Tricentis

# The next evolution of paperless validation in life sciences

## INTRODUCTION

The life sciences industry is poised for a drastic transformation. IoT devices are administering care in unbelievable ways, while algorithms and data are revolutionizing patient diagnosis and our understanding of diseases and ailments. Digital modernization is at an all-time high and the industry is innovating faster than ever before.

But compliance regulations can slow transformation's progress to a crawl, especially when compared to organizations operating in less-regulated fields. And the Agile and DevOps processes that facilitate progress aren't easily supported by traditional compliance, validation, and documentation practices.

When it comes to application quality, the very specific validation testing that must be performed doesn't always align with the fast, iterative release cycles that contemporary development and testing teams have adopted. Applications that have the potential to impact patient safety or product quality must be tested appropriately, and documentation of the process must be recorded with approvals and signatures from relevant stakeholders. How that process is managed, however, can vary greatly from company to company.

In its most rudimentary form, the traditional, paper-based approach to validation is not only time-consuming and expensive, it also can be difficult to track and control, adding stress to day-to-day operations and looming audit requests. In an increasingly digital patient-experience and insight-driven healthcare world, life sciences organizations must find ways to accelerate the validation process by integrating it more seamlessly into software delivery workflows.

## A COMPUTER SYSTEMS VALIDATION TIMELINE

Prior to the mid-90s, paper and ink signatures were the primary forms of validation and verification documentation in FDA-regulated environments. However, over the years the FDA–along with other industry organizations– have worked to modify regulations and guidance to better support the increased utilization of automation, digital systems, and velocity in the software quality landscape.

### 1997

In 1997, the FDA released these protocols by adding a new section to the Code of Federal Regulations. 21 CFR Part 11 expanded guidance around medical devices to include electronic records and signatures. This is when we see the first derivations of paperless validation, the most basic forms of what is available today. When the FDA introduced 21 CFR Part 11, it opened the door for more widespread use of electronic records and electronic signatures for verification and validation. This enabled greater efficiency in the computer systems validation (CSV) process.

However, not all variants of electronic-based CSV methodologies are created equal. Early iterations of paper validation simply recreate manual, paper-based processes in a digital format - a trend that continues today at many organizations.

Therefore, many of the limitations of paper-based validation continued to exist. For instance, electronic documents were still scanned from paper documents, and they were still "mailed" back and forth, now through email. Ultimately, they were stored in an on-premises server resembling a digital file cabinet. Often, those electronic records were (and are currently) printed out to present during an audit.

## 2001

The Manifesto for Agile Software Development was created by a group of software developers calling themselves the Agile Alliance. The manifesto laid out twelve principles that have since recentered the entire business world at large. These principles probably seem common sense by now, but the emphasis on simplicity in the software development process, flexibility in team collaboration, and adaptability to changing environments generated movement toward eliminating barriers to execution (e.g., inefficient validation procedures).

## 2003

In response to widespread confusion among life sciences organizations about how to interpret and implement 21 CFR Part 11 guidance, the FDA published a guidance document, "Part 11, Electronic Records; Electronic Signatures - Scope and Application." The goal was to clarify, update, and expand upon the original recommendations and seemed to be the FDA's way of acknowledging that this guidance can be difficult to interpret. This was particularly true as organizations began to modernize the way they developed, tested, and delivered software.

The updated guidance outlined a risk-based approach when validating electronic systems and implementing audit trails, encouraging organizations to tailor the extent of their validation processes to the nature and intended use of the system. This guidance essentially gave organizations the green light for interpreting and implementing the recommendations in a way that fit their product strategies, internal processes, and risk mitigation strategies.

## 2006

From 2006 onward we see a widely increased adoption of automated testing and test management tools. This was catalyzed by companies adopting enterprise-wide business operation systems like SAP, where a failure in the software would be immediately catastrophic for the organization and its clients.

The adoption of test management platforms for computer systems validation increased in this period as companies struggled to scale their current models for approvals and validations. Scanning physical documents or sending them via email in a Microsoft Word document just wasn't viable for teams spread across multiple locations across the globe.

## 2008

Up until 2008, organizations took a defensive posture in reaction to the vagaries of 21 CFR Part 11. Even with the published 21 CFR Part 11 guidance in place from 2003, the fear of fines and a continued lack of understanding around the regulation left many organizations still treating everything as high-risk. As a result, they over-documented and over-tested. In the worst cases, checking the boxes of compliance became more important than system quality.

Compliance documentation had hijacked the actual objective.

The year 2008 saw the introduction of GAMP 5: "A Risk-Based Approach to Compliant GxP Computerized Systems provides pragmatic and practical industry guidance that aims to achieve compliant computerized systems that are fit for intended use in an efficient and effective manner, while also enabling innovation and technological advances."

GAMP 5 gave companies the go-ahead to assign risk profiles to applications based on how much they might impact patient safety and product quality. By applying risk-based testing, companies had the potential to improve quality across the board because, in theory, they wouldn't need to perform high levels of testing and documentation on everything, but rather put emphasis on high-risk areas of testing and reduce testing in areas of low risk.

IT organizations without an understanding of GAMP 5 continued treating each application as high-risk, leading to over-documentation and over-testing. As a result, teams struggled to meet the demand for increased delivery velocity

After the release of GAMP 5, automated testing  became an enterprise standard in most industries. However, many life sciences teams still struggled to adopt test automation in their CSV process because

they hadn't yet modernized their approach to documentation and regulated testing strategies.

While GAMP 5 provided useful guiding principles for the implementation of a risk-based approach to software development, it didn't give sufficient guidance on how to apply its principles to test management.

### 2015

By this time, agile and digital transformation initiatives become more prevalent in life sciences organizations (especially pharmaceuticals), and several tools had made their way to market to facilitate these initiatives. To keep pace, the life sciences industry had to shift and adjust the validation processes it previously implemented, and automated test management tools start to become industry standard.

### 2022 and onward

The FDA's Computer Software Assurance (CSA) guidelines regarding non-medical devices and software (the recently published draft guidance can be found here) will enable life sciences organizations to streamline CSV by focusing the validation process on critical thinking about levels of risk. Whereas previous interpretation of guidance and regulations led to a principle of 80% documentation and 20% testing, CSA outlines a model to flip that percentage.

By focusing on applying testing and documentation rigor according to level of risk, the FDA's CSA guidance removes barriers to automation, enabling organizations to build a risk-based, pragmatic approach to testing that prioritizes the quality of a product without compromising compliance.

## TYPES OF PAPERLESS VALIDATION

Many organizations still use their digital systems to mimic manual processes. To create greater agility around validation requires a substantial reimagining of validation and the entire workflow surrounding it.

### Document-centric paperless validation

Document-centric validation is paperless validation that is still focused on the documents themselves. This is often the first stage in the shift from manual, paper-based processes. Sub-variations include static PDFs with electronic signatures or template-driven automated workflow solutions that capture and output documents in a more dynamic way than static PDFs.

With a document-centric approach, tasks that were previously done with a pen and ledger are now just transferred to a computer screen, and often the validation processes require manual intervention and the import of data, which limits the potential efficiency gains of paperless validation in the testing lifecycle. The only reason that doc-centric paperless validation has stuck around is that it feels familiar to quality teams when transitioning from physical documentation. Even those who have bought into solutions to manage the validation lifecycle with dynamic paperless validation still haven't transitioned to the new system effectively enough to go through an audit in the system, opting to print data from the system and then audit manually.

Document-centric paperless validation offers limited value over a paper-based process and severely hampers the ability of software developers to implement things like effective test automation and more of an Agile or DevOps process.

## Digital validation: The future of paperless validation

By leveraging automation and applying technical controls to drastically mitigate risks related to human error, organizations leveraging digital validation solutions can meet compliance with processes and regulations more quickly and easily. It is much more integrated with the testing lifecycle and the modern software quality landscape. Because it is designed to support a continuous testing methodology, it enables the utilization of Agile workflows within a CSV framework.

Digital validation can allow software development teams to break down documentation and capture requirements into workflows across the software testing lifecycle by embedding them directly within test management platforms. This enables more effective adherence to policies and procedures that can be defined according to regulatory requirements.

This mitigates risk in the testing lifecycle and triggers workflows for reviews and approvals as milestones take place. Digital validation solutions make the processes required by 21 CFR Part 11 invisible and eliminate roadblocks for software development teams, supporting higher-velocity testing while still increasing quality. By removing the extraneous layer of manually taking data and putting it into a document tool, digital validation automatically associates each action in the DevOps workflow to specific personnel. It makes each step more traceable, which in turn creates a more accurate audit trail and smooths out the development process. In essence, this approach is enabling compliance and documentation to be created as a byproduct of good software quality practices, rather than being managed as a separate process.

## Adapting to evolving regulatory and technology landscapes

Technology and methodologies will always be evolving and improving. So too will guidance and regulations, though at sometimes a slower pace. Remember the CSA model mentioned earlier? The goal of the FDA's Computer Software Assurance (CSA) guidelines is to remove activities that do not add value and limit the testing focus to those areas that are high-risk to improve overall quality. Taking this risk-based approach allows testing to be adapted to the application or system being validated instead of taking a one-size-fits-all approach to validation.

To support these types of changes, life sciences organizations should ensure that they have digital tools in place that when coupled with appropriate and strategic quality engineering, allow them to grow and flex with evolving regulatory and technology landscapes.

When it comes to looking for a tool for test management and digital validation, we ask you to remember this: due diligence is required. The tool you select must be able to streamline software delivery and be flexible enough to adapt to the specific testing requirements of life sciences organizations

To learn more about how Tricentis can support your digital validation efforts, watch this webinar.

## ABOUT TRICENTIS

**Tricentis is a global leader in enterprise continuous testing.** The Tricentis AI-based, continuous testing portfolio of products provide a new and fundamentally different way to perform software testing. An approach that's totally automated, fully codeless, and intelligently driven by AI. It addresses both agile development and complex enterprise apps, enabling enterprises to accelerate their digital transformation by dramatically increasing software release speed, reducing costs, and improving software quality. Widely credited for reinventing software testing for DevOps, cloud, and enterprise applications, Tricentis has been recognized as a leader by all major industry analysts, including Forrester, Gartner, and IDC. Tricentis has more than 2,500 customers, including the largest brands in the world, such as McKesson, Accenture, Nationwide Insurance, Allianz, Telstra, Dolby, and Vodafone.

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