Best Practices for 21 CFR Part 11 and GxP Validation for Electronic Records

EGNYTE

Introduction

Drug development has dramatically changed over the past 10+ years. A practice once dominated by pen-and-paper has since transitioned to computerized systems, cloud software, and artificial intelligence. In this dynamic environment, many biopharma companies struggle to adopt new technologies because of the uncertainty of how to comply with FDA regulations. Needless to say, developing a quality and compliance posture that meets the needs of both masters (business stakeholders and Regulatory Authorities and Auditors) is a tall order. In this piece, we will chronicle recent technological trends, specific challenges these trends pose for Quality and CSV teams, and best practices for tackling resulting compliance issues.

The Spirit of GxP Validation

Unlike other types of compliance, adhering to 21 CFR Part 11 and GxP requirements for electronic records varies from institution to institution. As a self-reporting compliance that is the outcome of validation, we will avoid the debate of what features or technologies are or are not compliant. Instead, we believe it is best to first re-orient the discussion towards principles and ask, "What is the spirit of the law?"

In our view, the spirit of these regulations is to:

1. **Ensure we can trust the data**
   - Make sure the systems that generate the data work properly
   - Make sure the data isn't tampered with
2. **Track and verify what people do**
   - Make sure we know who did what
   - Make sure individuals are attesting to a change

The outcome of these concepts is the variety of validation requirements, processes, and protocols.

Validation is More Complex Than Ever Before

In the early decades of digital transformation, software was predominantly developed, shipped, and deployed at customer sites. Updates were provided once per year. As a result, each piece of software and its underlying hardware typically required revalidation on an annual basis.

This "waterfall" mode of software development has changed dramatically over the past several decades.

The dominance of Agile development, including continuous delivery and continuous integration, means software is constantly changing. Additionally, applications are more frequently being hosted in the cloud as opposed to internally-controlled computing infrastructure.

To add further complexity, 50% or more of critical GxP work, such as pre-clinical studies, clinical trials, and batch-release testing are performed by outsourced vendors. In some cases, clinical trials for a given program could be supported by more than a dozen external vendors. Maintaining compliance of internal systems alongside a distributed network of collaborators is challenging, to say the least.

Best Practices for Validation

As technology and the operating model for drug development evolves, Quality and CSV teams need to adapt alongside. In this context, we have identified three sets of best practices to help companies manage their risk and compliance envelope. At a high-level, the three best practices are to: adopt a risk-based approach, build an ecosystem, and to choose the right partner.

- **Adopt a Risk-Based Approach:** Understanding how software changes may impact the use of the system should be considered when determining the most appropriate validation decision. This should also include leveraging validation work already performed or offered by your vendors and should be used to minimize your validation effort while complying with regulatory requirements for a validated system.
- **Centralize Data From Your Ecosystem:** A distributed network of collaborators, each with their own cloud or on-premises software can easily lead to a fractured set of regulated data. Tracking and ensuring the compliance posture of every vendor becomes very challenging, and only increases as the number of vendors increases. Instead, rely on vendors that have the ability to integrate, exchange, and centralize data across those providers. Through a holistic ecosystem, you can mitigate risk by having data flow in to a single, GxP repository that you control.
- **Future-Proof With the Right Partner:** Ultimately, it's all about partnership. Your team cannot do everything. Making the most of your vendor's Validation documentation and services,along with a robust ecosystem are the facets that set good vendors apart from great ones. In your search for a compliant solution, select the right partner whose product capabilities and validation enables your company to be regulatory compliant and to grow with them.

Conclusion

Science has fundamentally changed. Most biopharma companies outsource as much science as they do inside their four walls. Data sets at every stage of drug development are becoming larger, more diverse, and have higher fidelity. Software is no longer built by in-house software development teams, but rather provided as a service by hundreds of cloud vendors. Furthermore, the quantity of insider threats and sophistication of hackers make data breaches a near-daily occurrence. However, taking the time to fold in the right solution can help you to overcome those challenges while mitigating risks.

At a high-level, the three best practices are to adopt a risk-based approach, to build an ecosystem, and to choose the right partner.

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