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WHITEPAPER

Moving Beyond Paper-based Validation

AN INDUSTRY TRANSFORMATION

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Moving Beyond Paper-based Validation – An Industry Transformation

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INTRODUCTION

Over the last 10 years, the majority of life sciences organizations have successfully transitioned their regulated systems into the cloud, and almost all new companies are entirely cloud-based from the start. As technology proliferates across business units, the volume of validation work is increasing exponentially.

This challenge is amplified by a global staffing shortage, including validation experts. Historically, these resources have followed the industry practice of Computer System Validation (CSV), which is paper-driven, largely manual, and resource intensive.

The life sciences shift to Pharma 4.0 means that a broader transition needs to occur in validation. As technology evolves away from a legacy document management approach to a workflow-driven, data-centric solution, the industry is challenged by the fact that they are still predominantly leveraging paper processes (even if it is electronic copies of paper documents) when it comes to compliance management of those systems.

Regulators have acknowledged the cost and resource burden CSV is causing the industry, and are encouraging a transition to Computer Software Assurance (CSA) to help organizations improve product quality, product safety and patient safety. This transition provides a path away from time- and personnel-intensive, burdensome validation to a risk-based, digital, structured, workflow-driven process that preserves data integrity.

In this whitepaper we discuss how to assess your current state, build a team to embrace change, simultaneously update processes and technology, and scale and measure enterprise-wide performance.

ASSESSING YOUR CURRENT STATE

To advance to the next step in your organization's CSV to CSA transformation journey, it is critical to conduct an internal audit. Assess all the tools, technologies, processes, workflows, and resources handling validation. For example, are colleagues working in real time collaborating on validation projects, or are they working in silos? This assessment should include evaluating and documenting key aspects that impact your business such as:

- Has/Is the business moving to SaaS solutions with multiple releases a year?
- Do you have upcoming regulatory events that will be under increased scrutiny such as Phase III trials?
- Is your current solution/process always audit-ready? How did your last audit go?
- Do you struggle to find enough time/resources to complete validation work?
- Are you not turning on new features for the business because you don't have time to validate?
- How quickly can you recruit new talent to support your validation needs?
- Can you see across departments where you are with all validation activities?
- Are you getting consistent performance across validation team members?

With the assessment complete, key focus areas will come to the forefront. Next, assemble a team that will embrace change, create best practices, evaluate technology partners, and prioritize efforts.

"The measure of intelligence is the ability to change."

— ALBERT EINSTEIN

BUILDING A TEAM TO EMBRACE CHANGE

The ideal team is composed of individuals with deep expertise and those new to validation. It is helpful to articulate how CSA will bring people, quality, business, and IT together, and make their jobs easier.

Acknowledge that existing talent will need to transition to modern tools and methods, and while there is a learning curve associated with onboarding new technology, experienced resources will soon benefit from applying their domain expertise in new and high-value ways.

New talent entering the validation field have different expectations than colleagues who are familiar with CSV. In the competition for talent, validation candidates are more inclined to work with a company that is using a modern CSA-based approach with a digital solution. If they view the company's validation processes/technology as clerical and mundane, such as replicating stock content for each new project, they may accept an offer elsewhere where they can acquire transferable skills using tools and systems that will advance their career. Together, the experienced and new validation experts will make a powerful team.

Change management that encompasses timing, transparency, and collaboration plays a vital role. With the right team, you'll be able to move forward quickly and efficiently.

Keys to Supporting Change

Timing	→ Is there a "fresh start" to leverage?
Transparency & Tracking	→ How have you communicated the small goals you set? Are they achievable enough? → What does your tracking system look like? How will you use it in ongoing conversation?
Collaboration & Confidence	→ To what extent have you discussed progress and celebrated success? → How have you demonstrated that you believe change is possible?

Figure 1a. Source Sware

Desired Behavior: Thinking Critically in CSA

Do The Thing	→	Team members execute tests with few issues.
Do The Thing BETTER	→	Testing evidence is created more consistently and efficiently.
Do The Thing TOGETHER	→	Team members engage and support each other throughout the effort.

Figure 1b. Source Sware

UPDATING PROCESSES AND TECHNOLOGY SIMULTANEOUSLY

One of the great benefits of CSA is that unlike CSV, the organization must leverage critical thinking, planning, risk assessment, processes, and evaluation of workflows from the inception of the project. This means that validation becomes a focal point early in the overall process, enabling the team to define, structure, and automate workflows targeted on patient safety, data security and repeatable outcomes.

Automating your process requires effective supporting technology. Consider the efficiency that can be realized by using a solution compatible with validation lifecycle management. An effective solution will enable you to digitize your SOPs into an automated workflow and create reusable content for multiple validation projects while leveraging process knowledge and historical insights.

Under a new paradigm, organizations will implement solutions that automate and digitize the entire validation process. Process automation, structured risk assessments, and structured content will be key in enhancing the quality and efficiency of your validation efforts. Look for a CSA validation automation solution that will make compliance smart and seamless, enabling team members to function in a more strategic manner.

SCALING AND MEASURING PERFORMANCE ACROSS THE ENTERPRISE

To ensure your organization can scale and measure performance, select a technology partner with deep expertise in validation and with the applications you are using. The partner should have a system capable of managing validation activities across the enterprise, from implementations to release management. The solution should have decision-making tools that help customers figure out the needed documentation and scope for their validation efforts.

The ideal technology solution should guide users through the validation process, similar to popular tax filing software, and ensure the right steps are followed throughout the validation process (no skipping of steps allowed). Better tools, technologies, and automation ensure that changes are managed appropriately and maintained over time, making issues with vendor software release and last-minute changes a thing of the past. In the end, you will have a solution that ensures team members are thinking critically about the process, vendors, requirements, and execution.

What We Think About	Because We Need To	So We Can
Computer System Lifecycle Management	Understand how systems relate to each other	Explore approaches toward critical thinking in software assurance
Vendor Management	Have expertise in vendors and their systems	Learn through case studies as new systems are implemented from simple to complex use cases
Risk Assessment	Ensure objectivity	Determine what's working and not working: Are we over-assuring?
CSV & Change Control SOPs	Have clear instructions to get the job done	Processes can be automated to drive adherence and consistency

Figure 2. Source Sware

Leverage your new process, technology, and expert partner with one project, then scale to run validation consistently across all systems and throughout the enterprise. Take a date-forward approach with a new SaaS system and try the process, then apply key learnings and standardize.

An example of a CSA solution is Res_Q by Sware. Res_Q guides users through a structured workflow that aligns to your business processes. Intelligent decision-making tools help users figure out the scope and required documentation. The experts at Sware handle the migration process. This includes all documents and data to ensure a seamless migration effort. This includes one-time efforts importing Excel, PDF, and Word documents. For example, a document with multiple sections (such as a legal agreement) may have more than 20 sections, each containing separate content. Sware separates all sections so that customers can search, use, and reuse content, enabling them to track each requirement across systems. Notably, digital documents have a similar look and feel to Word and Excel and exist in a single system that manages all validation activities.

MEASURING PERFORMANCE

To effectively manage and measure compliance across system processes and teams, think about validation long-term, which includes a well-defined GXP roadmap and the technology-centric compliance implications. Factors such as the future use of AI, mobile strategies, and M&A plans should be key technology and partner considerations.

When determining the technology vision of the future, evaluate how you will grow and add applications as the company scales. Managing resources will ensure that your organization is poised for success, while responsibly replacing older systems with new technologies. Evaluate the cost of maintaining compliance and ways to further reduce resources and costs. Proactively address validation concerns, and how the technology is being used. While measuring success varies by company, here are a few common examples:

- Reduction of test scripts (a large reduction)
- ROI and cost reduction/Validation TCO
- 100% adherence to processes
- Updated, effective SOPs
- Audit readiness – always ready
- Reduction in validation time as measured in days/weeks
- Ability to turn on new features for the business in a short period of time
- Ability to leverage team members more strategically

CONCLUSION

As software development accelerates, teams and systems need to keep pace. Organizations that can effectively move beyond paperless to data-centric methodologies and processes will have clear advantages.

Modernizing validation is an emerging quality imperative. With a changing work environment, technology is required to keep pace and remain compliant. Between new regulations, an increase in vendor releases, and the FDA resuming audits, having the right partners, processes, and SOPs has never been more critical.

Electronic document management based systems cannot unlock the full benefits of CSA. Organizations need a purpose-built system that can enable true process automation with built-in risk assessments. Fortunately, there are modern tools that ease the pain points and reduce delays. As investments in life sciences accelerate, organizations with digitized and automated processes have distinct advantages.

To learn how Res_Q can help, please visit (or contact) sware.com.

About Sware

Sware is a healthcare and life sciences regulatory technology company addressing a vital unmet need: an enterprise-wide compliance engine that allows companies to successfully and easily navigate the validation burden.

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