

Egnyte for Life Sciences Quality

Powerful tools for Quality teams to manage regulated business processes



Egnyte for Life Sciences Quality gives Quality teams powerful tools to streamline the management of regulated documents in compliance with GxP and Part 11 requirements. Our software provides native, compliant workflows that enable your organization to initiate the review and approval of controlled documents with Part 11-compliant e-signatures, deployment to internal and external stakeholders, and report on the adoption and status of all documents on the platform.

The screenshot displays the Egnyte Quality DMS interface. On the left, a sidebar menu includes 'Documentation', 'Training', and 'Settings'. The main area shows a 'Documents' list with columns for ID, NAME, VERSION, STATUS, EFFECTIVE FROM, and EFFECTIVE UNTIL. The list includes documents like 'Delegation of Responsibility', 'Submitting Changes in Research', 'Protocol Deviation Reporting and Documentation', 'Reporting Study Non-Compliance', 'Process for Obtaining Informed Consent', and 'Process for Obtaining Informed Consent'.

ID	NAME	VERSION	STATUS	EFFECTIVE FROM	EFFECTIVE UNTIL
SOP-1	Delegation of Responsibility	1.1	EFFECTIVE	Feb 1, 2021	Jan 31, 2022
SOP-2	Submitting Changes in Research	1.0	EFFECTIVE	Jan 1, 2021	Jan 2, 2022
SOP-3	Protocol Deviation Reporting and Documentation	2.0	EFFECTIVE	Mar 1, 2021	Feb 28, 2022
SOP-4	Reporting Study Non-Compliance	1.3	EFFECTIVE	Mar 1, 2021	Feb 28, 2022
SOP-5	Process for Obtaining Informed Consent	2.0	DISOBTAIN	Mar 1, 2022	Feb 28, 2023
SOP-6	Process for Obtaining Informed Consent	1.0	EFFECTIVE	Jun 1, 2021	Feb 28, 2022

Below the table, a document preview for 'SOP-6 - Process for Obtaining Informed Consent' is shown. It includes a title, version (2.0), and a brief description: 'This document outlines the best practices, procedures, and policies adopted by the Clinical Development team for obtaining informed consent from study participants.'



Meet GxP & FDA 21 CFR Part 11

Digitize regulated documents and workflows within a compliant software platform.



Scale compliance processes quickly

Built with best practices gleaned from 16,000 global customers, the solution is easy to use, implement, and validate.



Manage effective documents

Easily define version numbers for new drafts, set expiry dates, and ensure only effective copies are available.



Perform e-Signatures

Customers can sign off on documents, like SOPs and clinical trial protocols, in a compliant manner, without 3rd party plugins.



The Egnyte Difference

Smarter Quality Processes

Egnyte's workflows streamline Quality Document Management, removing bottlenecks for your regulated business processes.

Better, Faster Collaboration

Accelerate the review and approval process with real-time cloud-based collaboration tools, notifications, and a global dashboard that tracks progress.

Visibility and Control

Reporting gives you visibility into the status and adoption of regulated documents and configurable roles and teams accelerate assignment of user permissions.

Audit-ready Platform

Satisfy any audit with granular user access control, detailed audit trails, checksums for data integrity, and electronic signatures.



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www.egnyte.com