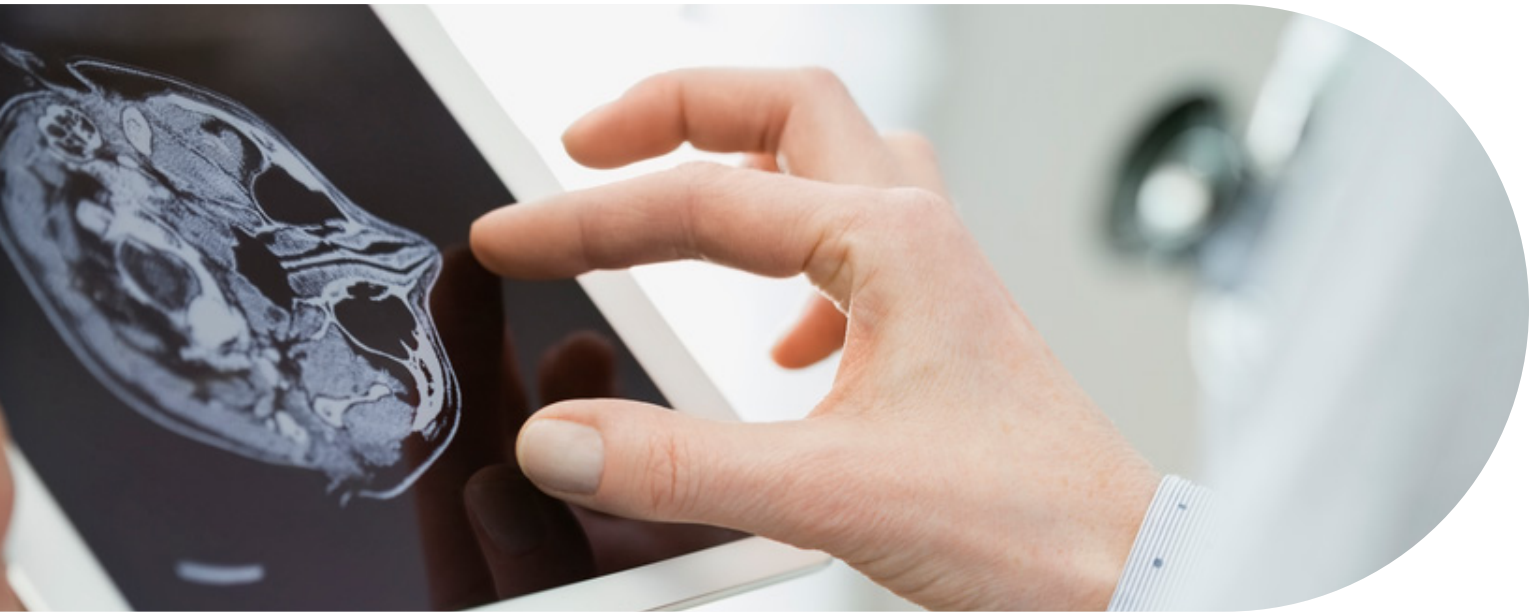
Risk Management enables you to lighten the amount of prep work needed for audits and inspections. Through the solution's dashboard and reporting capabilities, you can easily access all your Product Risk Files, which contain all product risk information necessary to fulfill your regulatory requirements. With a single system to manage your product risk, you can expect to get through regulatory inspections more quickly with reduced audit findings.

Facilitate it and regulatory compliance

SmartSolve allows you to automate your product risk management process with the confidence that your data is secure. The system provides role-based security, powerful password authentication, and a complete audit trail. These features help you facilitate IT and industry compliance with requirements for electronic signatures and electronic records, such as FDA 21 CFR Part 11, and EU Annex 11.

SmartSolve — the enterprisequality compliance management platform

IQVIA SmartSolve eQMS is built on life sciences industry best practices. Delivered on a compliance ready platform, SmartSolve provides closed-loop process integration unmatched in the market. Whether you are ready to automate a single process or optimize your entire quality management system, SmartSolve gives your enterprise a strategic advantage in quality leadership.



Features	Benefits
Policy-driven workflow 	Manage product family, product line, and product specific risk assessments through a consistent best practice based ISO 14971:2019 workflow for compliance. The workflow's series of tasks results in an always-current Product Risk File containing product risk information and documentation.
Single repository for risk data and documentation 	Easily access all product risk-related activities and documentation within a single location for quick reference during audits.
Dashboard and reports 	Gain visibility and quick access to pending tasks, upcoming periodic review dates and past-due activities. Configurable dashboards allow users to focus on most critical tasks first, without losing sight of other activities.
Email notification 	Stay aware of pending and completed tasks. Notifications can inform users of such actions as: risk acceptance, risk rejection, task initiations and routing forward or backwards in the workflow. Depth of notifications keep the risk assessment owner aware of all activities within a specific assessment.
Product Risk File 	Obtain a complete view of your product-specific risk assessments. The Product Risk File contains information specific to risk management tasks: risk analysis, evaluation, recording risk control, identifying new risk, risk planning and pre- and post-production reviews. The Product Risk File will also provide users with the most current attachments and cross references to other existing SmartSolve modules, plus other relevant documents.
Role-based security, password authentication, audit trail and electronic signature 	Maintain compliance with IT security standards and regulatory requirements for electronic signatures and electronic records, including FDA 21 CFR Part 11 and EU Annex 11.

Closed-loop integration with the SmartSolve ecosystem drives continuous improvement and increases overall quality system effectiveness

IQVIA TECHNOLOGIES

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