IQVIA SmartSolve® eQMS:

The complete eQMS solution to simplify quality compliance management.

Simplify the management of quality compliance to drive continuous improvement of quality processes for better results across the entire product lifecycle.

IQVIA TECHNOLOGIES

Introduction

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Transform your workflow with SmartSolve® — IQVIA's transformative eQMS

- Enables life sciences companies to enhance quality and boost regulatory compliance while still accelerating time to market and cutting risk
- Enhance quality and improve compliance throughout the product lifecycle
- Lower costs and better performance — all without compromising security

Purpose-built to meet the quality management needs of the life sciences industry

Introduction

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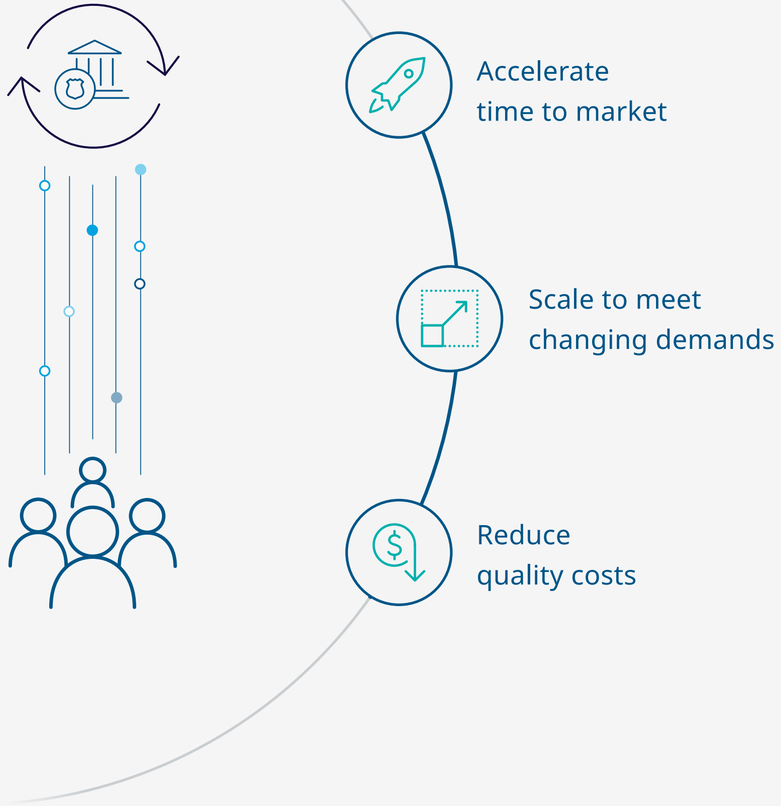
SmartSolve® — IQVIA's transformative eQMS

SmartSolve®
Innovation transforms
the quality function.

- *Built for life sciences*
- *Quality intelligence and reporting*
- *Cloud*
- *End-to-end eQMS deployment and optimization*
- *Intuitive and modern user interface (UI)*

Why SmartSolve?



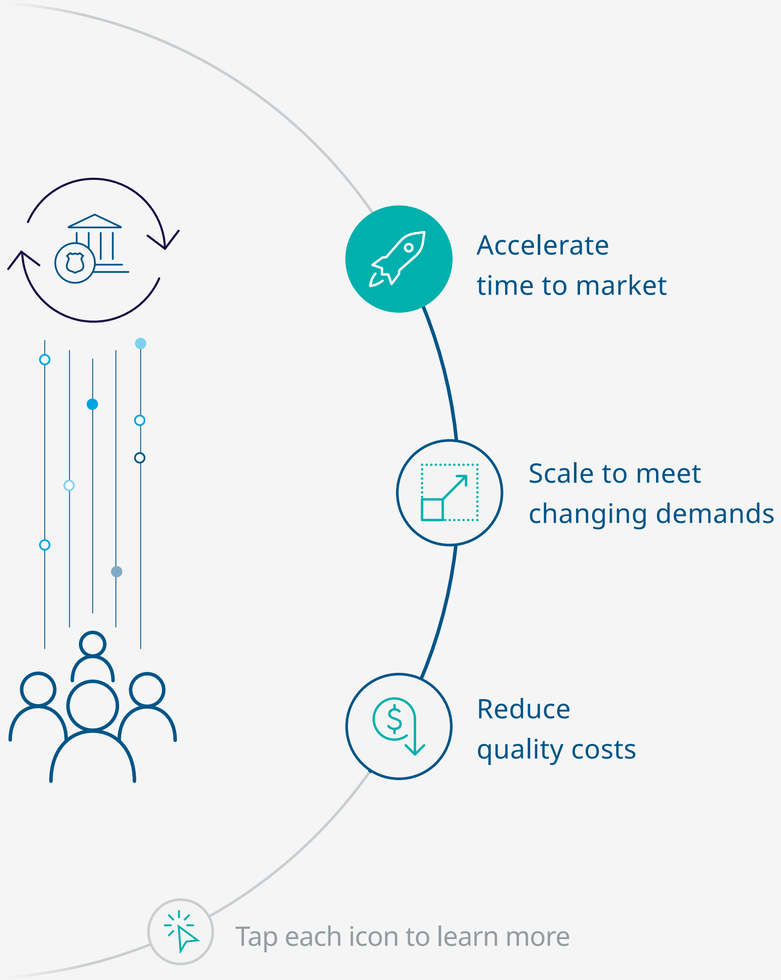
Why SmartSolve?

Enhance quality and reduce risk with connected compliance workflow processes

SmartSolve transformative eQMS with Connected Compliance: IQVIA's mature, compliant quality system with a harmonized, connected and integrated approach.

Tap each icon to find out how SmartSolve can help you meet your quality management challenges.

Why SmartSolve?



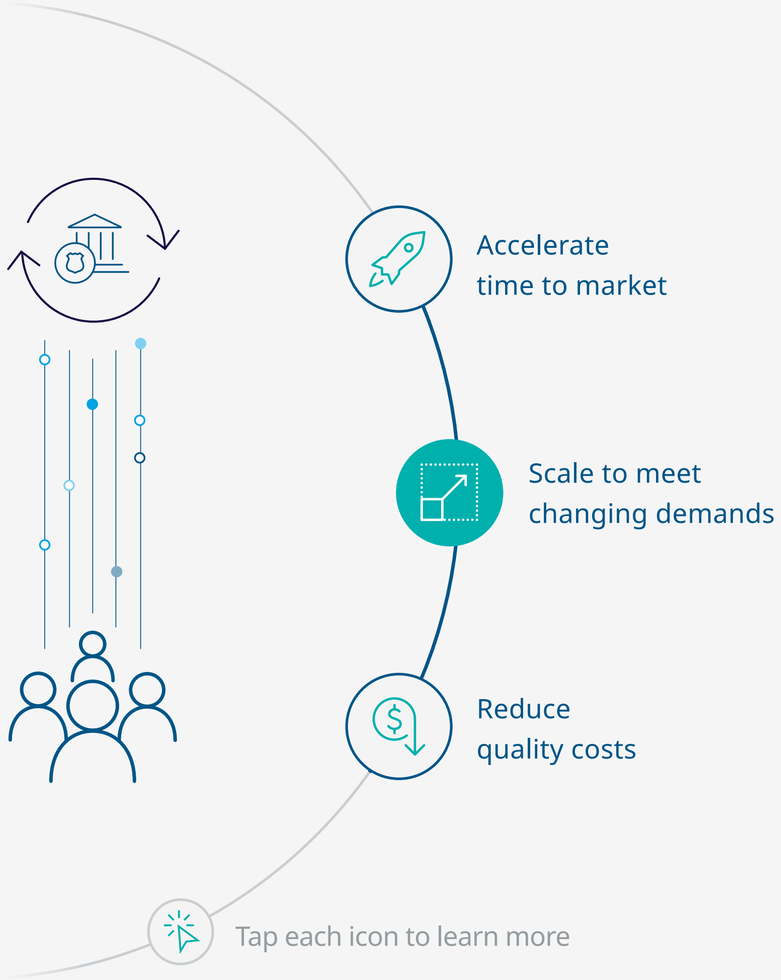
Accelerate time to market

Real-time information sharing between quality and regulatory

Purpose-built for the life sciences industry, SmartSolve brings enhanced quality assurance and faster time to market.

By providing more efficient real-time information sharing between quality and regulatory, SmartSolve enables your entire team to make the decisions that boost regulatory and quality compliance throughout the entire product lifecycle.

Why SmartSolve?



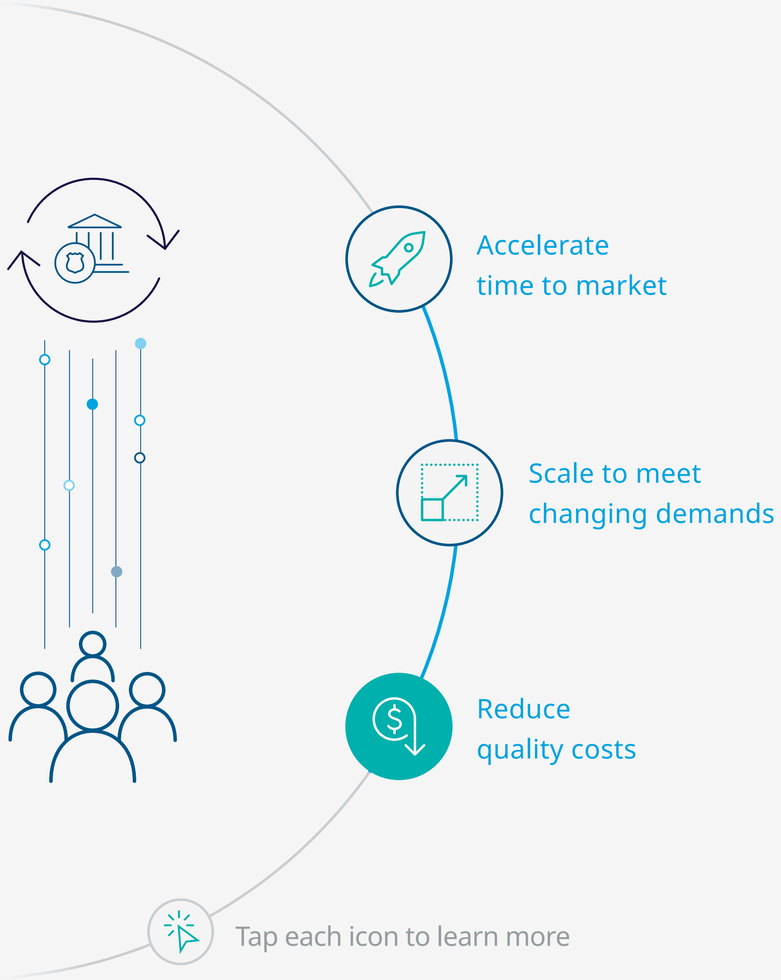
Scale to meet changing demands

Adapt to changing compliance needs

With SmartSolve, quality becomes a centralized hub for continuous improvement throughout the business, ensuring the organization can hit its regulatory compliance targets — however demanding they may be.

And, as the organization's requirements shift, you need a quality system that scales with them. SmartSolve offers that flexibility, elastically scaling to meet your organization's changing demands.

Why SmartSolve?



Reduce quality costs

Connected and integrated compliance reduces overall quality costs

SmartSolve is committed to assisting your organization in ensuring patient safety, improving product quality and minimizing risk. Our transformative eQMS is developed to enable your entire operation to be efficient and inspection-ready every day.

And it can deliver all that without driving up spend. By bridging departments and promoting end-to-end quality compliance maturity, SmartSolve can reduce total quality cost by up to 25 percent.

Discover the benefits of SmartSolve

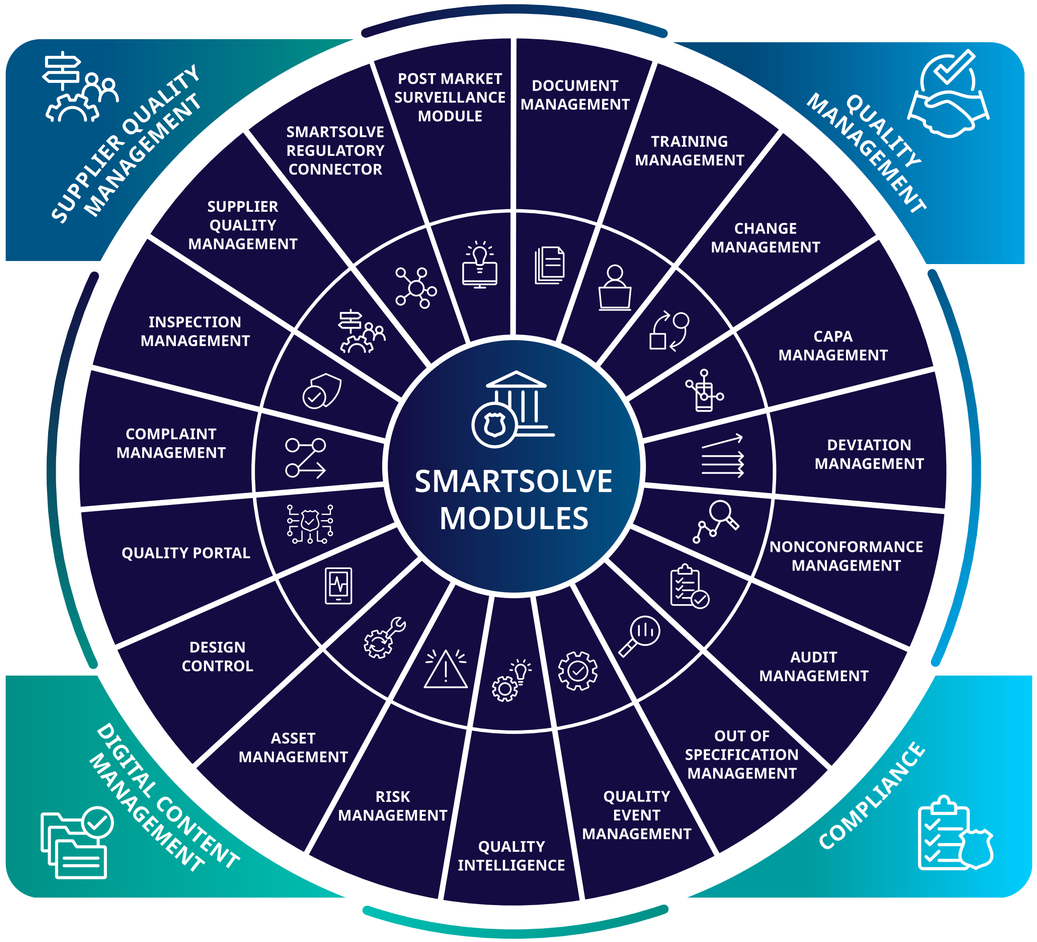
The single source of truth to manage the complexities of quality compliance.

IQVIA SmartSolve eQMS is your single source of truth to overcome challenges and manage the complexity of quality compliance. It is the only eQMS purpose-built for life sciences.

Automate a single process or optimize your entire quality management system to eliminate inefficient processes, facilitate collaboration, accelerate regulatory approvals, and simplify global control.

SmartSolve is purpose-built for Life Sciences. Over one million users depend on IQVIA enterprise quality management solutions to ensure the highest quality standards and deliver real business impact.

Click on one of the 4 sectors to **highlight** the modules



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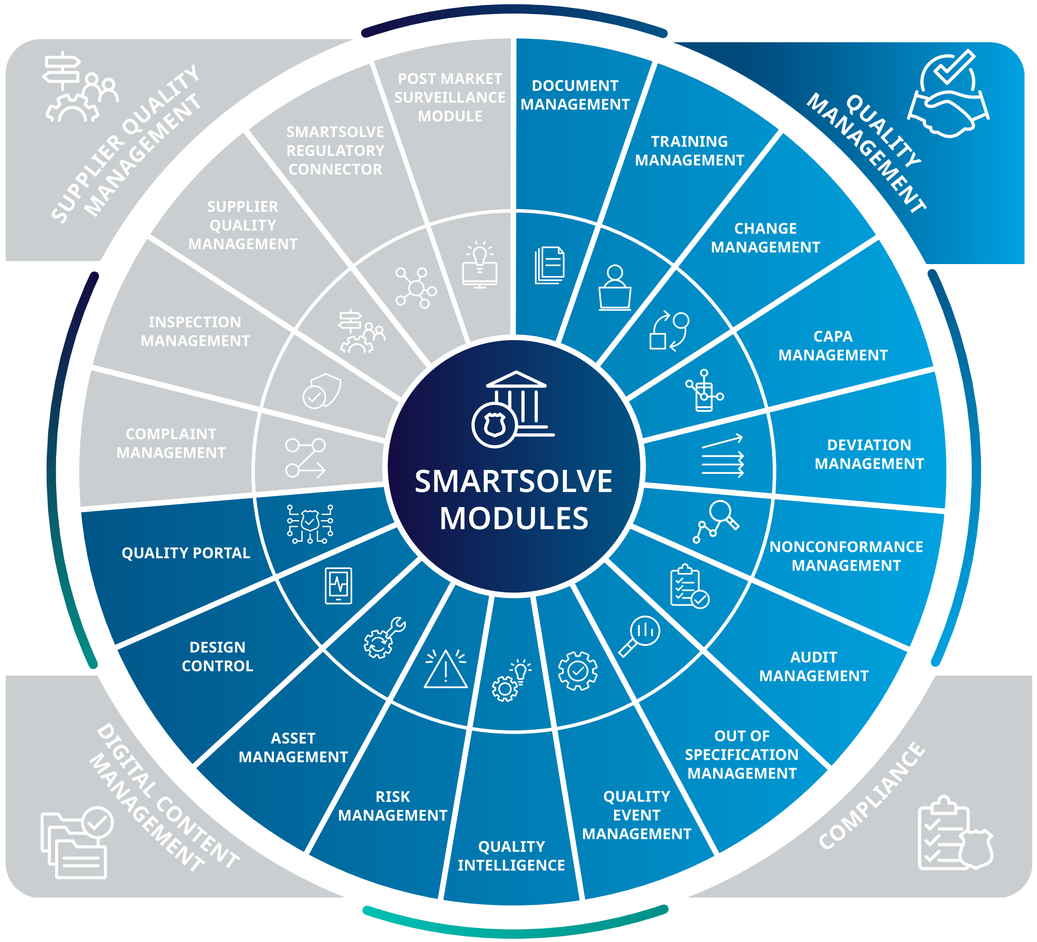

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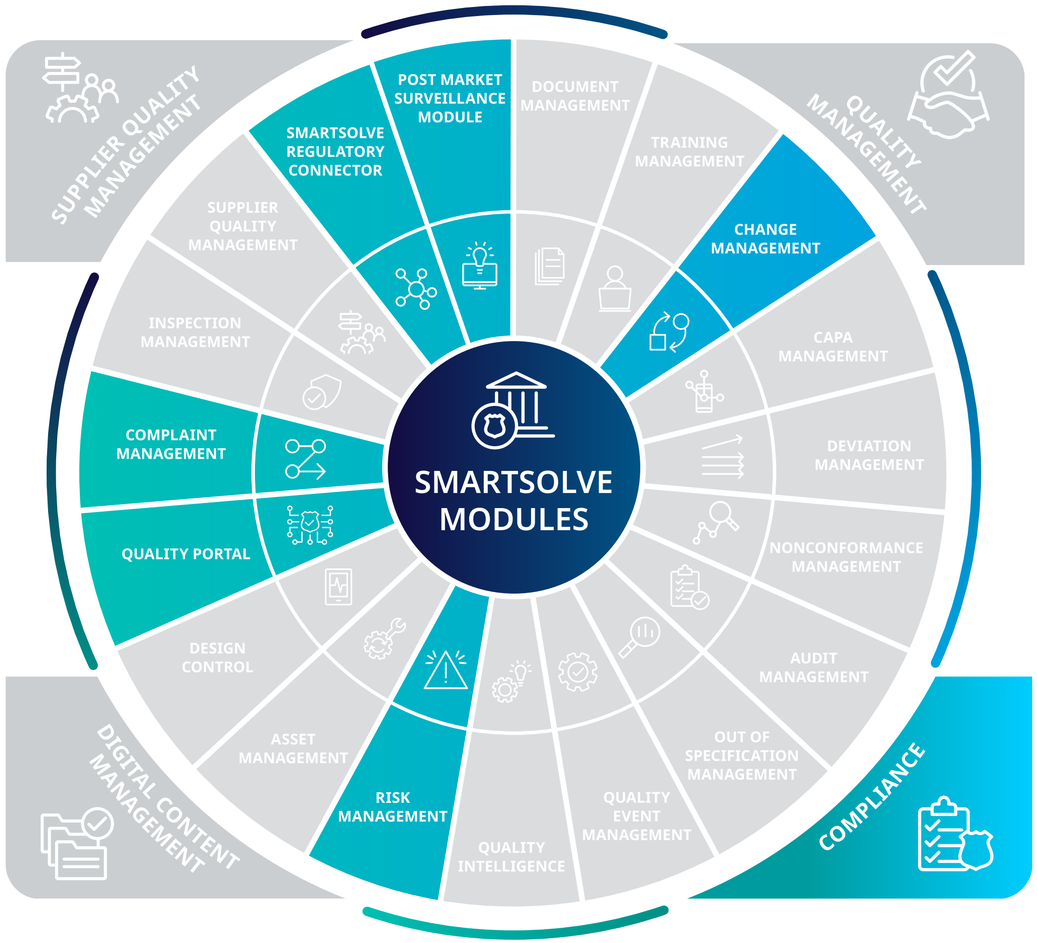

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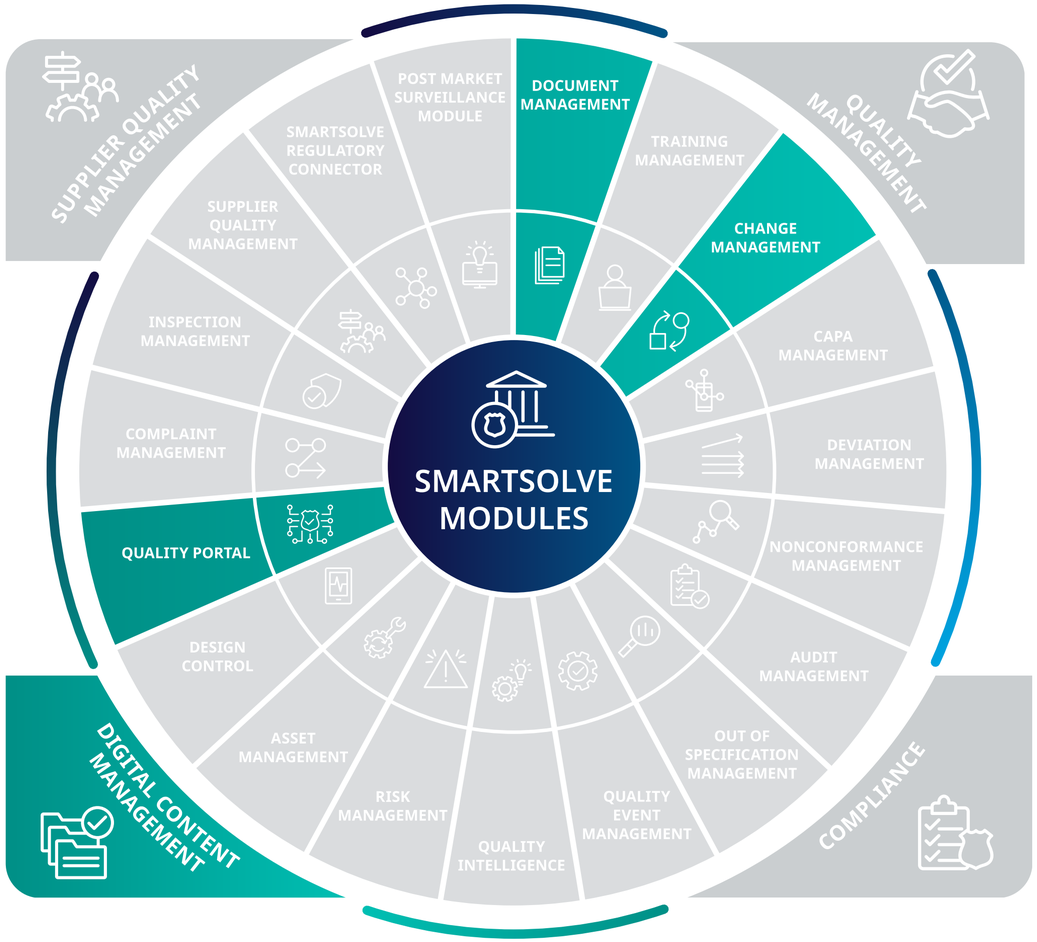

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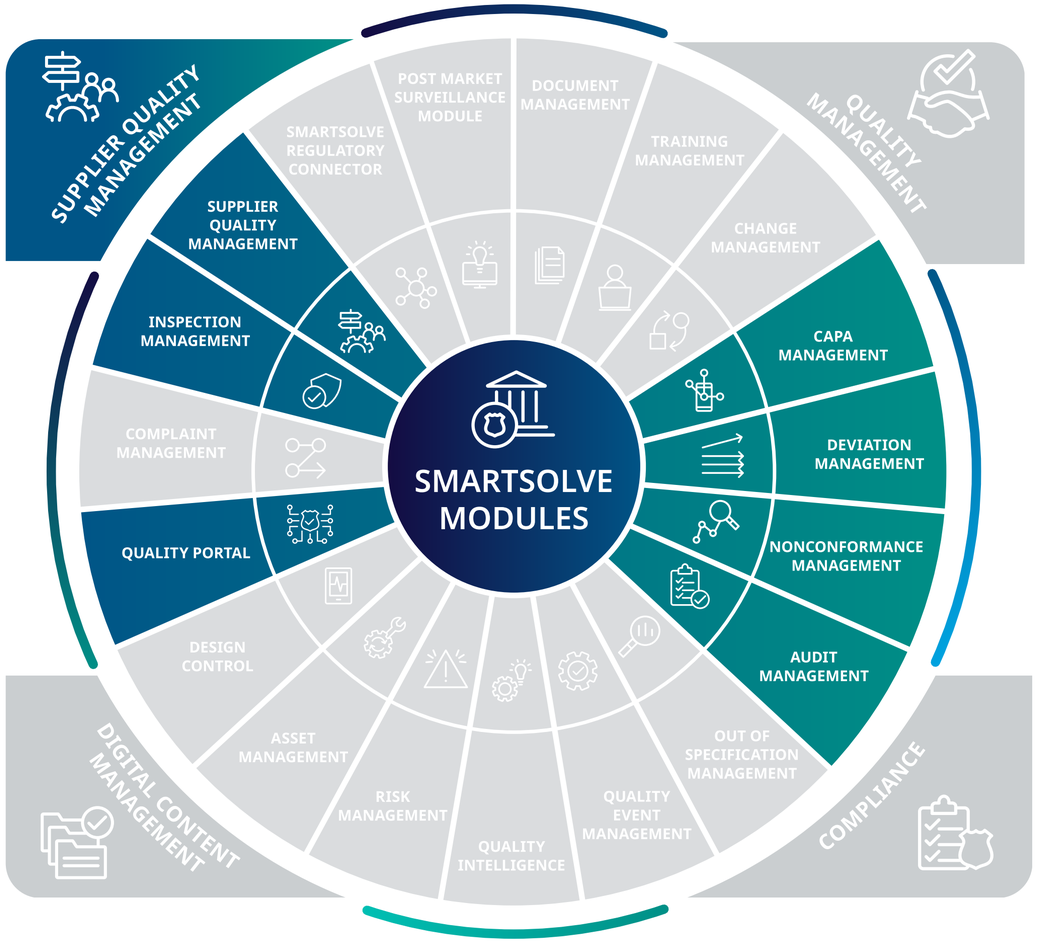

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CAPA Management

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Manage CAPAs and verify their effectiveness

SmartSolve® CAPA Management helps life sciences organizations develop a risk-based, streamlined problem resolution process.

KEY BENEFITS

- **Adopt a risk-based CAPA process** as our software automatically adjusts its workflow based on failure type, product, or other defect information.
- **Resolve problems quickly** with personalized email alerts and dashboards to help CAPA team members quickly weigh in with action plans and responses. Milestone dates and escalation triggers help you close out CAPA records on time.
- **Guide your team with best-practice CAPA workflows** and thorough, complete documentation of the entire CAPA process, including creation, risk assessment, investigation, verification, implementation, and effectiveness review.
- **Ensure CAPA effectiveness** with software alerts of scheduled effectiveness reviews so you can be sure that corrective and preventive actions have delivered the desired results.
- **Let CAPA software feed continuous improvement** by using CAPA data to provide design inputs for new products, processes, and preventive changes throughout your organization.
- **Tailor, extend, and integrate** your quality processes as demands on your quality management system grow.

Document Management

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Build a foundation for quality and compliance

Create, collaborate, approve, change, and train on documents within a single system.

KEY BENEFITS

- **Organize your document lifecycle** with flexible workflows to create, approve, and revise your documents and SOPs.
- **Accelerate reviews**. Eliminate your review and approval bottlenecks. You can easily track open tasks with personalized dashboards and email notifications. Our document control software automatically escalates approvals and reviews to ensure that they're completed on time.
- **Manage change with a system** that maintains a complete revision history for each document and allows you to compare versions by displaying insertions and deletions of each change. The most up-to-date version of each document is available throughout your organization, while expired versions are removed from use.
- **Enforce SOP training** with training notifications and quizzes designed to demonstrate that document-related training is complete and effective. Plus, our electronic signature capabilities capture employee and manager signoff, while helping you maintain compliance.
- **Enhance document visibility** with reporting and tools to create and distribute a wide range of reports. Interactive dashboards and quality KPIs can help you identify trends in your approval cycle times, assessment results, and change request aging.
- **Tailor, extend, and integrate** your quality processes as the demands on your quality management system grow.
- **Secure and simplify printing and distribution with Print Control.** Prevent printing of proprietary documents and effectively monitor the circulation of printed versions and recall when needed.

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Change Management

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Ensure consistent and complaint change

Make informed decisions and implement changes quickly.

Whether driven by FDA, EMEA or ISO regulations, change control is critical to your operations. That's why SmartSolve® Change Management software helps you make informed decisions and implement changes quickly.

KEY BENEFITS

- **Manage a wide variety of changes** and keep all of them in one place. You can easily document changes for facilities, equipment, products, processes, documents, or any other business-specific change.
- **Harmonize your change control procedures**. Change Management's standardized workflows help you stay in control of changes throughout your organization. Each change is automatically moved through its required steps, including impact assessment, review, approval, and implementation.
- **Maintain well-documented, transparent changes**. Change Management's user-friendly design helps you quickly capture all elements affected by a change. Approved changes generate plans where you can administer the actions needed to carry out each change.
- **Make change visible**. You can easily create and distribute reports to share change results, aging, and trends throughout your organization.
- **Tailor, extend, and integrate** your quality processes as demands on your quality management system grow.

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Training Management

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Ensure a competent, compliant workforce

Increase productivity, reduce job quality issues, and maintain compliance with industry regulations.

SmartSolve® Training Management helps you manage training and certification to support a qualified and skilled workforce. It makes your existing training management system easier to plan, implement, and monitor. Our Training Management software can help you increase productivity, reduce job quality issues, and maintain compliance with industry regulations.

KEY BENEFITS

- **Certify your employees for compliance** with the tools you need to manage training on industry regulations, SOP revisions, and your own internal processes. Built-in integration ensures that individuals are certified before completing critical quality-related tasks.
- **Streamline your training management system** with new optional course approval tasks, automatic notifications, and simple requirements tracking. Once courses are activated, you can easily monitor trainee progress, with assessment and checklist results.
- **Increase employee effectiveness**. Whether you're training to SOPs, scheduling classroom-based training, or using a SCORM-compliant e-learning system, Training Management helps you ensure that each trainee understands training content. Plus, electronic signature capabilities capture employee and manager signoffs and effectiveness checks, while helping you maintain due date compliance.

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Ensure a competent, compliant workforce

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- **Improve organizational oversight**. Do you need to be sure that a team member is qualified for a specific role? Would you like to quickly find a person who meets certain training requirements? Can you readily identify when training is due? Training Management's reports and quality intelligence dashboards can help by providing enterprise-wide visibility into training gaps, completion, and history.
- **Tailor, extend, and integrate** your quality processes as demands on your quality management system grow.

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Streamline complaint handling and regulatory reporting

Tailor, extend, and integrate your quality processes as the demands on your quality management system grow.

Complaint handling and regulatory reporting are an inescapable part of the life sciences industry. Our SmartSolve® Complaint Management software makes these processes easier to handle in a timely and compliant manner.

KEY BENEFITS

- **Demonstrate regulatory compliance**. Configurable intake decision trees help you consistently differentiate complaints from other customer interactions. You can also capture key product information like market approval date, product classification, unique device identifier (UDI), and license numbers. Then use our built-in reports and complaint history to show that specific products and failures were investigated consistently every time.
- **Streamline complaint intake for quick response**. Incidents are quickly recorded using our simple, configurable intake forms. Our Quality Portal enables members of your extended demand chain, including field personnel and healthcare professionals, to quickly and securely record incidents. Plus our integration with Vigilance Detect provides yet another source of data, via monitoring of social media.
- **Simplify global adverse event reporting**. This system streamlines your submissions with standard reporting for the FDA, EU, Health Canada, Japan, Australia, UK and Switzerland.. Are you expanding into additional countries? You can easily configure decision trees or add regulatory reports for any country in the world.
- **Increase management oversight** with reporting and tools that allow you to easily monitor and explore your complaint data, including due dates, critical tasks, recurring failure modes, and more.

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Quality Event Management

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Centralized and consistent, systematic handling of quality events or issues

Streamline your organization's quality event reporting and processing with a consistent and systematic solution that can be tailored to your organization's specific processes.

Through a centralized process, SmartSolve® Quality Event Management enables life sciences organizations to recognize and act on patterns and trends across all quality channels.

KEY BENEFITS

- **Track all quality events** by allowing any user to report an event without the need to categorize or select a particular quality process.
- **Simplify the event reporting process** through an easy and customizable intake form that allows anyone in your organization to report an event, even if they don't know if or how the event should be triaged or routed.
- **Utilize risk-based assessment and escalation** for all quality events through a custom decision tree that provides consistent and systematic triage and routing of all events.
- **Integrate with key quality systems** to automatically link related records, providing your organization with better insight into all quality-related events, and enabling better-informed actions, reduced cycle times, and improved end-to-end processes.

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Efficiently plan, manage, and conduct quality and regulatory audits

Simplify audit planning and preparation with target audit schedules, standardized audit checklists, and easy import capabilities that prepare you to ask the right questions at the right time for all audit types.

Effective audits lay the foundation for your organization's quality and compliance standards. But developing an efficient audit management system can be challenging. That's where SmartSolve® Audit Management comes in.

KEY BENEFITS

- **Improve audit management system efficiency** with automatic email notifications and calendar integration, giving you instant visibility into high-priority audits and tasks.
- **Enhance auditor productivity** with SmartSolve® Mobile Audit, which provides the flexibility to perform and review audits where a network connection may be limited or unavailable. You can easily download audit records and log audit results, evidence, and findings offline during the audit, and resync with your enterprise system to complete your audit workflow tasks.
- **Manage audit findings** to ensure high-risk findings are automatically escalated for further investigation, while low-risk findings can be monitored for future recurrence.
- **Share your results** and, with a single click, create a final audit summary. Explore trends in your audit findings within our pre-built dashboards or build your own dashboards to analyze your SmartSolve audit data.
- **Tailor, extend, and integrate** your quality processes as the demands on your quality management system grow.

Nonconformance Management

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Capture, track, and resolve defects and deviations

Drive continuous improvement with a closed-loop workflow to document, investigate, assess, and disposition product and process nonconformances.

The quality, safety, and reliability of your products depend on your ability to conform to specifications. So, when a deviation occurs, it is important to identify and resolve it in a timely and compliant manner. SmartSolve® Nonconformance Management software has a closed-loop workflow to document, investigate, assess, and disposition product and process nonconformances.

KEY BENEFITS

- **Capture nonconformances and assess their risk** through one simple reporting form that lets you quickly describe the nonconformance and capture relevant details like product, lot information, and failure mode. Nonconformance Management automatically adjusts workflows or triggers alerts for critical products or high-risk deviations.
- **Guide your team through the resolution process** with email alerts and personalized dashboards that help team members quickly weigh in with containment, disposition, and investigation results. Milestone dates and escalation triggers help you reduce nonconformance cycle time.
- **Create the right CAPAs at the right time**. Not every nonconformance requires a CAPA. SmartSolve's risk calculations incorporate severity, occurrence, and detection ratings to ensure that CAPAs for high-risk events are created in a structured, consistent manner. Then, seamless integration with SmartSolve CAPA Management automatically escalates nonconformances and deviations at exactly the right time.

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Capture, track, and resolve defects and deviations

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- **Drive continuous improvement**. Create an aging report or perform trend analysis within interactive quality intelligence dashboards. You can easily distribute reports to share nonconformance trends throughout your organization. Consistent failure mode reporting can be used to drive improvement in new product and process design, while aging reports can help you reduce nonconformance and overall cycle time.
- **Tailor, extend and integrate** your quality processes as the demands on your quality management system grow.

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Deviation Management

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Capture, verify, and investigate product and process deviation

It automatically adjusts workflows or triggers alerts for critical products or high-risk deviations.

Unexpected issues that impact products, processes, or materials can have huge financial implications. So, when a deviation occurs, it is important to resolve it in a timely and compliant manner. SmartSolve® Deviation Management is equipped with best-practice workflows to identify, mitigate, and reduce the risks associated with unexpected events in your manufacturing process.

KEY BENEFITS

- **Capture defects and assess their risk**. SmartSolve deviation handling and quality risk management software's simple initiation form lets you quickly capture details like classification, type, source, category, incident date, any initial actions or containment, description of the event, and notation of impacted products and batches. This lets Deviation Management automatically adjust workflows or trigger alerts for critical products or high-risk deviations. Deviation Management provides trend analysis to help you monitor low-risk deviations and act before they become critical issues.
- **Guide your team through the resolution process**. Email alerts and personalized dashboards help team members quickly weigh in with dispositions and investigation results. Milestone dates and escalation triggers help you reduce deviation cycle time. These capabilities extend throughout your value chain — you can communicate quickly and clearly with suppliers when deviations affect them.

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Deviation Management

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Capture, verify, and investigate product and process deviation

CONTINUED...

- **Create the right CAPAs at the right time**. Not every deviation requires a CAPA. SmartSolve's risk calculations incorporate severity, occurrence, and detection ratings to ensure that CAPAs for high-risk deviations are created in a structured, consistent manner. Then, seamless integration with SmartSolve's CAPA Management solution automatically escalates risky deviations at exactly the right time. You can create a new CAPA or work with an existing record to streamline your process for related deviations.
- **Drive continuous improvement**. Create an aging report or perform trend analysis within interactive quality intelligence dashboards. Drive improvements in new product and process design, while aging reports help you reduce deviation and overall cycle time.
- **Tailor, extend, and integrate your quality processes**. Deviation Management is developed on SmartSolve's Platform for Compliance. SmartSolve's Configuration Tools, Platform Services, and Enterprise Integration capabilities make it easy to tailor, extend, and integrate processes as the demands on your quality management system grow.
- **Streamline processes and increase efficiency** through integration with event, document, OOS and CAPA management.

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Out of Specification Management

Ensure consistent Out of Specification (OOS) lab result investigations

Stay in control of OOS lab result investigations, ensuring consistent intake, root cause identification, conclusions, and follow-up.

Investigating Out of Specification (OOS) lab results is a necessity for every pharmaceutical and combination product manufacturer. Both cGMP and 21 CFR Part 210 and 211 requirements guide the process for investigating OOS lab results for drug components, APIs, and finished drugs.

SmartSolve® Out of Specification Management software keeps you in control of OOS lab result investigations, ensuring consistent intake, root cause identification, conclusions, and follow-up.

KEY BENEFITS

- **Investigate consistently, every time**. Our software mirrors the two-phase approach from the FDA's guidance on OOS investigations to keep you compliant. Analyst and supervisor checklists ensure consistent investigations. Plus, you can easily show which test was followed by cross-referencing a standard operating procedure (SOP) or specification document. All investigation results are stored within one record for easy retrieval during an FDA inspection.
- **Resolve problems quickly** through email alerts and personalized dashboards to help team members quickly weigh in with root cause analysis and investigation results.
- **Integrate and escalate at exactly the right time**. Not every OOS lab result will require a CAPA. SmartSolve's integrated risk priority number (RPN) automatically creates the right CAPA at the right time by generating a new CAPA or attaching an OOS investigation to an existing CAPA record.

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Out of Specification Management

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Ensure consistent Out of Specification (OOS) lab result investigations

CONTINUED...

- **Identify out-of-trend (OOT) results to boost management oversight**. Over time, your data may show an underlying issue with a particular piece of equipment, test, or even lab analyst. OOT data and OOS investigation results tracked in our Our of Specification Management software can help you develop insight into systemic issues and improve your quality.
- **Tailor, extend, and integrate** your quality processes as the demands on your quality management system grow.

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Collaborative software improves design quality and compliance

Enables medical device manufacturers to provide documented evidence that a well-defined, controlled product design and development process is in place and has been properly executed.

KEY BENEFITS

- **Record and review design evidence** using policy-driven guided workflows to maintain control of your design process and ensure your organization fulfills appropriate medical device regulatory requirements.
- **Access design history records quickly** by maintaining all your design data and documentation, from pre-market designs to post-market design changes, in one readily accessible, centralized place.
- **Integrate with key quality systems** to record design evidence, reference external documents and reports, or execute medical device files and risk management tasks to help your organization reduce errors, cycle times, and audit findings, and improve end-to-end processes.
- **Complement current engineering processes**, including your PLM or PDM system, as this highly flexible and configurable solution enables you to coordinate all your design control activities to ensure compliance.

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Reduce product risk to improve patient safety

Streamline product risk management processes with a compliant, policy-driven workflow, based on ISO 14971. Reduce the challenges of audits and inspections by consolidating all risk information in a single location.

SmartSolve® Risk Management helps reduce product risk and demonstrates that you control an iterative risk management process.

KEY BENEFITS

- **Eliminate risk-related data silos** by consolidating all your product risk content into a single location. This results in shortened cycle times for risk assessments and simplified maintenance of your product risk files.
- **Control, identify and mitigate risk** with capabilities to effectively and efficiently define policies and thresholds to document and assess product risk.
- **Perform the right tasks at the right time** by following a built-in, streamlined workflow that ensures a consistent process for working through product risk.
- **Improve quality with closed-loop integration** that eliminates the need to chase data to manage your product risk and equips you with the data needed to improve your medical device quality and patient safety.
- **Reduce audit findings** by using Risk Management's Quality Intelligence dashboard and reporting capabilities to easily access each of your product risk files containing all your product risk details.

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Supplier Quality Management

Focus on the suppliers that matter most

Streamlined resolution workflows help you quickly resolve supplier-related issues and prevent them from recurring.

Do you know which of your suppliers are helping you meet your quality and compliance goals and which are not? Do you have the tools you need to give suppliers timely feedback on critical performance metrics?

SmartSolve® Supplier Quality Management software helps you take the guesswork out of your supplier quality management decisions.

KEY BENEFITS

- **Perform incoming inspections**. Automated sampling and inspection plans minimize the time and labor spent on incoming inspections while enhancing high product quality. The result? You'll spend less time inspecting materials from high-quality suppliers and better understand which suppliers and materials need your attention.
- **Correct and prevent supplier defects**. Our nonconformance software and CAPA management software give you instant visibility into each material's risk level. Leverage personalized email notifications to collaborate with suppliers on open defects, CAPA requests, and responses. Streamlined resolution workflows help you quickly resolve supplier-related issues and prevent them from recurring.
- **Manage supplier audits**. Stay on top of ongoing supplier quality performance. Our Audit Management software helps you efficiently schedule supplier audits, manage audit criteria, document results, and perform follow-up activities. Supplier audit findings and follow-up are integrated with our built-in CAPA workflow so that all supplier defects and non-compliances are managed using a single, harmonized process.

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Supplier Quality Management

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Focus on the suppliers that matter most

CONTINUED...

- **Prepare and share supplier scorecards**. Sometimes the toughest supplier quality management challenge is understanding the full picture so you know how each supplier measures up. That's why our Supplier Quality Management software continuously monitors delivery performance, incoming inspection results, deviations, CAPAs, and audit findings for each supplier. The solution automatically rates suppliers globally, by site, or by material, and shares scorecards and results with both your suppliers and your internal team.
- **Tailor, extend, and integrate** your quality processes as the demands on your quality management system grow.

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Streamline incoming inspection and reduce risk

SmartSolve® Inspection Management software helps you simplify the complex challenge of managing incoming quality control.

Whether you are performing incoming inspection at a single site or at a global level, the solution enables you to minimize time and labor associated with incoming inspection, while maintaining high quality. This can mitigate risk and reduce costs associated with scrap, rework and customer returns.

KEY BENEFITS

- **Perform incoming inspection**. Simplify the challenge of managing incoming quality using a risk-based workflow to ensure that you are inspecting the right products from the right suppliers at the right time.
- **Mitigate supplier-related risk**. Control incoming inspection requirements and efficiently monitor high-risk suppliers and materials, then use resulting system-generated data to optimize your supplier base.
- **Control incoming quality requirements**. Define, approve and control incoming inspection plans with integrated visibility into current SOPs so you can outline exactly which characteristics need to be inspected.
- **Streamline supplier inspections**. Ensure compliance and control while maintaining an efficient incoming inspection process. Inspection Management's dashboards and email notifications provide inspectors with insight into the specific product characteristics to be measured.

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Streamline incoming inspection and reduce risk

CONTINUED...

- **Integrate with existing business systems**. Streamline the investigation and resolution process through integration with your existing ERP system and with other SmartSolve solutions that allow you to address supplier defects before their materials enter the manufacturing process.
- **Monitor delivery and inspection trends.** Make informed decisions about your supplier base using trend reports to pinpoint high-risk suppliers and products. Automatic scheduling and email notifications keep your entire team aware of incoming quality trends and data.

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Everything you need to perform regulatory impact assessments in one place

Optimize your organization's compliance processes and reduce cost by removing silos and improving productivity and compliance accuracy.

Life sciences companies are changing the way they stay compliant. A proliferation of regulations, products, markets and data sources — combined with intense cost pressures — means that compliance functions must go beyond merely following rules and deliver more value to the business.

Orchestrate your success across the complete compliance lifecycle. IQVIA Connected Compliance for Regulatory Intelligence and eQMS removes silos, reduces overall cost and improves productivity and compliance accuracy, keeping you ahead of change so you can add more value to your business.

Everything you need to perform regulatory impact assessments in one place. It connects SmartSolve Document Management, SmartSolve Change Management and IQVIA Regulatory Intelligence in a guided, seamless and automated regulatory workflow to improve productivity, efficiency and accuracy.

KEY BENEFITS

- **Policy-driven guided workflows**: Guides the regulatory workflow process and is automated for improved productivity, efficiency and accuracy.
- **Leverages SmartSolve ecosystem**: Connects SmartSolve Document Management, SmartSolve Change Management and IQVIA Regulatory Intelligence.
- **Centralized access to data**: Everything you need to perform regulatory impact assessments is available in once place. Closed-loop access for customers to access quality and regulatory documents.

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GMP-compliant equipment, calibration, and maintenance management

SmartSolve® Asset Management, powered by Blue Mountain Quality Resources®, specifically addresses the unique regulatory, quality, and productivity needs of calibration and maintenance professionals for life sciences organizations.

KEY BENEFITS

- **Manage the equipment lifecycle**. Manage all your equipment-related needs in a single place. This equipment asset management software enables GMP-compliant control of the equipment lifecycle from induction to retirement, while integrating with SmartSolve's broader quality management platform when corrections need to be made.
- **Establish consistent procedures**. Establish schedules and procedures to ensure that equipment is routinely calibrated and maintained. This reduces the risk of regulatory noncompliance due to lack of inventory control, past-due calibrations, or maintenance work. Asset Management's automated scheduling and electronic notifications, together with its built-in KPI tools and reporting capabilities, enable you to make better decisions.
- **Record calibration and maintenance results**. The asset maintenance software enables users to record calibration and maintenance results on the spot, sign off on completed work, and automatically maintain these results as part of each equipment record. You'll be able to easily provide the evidence needed to demonstrate that a piece of equipment was properly calibrated or maintained at required intervals.

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GMP-compliant equipment, calibration, and maintenance management

CONTINUED...

- **Trigger quality events based on results**. Asset Management enables you to seamlessly manage out of tolerance and failure events for more efficient and effective remediation. SmartSolve facilitates the collaboration between calibration, maintenance, and quality personnel to speed an asset's return to production and ensure follow-up. This includes the ability to trigger a quality event when a piece of equipment is out of tolerance.
- **Conduct reverse traceability of standards**. Asset Management offers best-in-class reverse traceability of standards. Since any field can be designated as a report field, a reverse traceability report configured to your exact needs can be pulled directly from the master standard record.
- **Quantify performance**. Asset Management enables you to quantify performance with KPI tools and reporting functionality. Its measurement data entry feature can be used in combination with the solution's built-in measurement data templates, saving you time with certainty and uncertainty calculations and determining test accuracy ratios.

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Built-in tools to keep quality data at your fingertips

Proactively manage quality, comply with regulations, and mitigate risk more easily and with greater confidence.

SmartSolve® Quality Intelligence allows you to dynamically slice and dice your SmartSolve quality management data and makes it easier to build and share management dashboards. SmartSolve Quality Intelligence also includes a robust set of pre-built metrics and dashboards to help you jump-start your analysis. No other quality intelligence solution makes it easier to get started or gives you deeper, richer insight into quality metrics that matter. Let SmartSolve Quality Intelligence help you anticipate CAPAs and complaints, improve control over document trends, and stay abreast of employee training needs.

KEY BENEFITS

- **Quality management system.** Repository of discreetly captured quality data provides a single source of truth.
- **Mapped data.** Pre-mapped SmartSolve data for all your quality processes.
- **Create and modify.** Create new analyses, modify existing dashboards, or perform ad hoc exploration of your data.
- **Key quality metrics**
  - Interactive dashboards
  - On-time CAPAs and effectiveness rates
  - Product complaint trends
  - Frequency of NCs and related failure modes
  - Training compliance
  - Adverse finding trends
  - Change control metrics

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A true postmarket surveillance solution

Manage, track and document all your PMS activities from planning through reporting with SmartSolve® eQMS.

KEY BENEFITS

Reduce costs and demands on resources

A robust and effective postmarket surveillance (PMS) system can reduce both costs and demands on resources, while increasing product safety and performance. The SmartSolve Postmarket Surveillance module for MedTech will provide your organization with a workflow to manage, track and document all the steps from PMS planning through data collection, analysis and reporting.

Managed surveillance process

- Centrally-managed activities increase visibility and communication
- Real-time status and access to surveillance evidence and reports

Setup flexibility

- Centrally-managed activities increase visibility and communication
- Real-time status and access to surveillance evidence and reports

Integrated with other QMS

- Create Change Plan
- Initiate CAPA
- Perform Risk Assessment / Update Product Risk File

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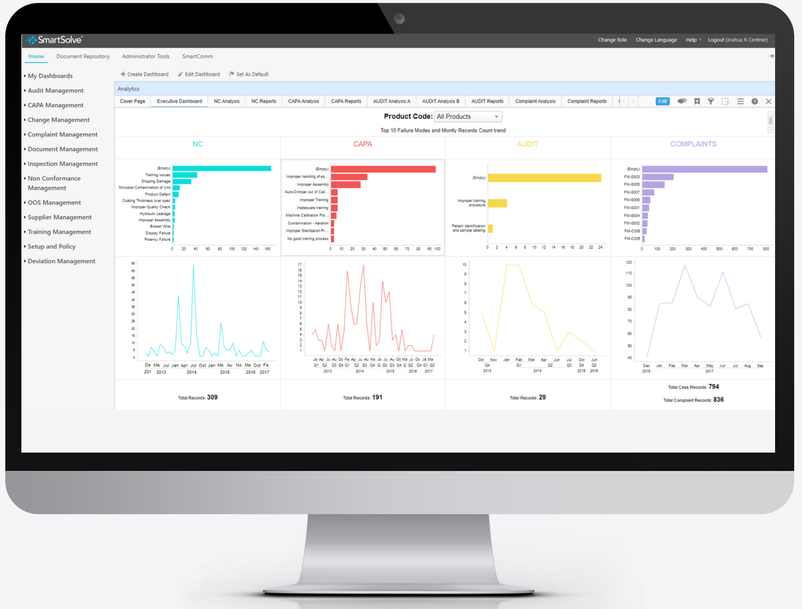
Secure portal for your quality transactions

Dedicated portal for suppliers and third-party clients to participate in quality transactions, with secure and controlled access to your data.

Communicate and transact effectively across an organization's extended value chain by including suppliers and third-party participation in your quality management processes via a safe, secure quality portal.

KEY BENEFITS

- **Designed to work directly with SmartSolve:**
  - CAPA
  - Nonconformance
  - Supplier onboarding
  - Audits



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Conclusion

SmartSolve® is a powerful platform for compliance that makes it easy to scale your quality system as the demands on it grow. The platform enables quality to become a centralized hub for continuous improvement throughout your business while maintaining regulatory compliance.

Contact us to learn more.

CONTACT US