

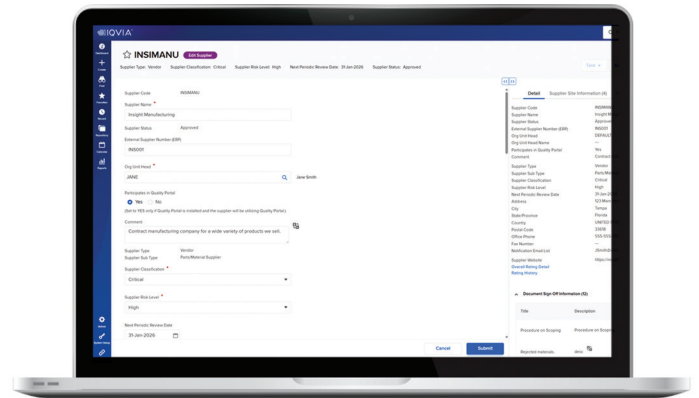
SmartSolve® Supplier Management

Automate supplier controls: Minimize organizational risk

Your organization's supply chain requires regulatory compliance and process resilience to drive innovation and continued market access for your company's solutions. Both are achieved through proper management of your supply chain. IQVIA SmartSolve eQMS Supplier Management simplifies the complex task of managing your suppliers and minimizing organizational risk to drive operational performance. Our risk-based, best-in-class workflow ensures the appropriate rigor is applied to supplier evaluation and selection and that on-demand evaluation of supplier performance is always at hand. Establishing and maintaining appropriate supplier controls is paramount to proactively mitigating supply chain risks.

Supplier Management provides an integrated solution to help you:

- Plan and execute an effective supplier evaluation process based on risk
- Improve ongoing management of suppliers and supplier controls
- Manage risk-based supplier change control
- Integrate supplier activities for real-time supplier performance and control
- Provide extended supply chain traceability
- Manage periodic reviews and supplier decommissioning
- Tailor, extend and integrate your quality processes
- Maintain on-demand analytics of current supplier performance



Plan and execute an effective supplier evaluation process based on risk

To minimize supply chain risk, Supplier Management's risk-based policies allow your organization to direct the rigor of the supplier evaluation process, including supplier sites and the products to be purchased from them. The system will plan and route for execution, tasks such as supplier audits, regulatory reviews, engineering reviews, QMS assessment, document reviews, certification verification and commercial reviews based on supplier and part risk. These activities allow for the most robust, quantitative Approved Supplier List (ASL) on the market.

Improve ongoing management of suppliers and supplier controls

The integration of Supplier Management with SmartSolve Inspection Management, CAPA Management, Nonconformance Management, Supplier Rating, and other company solutions such as Enterprise Resource Planning (ERP), ensures that purchasing, supply chain and quality personnel can have the insight to verify that suppliers are meeting organizational requirements, material is properly sourced, inspected at time of receipt, and then dispositioned into inventory. Real-time insights allow for the adjustment of supplier controls and the establishment of periodic review frequency.

Manage risk-based supplier change control

Change often introduces risk. When requests for changes to a supplier occur, the addition of a supplier site, supplier site changes, or even the expansion of materials being purchased from the supplier require appropriate oversight to ensure the supplier's continued ability to meet your requirements. Our risk-based change policies allow your organization to direct the tasks to be executed for review and approval of these changes. Risk-based supplier change control keeps your supply chain healthy and records of the communications between the company and the supplier ensure that a company always remains audit ready.

Integrate supplier activities for real-time supplier performance and control

When quality issues arise, providing suppliers with the ability to post their investigation results, corrective and preventive action plans, and audit finding responses facilitates and encourages timely and substantive engagement. This shortens corrective cycle times, reduces supply chain interruptions, and ensures future quality supplier deliverables. Including suppliers in your supply chain quality processes also ensures the accuracy of data, as it will be entered from the source. Additionally, the inclusion of all quality data in supplier ratings will improve supplier monitoring and enable early detection of trending issues through signal detection, which flags the need to tighten supplier controls.

Provide extended supply chain traceability

In this era of increased regulatory oversight, global regulatory bodies are holding organizations responsible for their extended supply chain. In many industries, regulators expect brand owners to have full supply chain traceability, which means knowing who your suppliers do business with. To that end, Supplier Management will allow you to track your suppliers, suppliers by type, and, through risk-based policy, determine what evaluation and oversight activities are required for that

supply chain. Supply chain traceability not only provides your organization with the tools needed for regulatory compliance, but also improves supply chain control and reduces supply chain risk.

Manage periodic reviews and supplier decommissioning

To manage the entire lifecycle of a supplier, Supplier Management allows you to establish controlled periodic reviews. Policies allow you to define the required tasks and frequency of the periodic reviews based on risk. When a supplier relationship reaches end of life, supplier decommissioning will allow for the deactivation of the supplier's extended supply chain as well.

Secure supplier records and data

IQVIA SmartSolve eQMS allows you to automate your supplier 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 to facilitate IT and industry compliance with requirements for electronic signatures and electronic records, such as FDA 21 CFR Part 11 and EU Annex 11.



Supplier request — Quality portal transactions

For a supplier granted access to participate in the quality portal, the supplier request workflow allows assigning documentation-related tasks to a Supplier Contact to complete. These tasks include:



Document sign-off

Routes internal documentation to a Supplier for review and acknowledgement. Documents can be selected from either SmartSolve Document Management, or a client user can browse and select from their local file system.



Documentation upload

Requests that Supplier provide documentation for various types of information, such as supplier certifications, policies and procedures, technical specifications, etc.

These tasks are defined in the 'Review Supplier Request' workflow step, and upon sign-off, are routed to quality portal and assigned to the selected contact. When tasks are completed, and the Supplier Request has been QA approved, all documents and associated details are added to the supplier record, with the following sections:



Certification

Includes details of all supplier certifications, including expiration date and supplier site.



Document sign-off information

Includes details of all documents reviewed and acknowledged by the Supplier.



Additional required information

Includes details of all other requested document types, such as policies and procedures.



Attachement

Includes all file attachments for both Document sign-off and Documentation upload.

About SmartSolve®: SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. [SmartSolve® eQMS](#) centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while [SmartSolve® RIM](#) manages regulatory submissions, product registrations and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.