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WHITEPAPER

How to Transition to Validation 4.0

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INTRODUCTION

The International Society for Pharmaceutical Engineering (ISPE) is providing guidance and best practices to achieve its vision for Pharma 4.0, a future state where organizations leverage the full potential of digitalization to provide faster innovations for the benefit of patients.

WHAT IS PHARMA 4.0?

Pharma 4.0 is the pharmaceutical industry's response to Industry 4.0, exemplifying the integration of digital technology into the manufacturing process. The Pharma 4.0 definition encapsulates a future where enhanced operational efficiency, product quality, and patient-centric approaches are driven by Industry 4.0 techniques for Pharma sectors. By automating pharmaceutical processes and capitalizing on advanced analytics, Pharma 4.0 significantly reduces costs and accelerates drug development, ensuring Pharma Industry 4.0 remains at the forefront of innovation. This transition highlights the shift toward digital infrastructure, making Validation 4.0 essential for regulatory compliance and efficiency in the pharmaceutical industry.

Our industry's current approaches to validation are viewed as a key barrier to making the transition to Pharma 4.0 successful. Recognizing this, ISPE is providing guidance on Validation 4.0 to assist the industry in adopting new technologies that help organizations transition away from creating documentary records for compliance, "validating" absolutely everything, and ignoring previous assurance activity or related risk controls.

A Validation 4.0 approach provides organization-wide benefits for companies:

- **IT:** allows companies to scale capabilities within an organization faster, while reducing costs and the number of people needed to manage the process.
- **Quality:** improves data integrity, inspection readiness, and allows for a better level of quality management.
- **Business:** enables new capabilities to be turned on faster, helping make the business more efficient.

This would seem to make the decision to move into Validation 4.0 sound like a "no brainer," however, many companies struggle to find a starting point for the implementation.

KICKING OFF THE VALIDATION 4.0 IMPLEMENTATION PROCESS

When starting the implementation process for Validation 4.0, it's helpful to take a step-by-step approach that starts with looking at where your company is currently. For example, are you a pre-commercial or commercialized company?

Understandably, a new company's starting point should coincide with the implementation of the first systems brought on board that require validation. On the other hand, if you're a commercialized company, you should apply newer, more modern technology to work alongside your existing cloud-based system. Companies should look for a management system that encompasses the entire validation lifecycle and engage with vendors possessing a mature quality approach. This ensures the risk-based approach around the applications can be done correctly.

Another important place to start is evaluating your current SOPs. Through step-by-step instructions compiled by your organization, SOPs help your colleagues (or team) carry out routine operations. SOPs aim to achieve efficiency, quality output, uniformity of performance and compliance with industry regulations, while reducing miscommunication.

- For new companies without preexisting SOPs, you'll want to establish SOPs that are already designed and optimized for a Validation 4.0 approach. This allows you to start fresh with the correct steps already in place and ensure a seamless adoption.
- To assess how much change is needed to evolve to a Validation 4.0 approach, companies with existing SOPs should evaluate current procedures related to CSV – which are not limited to CSV – Change Control, System Lifecycle Management, and ERES. Once you've evaluated your current SOPs, your company can implement change management strategies to facilitate a transition. These strategies serve as a roadmap for implementing new technologies and prioritizing the application of your more updated SOPs to cloud-based systems.

WHAT'S NEXT? COMMUNICATION AND EDUCATION

ISPE Pharma 4.0 is a monumental change to the existing pharmaceutical manufacturing, and any time a company makes a significant transition, clear and transparent communication across the organization is imperative to ensure everyone is on board. This can be approached via three steps:

3 Steps to Clear & Transparent Communication

Build your team of stakeholders	→ Bring together the teams that are most involved in validation - business owners, IT, quality department, and users.
Engage your stakeholders	→ Involve every member of the team throughout the process. Clearly communicate the benefits to motivate everyone.
Establish a process	→ Establish and engage in a specific, consistent process to implement a new system or manage change to an existing system.

Figure 1a. Source Sware

Communication is incredibly important for continuous improvement, but with it comes the very necessary step of educating your employees on how these new technologies will benefit them specifically. Modernizing your technology allows a little bit of productivity to go a long way, which is a major benefit from the employee perspective. This gives full-time validation employees more time to focus on things like better work/life balance or other work responsibilities.

For example, a leading pharma company had 400 test scripts that had to run four times annually for an enterprise system. This equated to 4,000 employee hours a year (nearly two FTEs) running test scripts for the sole purpose of verifying that the system worked the same way as before. The company solved this by digitizing its validation process – regaining 4,000 hours of productivity by implementing a technology solution that automated the process and the risk assessment, while supporting electronic and automated testing.

In general, education and communication center upon individual application teams. It's crucial to start by identifying the teams you need to motivate and then help them understand how it makes their future lives easier. This incentivizes people to put in the effort to adopt the process. By doing this one team at a time, you're able to take a truly personalized approach. From there, a modernized approach that utilizes the newest technology becomes institutional. When other teams are doing it and it's proving successful, everybody tends to jump on board.

USING INTELLIGENT TECHNOLOGY TO MAKE THE TRANSITION EASY

Communication and education must be executed to ensure a successful adoption process, but the key to making the transition seamless is intelligent technology. Intelligent technology is defined by data-centric, workflow-driven technologies that go beyond paper to truly transform the process.

Modernizing can be intimidating, but the tools to do so seamlessly already exist.

Change in the life sciences industry, especially as pertains to validation, is inevitable. However, it doesn't have to be troublesome. Pharma 4.0 solutions intend to benefit employees and businesses, and when it comes to a successful adoption process, it all boils down to intelligent technology, education, and communication.

Learn more about Sware's validation process automation platform Res_Q at 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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