GxP and FDA 21 CFR Part 11 Compliance with Egnyte for Life Sciences

EGNYTE

Introduction

In developing medicines, food, devices, and other products related to human health, teams must comply with specific standards known as "GxP." GxP, which stands for Good "x" Practices (x corresponds to manufacturing, laboratory, clinical, or other scenarios), is a set of best practices established to ensure high-quality standards for life sciences. Further, for the electronic records associated with these practices, institutions must comply with FDA 21 CFR Part 11 or EU Annex 11 guidelines.

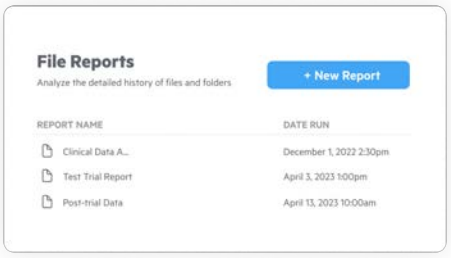
Egnyte for Life Sciences meets these requirements with seamless integration and customer implementation support. The first is a software platform that meets FDA 21 CFR Part 11 and EU Annex 11 requirements. The second is that the software undergoes rigorous qualifications to produce a validation package that can be procured alongside the compliant software.

OUR PERSPECTIVE

FDA 21 CFR PART 11 + Validation = **GxP** Compatibility

OUR SOFTWARE

Egnyte for Life Sciences is an industry-specific platform that has features and functions required to meet FDA 21 CFR Part 11. These features include:

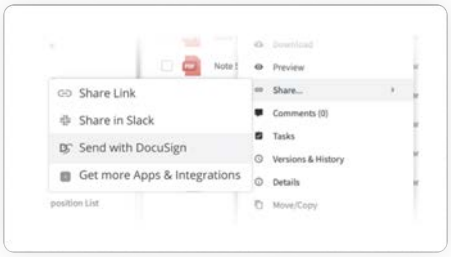


Audit Trails

- Automatically log reports on a folder that lists the files and folders underneath them
- Know when files and folders are updated, downloaded, previewed, edited, or deleted

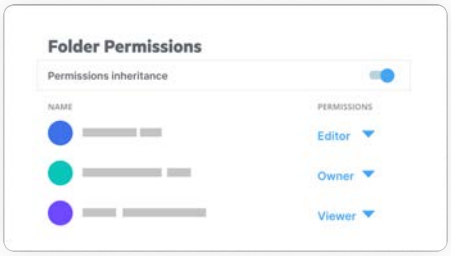
Data Integrity

- Maintain data integrity over time
- Report checksum values for every file in a regulated repository



eSignature Capabilities

- Approve regulated documentation with e-signatures
- Capture Part 11 compliant electronic signatures on your documents



User Access Control

- Grant users access to files as needed
- Seamlessly track user actions and monitor audit trails

VALIDATION

The validation package that supports Egnyte for Life Sciences provides a large portion of the required documentation to facilitate implementation. This approach lets you focus on accomplishing your business goals and less time on manual paperwork.

Below are the components of our validation package*:

1. **Functional Requirements Specifications (FRS)**
   This document describes the functionality of the Egnyte software along with any additional operational and system requirements.
2. **Validation Plan**
   This document serves as the guide to the validation of Egnyte software. It describes the validation approach, activities, validation testing coverage, and deliverables needed to document the validation of the software.
3. **Validation Testing Results**
   Documentation consisting of the test cases performed which demonstrates that the functionality of the Egnyte software operates as described.
4. **Traceability Matrix**
   This document correlates the test cases performed to the requirements outlined in the FRS document.
5. **Validation Summary Report**
   This document reports the outcome of the validation. It confirms that Egnyte software will operate to specifications, within the specified limits, consistently and dependably.
6. **Installation Qualification**
   This document contains the qualification of a newly created GxP domain for a customer. It verifies that all aspects of the software adhere to the approved specifications and is correctly installed.
7. **Platform Qualification**
   This document lists the architectural and security features of Egnyte and the infrastructure it uses. Further, this qualification corresponds to the underlying infrastructure for our applications.
8. **Electronic Records, Electronic Signatures (ERES) Compliance Assessment**
   This document is created by an independent third party that verifies Egnyte's compatibility with requirements identified in Part 11 and Annex 11.

*Our validation package does not include user requirements specification and user acceptance testing. They are the customer's responsibility.

Ongoing Support

One of the benefits of cloud software is that it is constantly improving. To accommodate our customers handling regulated data, we provide specialized services to support your ongoing compliance posture.

- **Test Environment:** Customers are provided with a dedicated test environment that can be used to perform testing, prepare internal operational procedures, etc.
- **Preview of New Features/Enhancements:** Our team provides a preview period of new releases prior to the availability of new features and enhancements into your GxP production environment. This allows customers to preview upcoming functionality.
- **GxP Compliance Portal:** Customers are provided with 24x7 access to the Egnyte validation packages and related information for Egnyte software.
- **Risk Assessments & Release Notes:** Egnyte can perform risk assessments on new features and functions and share those, alongside release notes, with our GxP customers.
- **Audits:** Customers of our GxP software are given the opportunity to remotely conduct an audit our Quality System procedures (e.g., SOPs) and related processes once per term.

Takeaway

For many companies in the life sciences industry, compliance is a mission-critical requirement. Egnyte makes it easy to meet the requirements highlighted in Part 11 and Annex 11. Egnyte for Life Sciences enables companies to rapidly create a compliant repository, validate it, and use it for their regulated data - with less IT effort and greater security.

EGNYTE

Egnyte provides the only unified cloud content governance solution for collaboration, data security, compliance, and threat prevention for multi-cloud businesses. More than 17,000 organizations trust Egnyte to reduce risks and IT complexity, prevent ransomware and IP theft, and boost employee productivity on any app, any cloud, anywhere. Investors include GV (formerly Google Ventures), Kleiner Perkins, Caufield & Byers and Goldman Sachs.

For more information, visit **www.egnyte.com.**

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