Fact Sheet

SmartSolve® Automated Validation and Extended Validation Services

Shorten the SmartSolve validation process from weeks to days

For organizations looking to automate the collection of validation evidence and expand coverage to reduce risk without increasing resources, this patented capability streamlines and manages the entire validation process. It eliminates manual script authoring and execution, adapts efficiently to changes, improves accuracy, and reduces risk.

Situation

Computer System Validation has traditionally relied on human judgment and expertise. Manual processes often extend project timelines and increase costs, delaying deployment of new software versions for life sciences organizations. The critical link between requirements and tests depends on individual diligence and specialized knowledge, creating challenges for consistency and efficiency.

The Solution

SmartSolve® Automated Validation Script Authoring and Execution streamlines go-lives and upgrades by automating critical validation steps. This reduces reliance on skilled personnel for script writing, allowing them to focus on managing and reviewing the validation process rather than performing error-prone tasks. IQVIA's Extended Validation Services also enable clients to rely on an experienced provider for comprehensive, end-to-end validation.

Features and benefits

- Shorten both script authoring and execution timelines while improving quality and eliminating human errors.
- Expand coverage to reduce risk without increasing staff or cost.
- Enable more frequent upgrades while minimizing security risks.
- Improve quality compliance by adhering to GAMP 5 standards and guidelines.
- Reduce risk and increase quality by automating processes, eliminating human errors in interpreting requirements and scripts, and providing richer evidence through a robust, reliable, and consistent approach.

Service options

Managed Services

- PQ scripts created during first release.
- Includes execution of PQ scripts via Automated Validation.
- Includes review of release notes and “What’s New” for each release for upgrade.
- Cost model based on number of modules and configuration complexity.
- Paid annually in advance.

Extended Validation Services

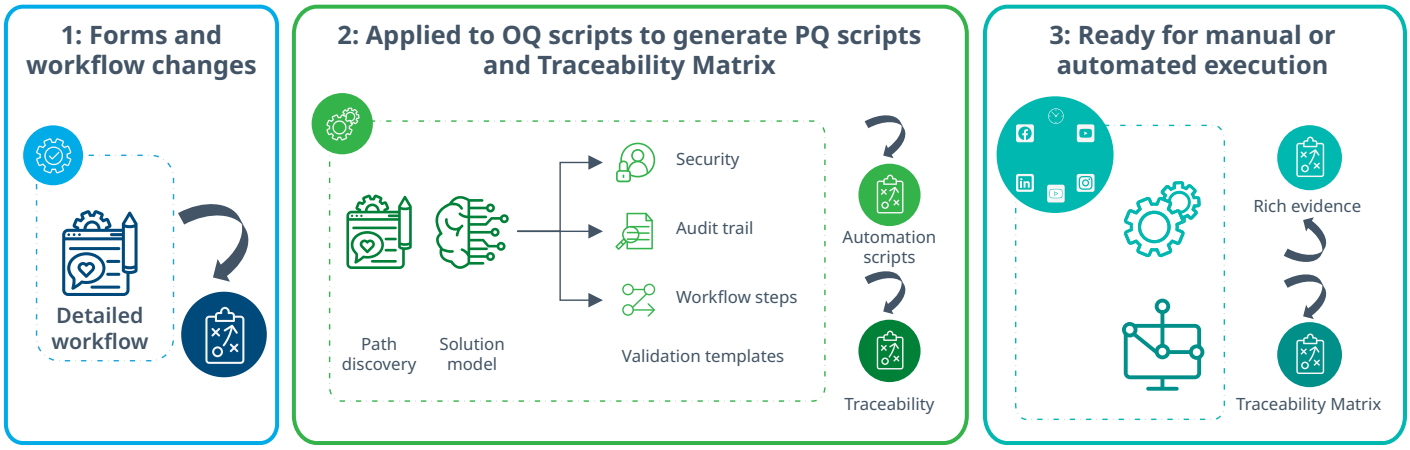
- Assigned Validation Manager to manage the end-to-end process validation and deliverable reviews.
- Additional deliverables: Validation Plan, Trace Matrix, Deviation and Summary Report.
- Cost model based on number of modules.

How it works

At the solution’s foundation is the ability to streamline the definition and documentation of business requirements, which become the basis for the automated PQ validation scripts.

- Visual workflow definition describes business processes.
- Form definitions specify data elements for each task.
- Team and role descriptions.
- Policy descriptions for conditional workflow execution.

The Automated PQ Validation Script Authoring engine analyzes workflows, compiles paths, and applies solution models to derive use cases as executable steps. Scripts are organized by validation templates and executed by the automation platform, emulating user interactions and generating rich evidence (screenshots, video recordings, traceability matrix).



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.

IQVIA TECHNOLOGIES

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