Impact Assessment Workflow

Life sciences companies are transforming their approach to compliance as regulations, products, markets, and data sources multiply. With rising cost pressures, compliance teams must move beyond simply following rules to deliver greater strategic value to the business.

INDUSTRY CHALLENGE: NAVIGATING GLOBAL COMPLEXITY

SITUATION

- Global regulations are variable and constantly evolving
- New regulations can be published
- Product complexity impacts the range of regulations needing to be monitored

CHALLENGE

- Global healthcare product providers need to **monitor the evolution of global regulations** pertaining to their design, manufacture, sale, import, distribution, and post-market activities
- Failure to identify and meet updated regulations can result in penalties, importation issues and damaged relationships with regulators and customers

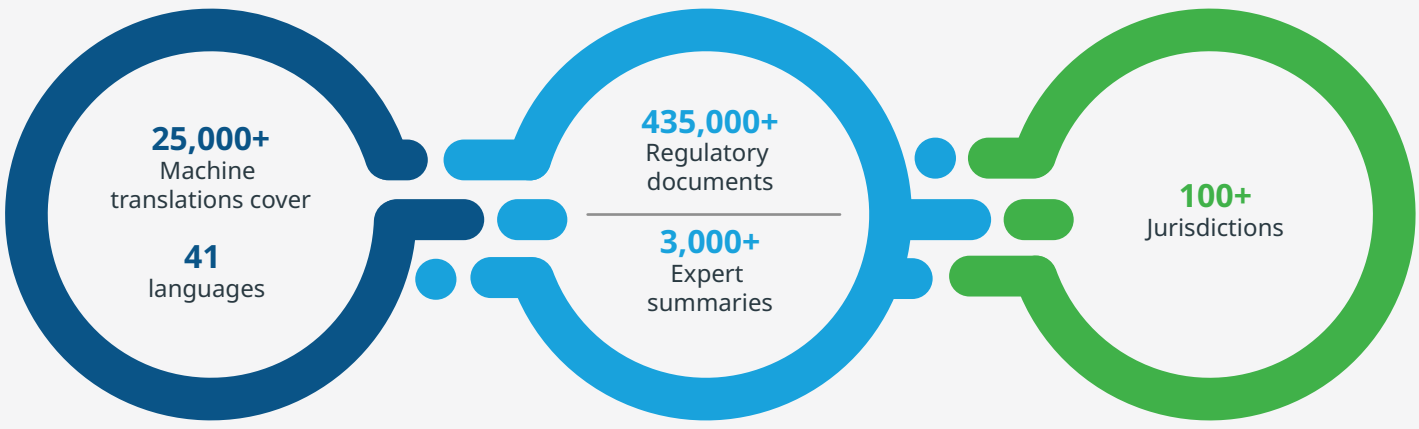
SOLUTION

- **Automate** the tracking of global regulations
- Trigger an impact assessment and change plan at the time where there is a change in the status of the surveilled regulation(s)
- **Track** and **monitor** impact plans with an automated solution

SOLUTION BENEFITS

Utilize automation to drive a dual focus on patient safety and commercial performance

IQVIA Regulatory Intelligence



Coverage: Medical Devices, In Vitro Diagnostics (IVDs), Human Drugs, and Biologics.

Define monitoring parameters

- Identify a range of company-specific governance documents to be monitored
- Define through search capabilities and selecting individual 'in-scope' documents
- See a list of what is being monitored

Auto notification of change

- Receive a notification whenever one of the set of company-specific governance documents changes
- Receive notification when a new governance document within the same search parameters appears

Impact assessment and change plan

- Use a workflow to confirm whether the company/products are impacted by the change
- Draft an action plan with times/owners
- Monitor progress of the actions to closure

Search quality/product documents

- As part of a change plan, run an automated search in quality/product documentation to see what documents are impacted by the change

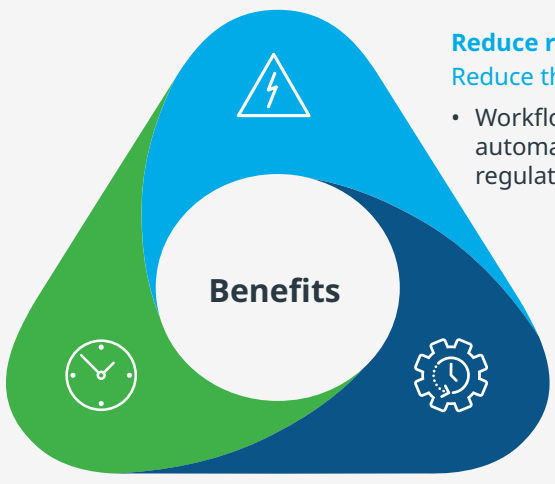
DELIVERING WHAT MATTERS

Accelerates decision-making, improves process efficiency, reduces compliance risk, and strengthens QARA operations

Save time

Optimise your team's time:

- Automated surveillance of global regulatory changes
- Reduced need for manual tracking of regulations



Reduce risk

Reduce the compliance risk with:

- Workflow for impact assessment driven by automated tracking of real-time regulatory changes

Faster execution of plans

Enhance timelines through:

- Real-time flagging of regulatory changes
- Enhanced visibility of remediation plans

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.

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