Helyx™ Controlled Documents
Simplified, Secure & Compliant Document Management for Life Sciences

Empowering life sciences teams with a modern, compliance-driven document control solution

The Business Problem We Solve

Life sciences companies often face high costs, complexity, and inefficiencies when managing controlled documents. Many existing solutions require extensive setup, ongoing administration, and expensive validation efforts, making compliance management resource-intensive. Others lack seamless integration with quality, training, and regulatory workflows, leading to disconnected systems, operational bottlenecks & create compliance risks, complicate version control, and slow down approvals and audits.

Built on the Helyx Platform with the Industrial Power of Microsoft Azure

Key Use Cases

1. Efficient Document Creation and Approval:
Streamline the creation and approval of SOPs, policies, and batch records using pre-configured workflows and templates.

2. Version Control for Regulatory Compliance:
Maintain full version histories to demonstrate compliance during audits and inspections.

3. Real-Time Collaboration Across Teams:
Collaborate on controlled documents across departments and external partners without delays.

4. Audit-Ready Documentation:
Automatically generate audit trails linking document approvals, changes, and access history.

The Helyx™ Advantage

- **Built for Biotech & Pharma:** No costly customizations needed.
- **Pre-Validated & Audit-Ready:** 21 CFR Part 11 compliant.
- **Lower Total Cost of Ownership:** Cloud-based, automated setup, and pre-validated compliance.
- **Unified Platform:** Eliminating Silos across applications.
- **Microsoft 365 Integration:** Real-time, multi-user collaboration.
- **Rapid Deployment:** Ready in weeks, not months.
- **Scalable & Flexible:** Grows with biotechs, cost-effective without sacrificing compliance.

Key Features

Document Lifecycle Management

Manage the creation, approval, and controlled distribution of critical documents such as SOPs, batch records, and policies.

Automated Workflows

Streamline approvals, reviews, and notifications with automated routing to the right stakeholders.

Version Control and Tracking

Automatically maintain and store previous document versions for full traceability.

Side-by-Side Document Comparison

Quickly identify changes between versions to speed up reviews and approvals.

Real-Time Collaboration

Enable teams to collaborate on documents in real time using Microsoft 365 tools.

Role-Based Access Control

Assign role-based permissions to ensure that only authorized personnel can access, edit, or approve documents.

Audit Trails

Automatically log all actions related to document creation, approval, and distribution, ensuring audit-ready records.

Enterprise-Grade Security

Built on Microsoft Azure, offering multi-factor authentication, encrypted storage, and continuous security monitoring.

Why Helyx™ Controlled Documents?

Helyx Controlled Docs streamlines document management while ensuring full traceability and compliance, helping life sciences companies improve efficiency and regulatory readiness. With pre-configured workflows, deployment is fast, typically within weeks. Its modular, scalable pricing makes it cost-effective for early-stage and mid-sized biotechs, while seamless integration with Helyx Quality and Learning ensures unified compliance. Built on Microsoft 365 and Azure, it offers secure, high-performance access, easy adoption, and customizable workflows to fit unique organizational needs.