FACT SHEET

SmartSolve® Automated Validation Script Authoring and Execution

Shorten the SmartSolve validation process from weeks to days

For companies who want to automate the collection of validation objective evidence while expanding coverage to reduce risk without extra people, time, or money, IQVIA introduces SmartSolve® Automated Validation Script Authoring and Execution. This patented, innovative capability enables you to streamline and manage the validation process instead of authoring or executing elaborated scripts, adapting to change more efficiently and with increased accuracy while reducing risk.

THE CHALLENGE

Computer System Validation has traditionally relied on human intent and decision-making within the scope of human knowledge and wisdom. Traditional validation processes present challenges, since they extend project timelines and costs, impacting go live and resulting in the inability of life sciences organizations to deploy new versions of the software. Specifically, the needed relationship between requirements and tests depends mainly on the diligence and expertise that is often personally held.

OUR SOLUTION

IQVIA SmartSolve® Automated Validation Script Authoring and Execution facilitates go-lives and upgrades by automating key steps in the validation process. This removes the burden of skilled human resources in writing automation scripts, enabling them to focus on managing and reviewing the validation process rather than performing tasks prone to human errors.

- Shorten the timeline of both your script authoring and script execution while improving quality and eliminating human errors.
- Expand coverage to reduce risk without increasing staff and cost.
- Take more frequent upgrades while reducing security risks.
- Improve quality compliance with adherence to GAMP 5 standards/guidelines.

Automation allows for a robust, reliable, and consistent approach that reduces risk and **increases quality** by **eliminating human errors** in interpreting requirements and scripts, and ultimately providing richer evidence.

THE DIFFERENCE

The difference is **patented technology.** The *Automated Validation Script Authoring* and *Execution system* was granted a patent from the United States Patent and Trademark Office (United States Patent: 11106569 (uspto.gov)) for the uniquely innovative combination of an automated script generation process coupled with an automated testing process that executes generated test scripts against the system.

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. Business requirements are defined in terms of the following:

- A visual workflow definition to describe a business process where each block in the workflow diagram represents a task.
- A form definition for each task in the workflow describing the list of data elements that need to be entered when performing the task.
- Description of the team (set of personas participating in the business process), including roles and team members.
- Description of policies that determine conditional execution of the workflows.

The Automated PQ Validation Script Authoring engine automatically analyzes workflows to compile a series of paths by exercising all discovered conditions to enforce that the test scripts visit each task in the workflow. Once the paths are built, solution models are applied to derive how the software will be used, describing those use cases as a series of executable steps. These steps are organized in validation scripts based on pre-defined validation templates. Validation scripts are, in turn, executed by the automation platform against the software, emulating how the various personas will operate (navigation, data entry, clicks, selection). This process generates rich evidence of actual vs. expected results, including screenshots visually highlighting those comparisons, complete video recordings of the entire execution, and a traceability matrix mapping requirements to tests.

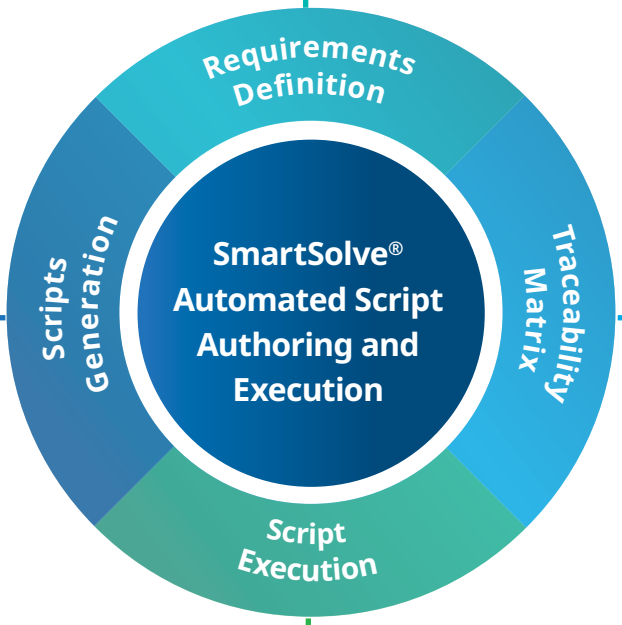
The solution also captures user requirements that surface during the implementation of SmartSolve Quality Modules - typically implemented with the low-code development platform embedded within SmartSolve, SmartStudio - and automatically generates PQ scripts directly from those requirements.

FEATURES	BENEFITS
A robust, reliable, and consistent approach	Efficiently manage the validation process instead of spending time authoring or executing tedious scripts
Improved efficiency in authoring validation scripts	Availability and access to the finished product is are not required to undertake the script authoring process.
Improved quality of the authored scripts	Scripts driven directly from requirements cannot omit scenarios or assert the wrong expected results.
Improved overall validation methodology	Scripts test the requirements, not the implementation of such requirements (based on a potential wrong interpretation by the implementation team).
Improved quality and efficiency of script execution and summary reports	Automated execution removes human errors and the need to have experienced personnel with knowledge of the system executing scripts.
Improved efficiency of implementation	The implementation team can verify the requirements before delivery to the validation team for formal execution (test-driven development), reducing loops between developers and testers.

What's at the core of the IQVIA SmartSolve® Advanced Validation Management Suite?

Customer-specific requirements that pertain to business flow, task routing, business rules, and data entry elements in the quality modules' forms can be captured in an intuitive user interface as changes from the out-of-the-box product requirements.

Customer-specific requirements utilize an AI-driven automated engine to discover paths through the workflow and a series of executable steps for the paths, which detail how the software will be used. Ultimately, test scripts are generated using pre-defined validation templates that enforce validation standards and best practices.



The automated generation of the scripts from requirements goes together with the automated traceability between requirements and steps within scripts. Customer requirement numbers are automatically applied as configuration requirements are captured and mapped to the specific steps that test them.

IQVIA's automation technology differs from traditional record-and-playback automation technologies. It does not require pre-recording or manual execution of the validation script or re-recording for application upgrades. It also separates itself from API-based technologies, where the execution is hidden in the background, losing traceability to the user action. SmartSolve Automated Validation Script Execution allows emulating all user interactions with the system, automatically executing the scripts the same way as a manual tester would.

SmartSolve Automated Validation Script Execution output includes:

- The ability to automatically compare and highlight expected and actual results
- E-signatures
- Recording the pass/fail results and providing rich evidence, including screenshots
- Videos

Find the solution with IQVIA

Drive continuous improvement of quality processes for better results across the entire product lifecycle. **SmartSolve** is the most complete enterprise quality management platform. With a comprehensive suite of software solutions, purpose-built for life sciences organizations that simplifies the management of quality compliance, you can drive continuous improvement of quality processes for better results across the entire product lifecycle.

SmartSolve enables the automation of a single process or optimization of the entire quality management system. With over one million users, SmartSolve helps to streamline quality processes, ensure the highest quality standards, and deliver real business impact.

IQVIA TECHNOLOGIES