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

Introduction

As teams develop medicines, food, devices and other products that are involved with human health, they are expected to meet a set of standards best described by the acronym 'GxP'. GxP, which stands for Good ___ Practices (corresponding 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 are required to comply with FDA 21 CFR Part 11 or Annex 11.

Egnyte for Life Sciences' GxP-compatible platform meets these requirements and how we support customers in its implementation. This process comprises two parts. The first is a software platform that meets requirements in FDA 21 CFR Part 11. The second is that the software undergoes rigorous qualifications to produce a validation package that can be procured alongside the compliant software.

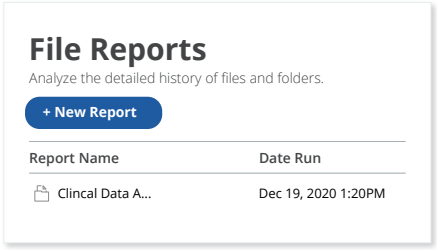
Our Perspective

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

When digging deeper, accomplishing this can become daunting. Don't worry, Egnyte can help. Here's how we make it easy for you.

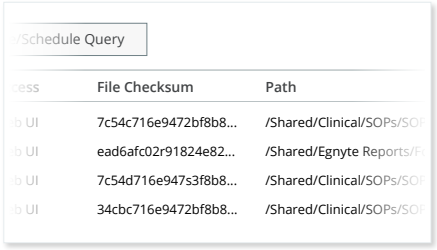
Our software

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:



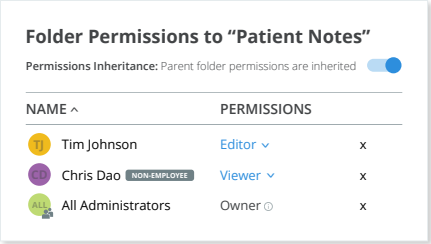
Audit trails

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



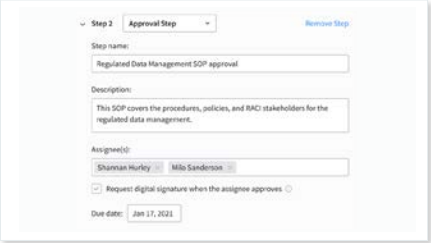
Data Integrity

- Customers require data to maintain integrity over time. We help you prove this by reporting on checksum values for every file in their regulated repository.



User access control

Maintaining proper security is essential; granting access only to those that need access is the first step. Egnyte for Life Sciences ensures granular control: Granting a user access to only their program data, for example, but restricting access to the others in an easy to administer interface..



GxP-compliant workflow

Sign off and approvals may be required for your regulated documentation. We have made it easy for anyone in your organization to initiate the review and approval of quality or SOP documents with Part 11-compliant e-signatures. Alternatively, we have integrations with all major eSignature providers.

Validation

The second step in the process of implementation is validation. This process involves verifying and documenting that software is performing as described.

This responsibility typically falls upon the customer, but 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**
   a. This document describes the functions Egnyte will perform and facilities required to meet the user requirements (often defined in a prior URS – User Requirements Specification) document.
2. **Installation Qualification**
   a. This document contains the qualification of the newly-created GxP domain for a customer. It catalogues that all aspects of the software adhere to the approved specifications and is correctly installed.
3. **Platform Qualification**
   a. This document lists all of the architectural and security features of Egnyte and the infrastructure it uses. Further, this qualification corresponds to the underlying infrastructure for our applications.
4. **Test Summary for our Operational Qualification (OQ)**
   a. This document catalogues the successful completion of a series of tests of the software's key components. The summary confirms that the software will operate to specification, within their specified limits, consistently and dependably.
5. **Traceability Matrix**
   a. This document correlates the requirements outlined in the FRS with the completion of test cases performed in the OQ.
6. **Electronic Records, Electronic Signatures (ERES) Assessment**
   a. 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 includes 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

We can provide a test environment for customers to configure and review updates prior to release to their production environment.

Risk Assessments & release notes

Egnyte can perform risk assessments on new features & functions and share those, alongside release notes, with our GxP customers.

Delayed releases

Our team is able to withhold releases from your GxP production environment to facilitate review and acceptance.

Review of Standard Operating Procedures (SOPs)

Customers of our GxP compatible software are given the opportunity to audit remotely our SOPs 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.

Book a Meeting

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In a content critical age, Egnyte fuels business growth by enabling content-rich business processes, while also providing organizations with visibility and control over their content assets. Egnyte's cloud-native content services platform leverages the industry's leading content intelligence engine to deliver a simple, secure, and vendor-neutral foundation for managing enterprise content across business applications and storage repositories. More than 16,000 companies trust Egnyte to enhance employee productivity, automate data management, and reduce file-sharing cost and complexity. Investors include Google Ventures, Kleiner Perkins, Caufield & Byers, and Goldman Sachs. **For more information, visit www.egnyte.com**

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