WEBINAR SUMMARY

November 17, 2022

Pink Sheet
Pharma Intelligence

Transforming The Computer Systems Validation (CSV) For Your QMS Through Automation

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KEY TAKEAWAYS

- Adding automation to computer system validation offers significant business benefits.
- CSV and CSA depend on validation through a proven IQ-OQ-PQ test strategy.
- IQVIA's innovative requirements-driven validation automation improves validation methodology.

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OVERVIEW

Computer systems validation (CSV) has long been a regulatory necessity but is considered time and resource-consuming to execute. Traditional validation processes for life sciences organizations often extend project timelines and costs, impacting time to market and creating barriers to deployment of newer versions of the software. Utilization of automation within the framework of the CSV process can create the same required artifacts as manual execution, with increased accuracy and coverage, and can accelerate the timeline for upgrades.

IQVIA provides services and technology to help organizations advance their quality maturity, from development to sustained quality leadership. IQVIA services, such organizational change management, initial process development, and more, help build a foundation for improved quality and compliance. Technology such as IQVIA's SmartSolve EQMS becomes the fuel for moving to higher levels of maturity. Together, IQVIA services and technology eliminate siloed systems, enable harmonization, and provide the structure needed to measure quality KPIs.

CONTEXT

The presenters discussed the value of adding automation to computer systems validation and explained the features of IQVIA's latest automated validation script authoring system in its SmartSolve solution.

KEY TAKEAWAYS

Adding automation to computer system validation offers significant business benefits.

When a business is in its early stage, the focus is on developing processes based on regulatory and other requirements. However, as the business grows, so does the need for greater system validation through software and services. From control to integration, to harmonization and eventual industry leadership, adding automation to computer system validation (CSV) supports flexibility, agility, speed, and scale, propelling business forward throughout the quality maturity model.

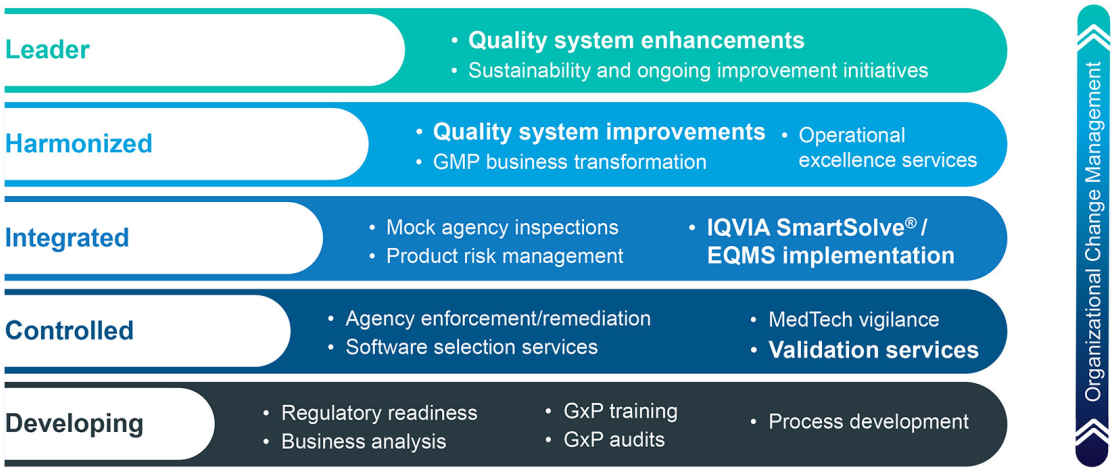
There are several factors through which automation can help overcome barriers to CSV. These include:

- **Regulatory landscape.** Non-negotiable but changing requirements can disrupt development, and global complexities require compliance with different regulations. Staying audit-ready can create a dependency on stability that prevents upgrade work. Automation reduces timelines associated with regulatory rigor and change.
- **Substandard quality.** Human error in test script creation and execution and incorrect or incomplete documentation for requirements and traceability are areas where automated CSV can help.
- **High cost of quality.** Not addressing operational inefficiencies and/or using older or out-of-date IT systems that contribute to a high TCO can impact the bottom line. The cost of noncompliance, such as warning letters, 483s, or recalls, and the type of validation approach used (full regression versus risk-based) can also drive up the cost of quality. Automation eases the adoption of the latest technology, incorporating up-to-date regulatory, functional, security and performance enhancements without the need for manual time investment.
- **Resource constraints.** Competing projects and priorities, such as validation and operational demands, can limit resources for upgrades or enhancements. Automation reduces the impact of CSV in enhancement, upgrade, and deployment decisions.

From requirements to script creation, to execution and delivery of a final summary report, automated validation increases process efficiencies and lowers total cost of ownership.

> As we move forward as an industry, we have to consider how technology can help accelerate things that have traditionally been very manual . . . overall technology is a tool to help accelerate the activities associated with validation of computer systems . . . [and to help] resource reduction.
>
> *Don Soong, IQVIA*

Figure 1: Validation as Part of Quality Maturity Progression



CSV and CSA depend on validation through a proven IQ-OQ-PQ test strategy.

CSV is also called software validation. Regulated companies must provide evidence that their software systems are performing as they are intended to perform—meaning, companies are required to document all validation activities and test results to define both what the user needs to do with the software and how the software is used. This documentation is used to confirm that the software works as intended in all anticipated situations.

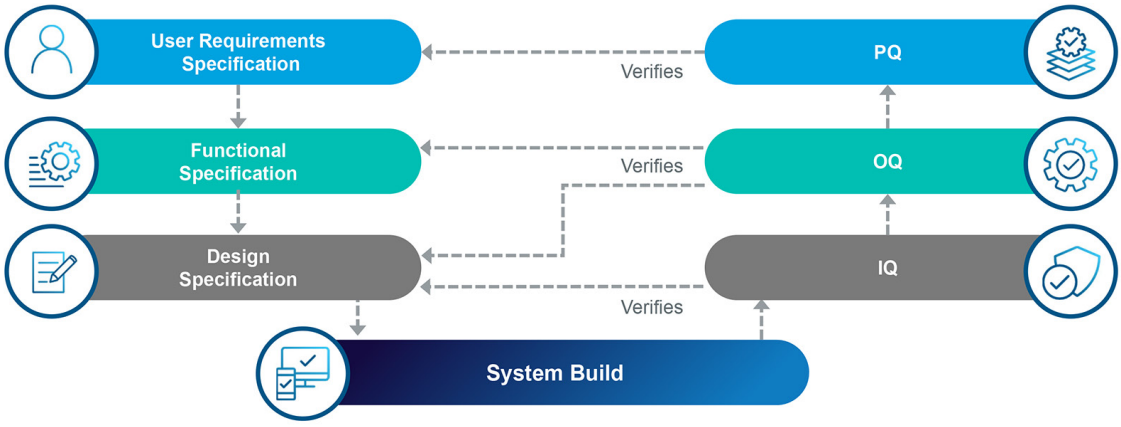
Computer software assurance (CSA) is a risk-based approach that limits testing to functions directly impacting product quality and patient safety. In a draft guidance for computer software assurance (CSA) issued by the FDA, the traditional CSV approach of 80% of time allocated to documentation and 20% to testing systems is reversed, allocating 80% of time to critical thinking and applying the right level of testing to higher-risk activities and 20% of time to documentation. CSA also encourages companies to use the software vendor's documentation to reduce the testing burden and deploy applications faster. The upcoming CSA guidance document brings no changes to the current governing regulations.

Per FDA guidance, the test strategy should be defined with the appropriate approach for testing for each IQ-OQ-PQ requirement to ensure a reliable outcome of the validation process. These sequential activities are:

- **Installation qualification (IQ)** testing provides confirmation that software or the system is installed and set up according to pre-approved design specifications.
- **Operational qualification (OQ)** testing confirms that functionality defined in the functional specification is working correctly and that there are no bugs.
- **Performance qualification (PQ)** testing confirms that the software will meet user needs and is fit for intended use as defined in user requirements.

> The FDA [does] not tell us how to execute the validation. We must perform adequate testing to the intended use and obtain adequate documentation as objective evidence . . .When it comes to automation, it is important to note that automation tools must be validated.
>
> *Davor Milosevic, IQVIA*

Figure 2: IQ-OQ-PQ Testing



IQVIA's innovative requirements-driven validation automation improves validation methodology.

The IQVIA software development life cycle mandates that every software release be validated before being made available to clients. Therefore, every release of the IQVIA SmartSolve solution is deployed in a controlled cloud validation environment and IQ and OQ tests of functional requirements are executed per a pre-established validation plan, and comprehensive validation packages are made available to customers.

IQVIA uses the same methodology to test user requirements using PQ validation. However, IQVIA's unique approach to PQ no longer confines PQ to automated execution only; IQVIA has extended its capabilities to include automated *generation* of validation scripts, as well, deriving high-quality validation scripts directly from user requirements.

- **Built-in requirements management improves validation methodology.** Validation scripts are automatically generated from requirements. This approach shifts the validation methodology, as it enables the ability to work on authoring validation scripts even before requirements are implemented in the software.
- **Automated script generation improves efficiency of script authoring and quality of scripts.** By removing human intervention from the authoring of the scripts process, IQVIA eliminates the risk of misinterpreting or missing requirements.
- **Automated execution improves efficiency of script execution and quality of artifacts.** Once scripts are automatically generated from the user requirements, they are integrated into the IQVIA automation console to perform OQ validation without human intervention.

> Where our clients have been exposed to automated validation, [they] want to add that capability into existing projects . . . The main reason is really about reducing the resource load—automating that and allowing resources to focus on their day-to-day job.
>
> *Anthony Hudson, IQVIA*

The patented automatic generation process analyzes user requirements to discover use case variations and potential workflow paths to make sure the resulting script hits every possible scenario. This process depends on the two core components of the IQVIA technology: validation templates and solution models.

The type of testing that needs to be done given a particular scenario is built in validation templates, which are the synthesis of all the validation expertise and best practices acquired by IQVIA through decades of validation projects using various software. The solution models, instead, are specific to the SmartSolve software. It is where navigation patterns are described and how functionality is presented to the user.

SmartSolve offers a very robust **Requirement Management tool** that streamlines the capturing, definition and documentation of User Requirements as changes from the out of the box product requirements, for everything that pertains to client's specific needs in terms of business workflows, business rules, data entry elements in forms that are routed to users to perform specific tasks.

Requirement Numbers are maintained within the system, and automatically generated as requirements are captured and used down the line to trace to steps in the validation scripts that test it. Version control of the Requirements is automatically maintained in the system: when a new set of User Requirements is captured, a new version is created, allowing to go back and complete the requirement elicitation and documentation. Once completed, requirements can be approved and published and baselined with a new version of the Validations Scripts, ready to be executed.

The generated validation scripts are immediately ready to be consumed by the proven SmartSolve automated validation engine, and execution of the scripts generates rich evidence of actual versus expected results. A comprehensive map called the Traceability Matrix is automatically generated in the script execution process, containing a detailed map between requirements and related tests, and the results of execution of each of those tests.

IQVIA's automation technology differs from **traditional record-and-playback automation technologies**. It does not require any 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.

IQVIA's Automated Validation, instead, allows emulating all user interactions with the system, automatically executing the scripts the same way as a manual tester would have executed them. On upgrades, a new version of the baseline Functional Requirements is made available within the system. At that point the User Requirements project can be opened, and a new set of Validation Scripts generated, right away if no new User Requirements are to be added. Or in a new version of the User Requirements if additional changes are needed.

The new version of the User Requirements will lead to a new version of the Validation Scripts.

> Whether it's a unique path in the workflow that is requested, whether it's a new field in a form . . . the full spectrum of changes is tracked and reflected into an updated version of the script to validate that requirement. It allows organizations to embrace change relying on a system that automatically adapts validation scripts to those changes.
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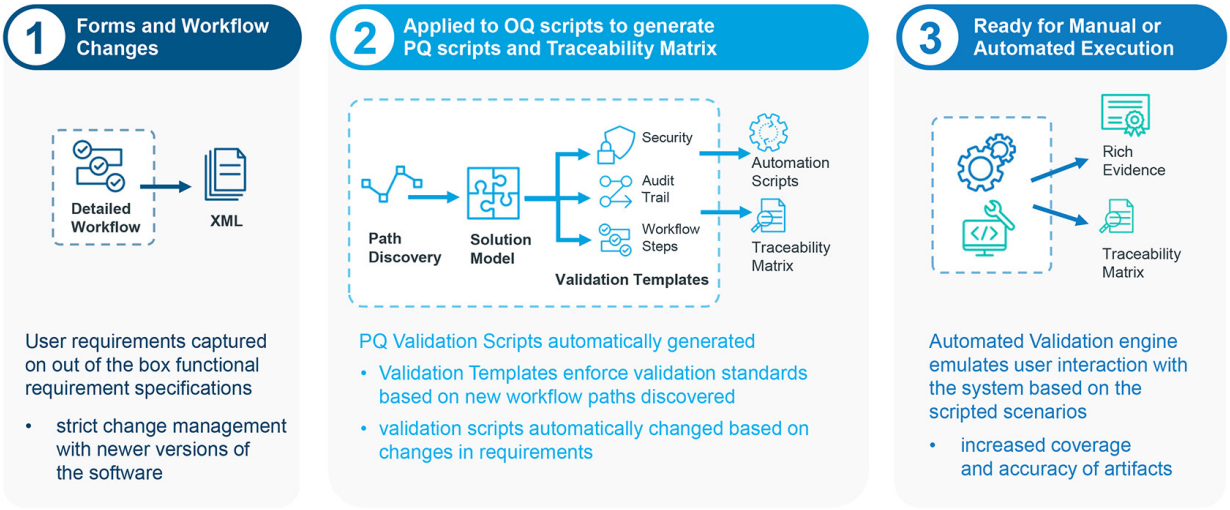
> *Massimo Franza, IQVIA*

Figure 3: Automated Validation Script Authoring System



BIOGRAPHIES

Massimo Franza

Senior Director, Software Engineering, Quality Solutions, IQVIA

Massimo Franza is senior director of software development for quality and compliance solutions at IQVIA and is responsible for the overall development, testing, and release of IQVIA's enterprise quality management system, SmartSolve, including technical documentation and validation packs. With over 25 years of experience in enterprise class software applications in Europe and the US, Franza joined IQVIA in 2007, where, before taking the role of director of software development, he managed the product development and the team responsible to build SmartStudio, the low-code development quality and compliance platform used to build the integrated modules that compose the SmartSolve suite. Expert in agile practices, Franza is certified in IT project management (ITCPM) and in CMMI for continuous process improvement.

Anthony Hudson

Senior Principal, Tech Quality and Compliance Solutions, IQVIA

Anthony Hudson has devoted his career to the delivery of best-of-breed quality systems and processes to support the life sciences industry. Hudson has over 25 years of experience covering electronic quality management systems (eQMS), program and project management, quality system auditing and validation, solution design and solution sales. Hudson has served in several capacities in the regulated space including director of quality and quality systems. His experience brings a well-rounded customer and vendor perspective to successful quality system implementation and validation. Hudson currently leads the team of US principals supporting eQMS sales and implementation for IQVIA's QMS pillar.

Davor Milosevic

Safety, Regulatory, and Quality, Quality Assurance Director, IQVIA

Davor Milosevic has extensive experience within the quality assurance function of the life sciences industry. Over the last 15 years, Milosevic has designed, implemented, and maintained various GxP, quality assurance (QA), and quality control (QC) programs, as well as compliance infrastructures, including documentation (SOP) systems and training programs, and has performed hundreds of internal and external audits. He has led and managed inspections by FDA, other regulatory agencies (AABB, AATB, ISO, etc.), and commercial partners. His ability to build trust and confidence in an organization's quality management system has established his expertise in the quality assurance arena. Milosevic is currently the quality assurance director of safety, regulatory, and quality for IQVIA.

Don Soong (Moderator)
Senior Director & GM, Quality Solutions, IQVIA

Don Soong has devoted his career to the delivery of technology solutions to the life sciences industry. Don's experience over 25+ years has covered CRM, MDM, and compliance solutions by combining technology, product strategy, and regulatory knowledge. Don has led all aspects of the product evolution process including product management, engineering, delivery, and client engagement. His ability to combine technology and business knowledge has established his expertise within IQVIA and the industry. Don currently leads the product team for IQVIA's QMS pillar.