

Helyx™ Quality Security White Paper

A QUALITY MANAGEMENT SYSTEM FOR CONTROLLED
DOCUMENTS AND USER TRAINING MANAGEMENT

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1. Executive Summary

Helyx Quality is a cloud-based Quality Management System (QMS) offered as Software as Service (SaaS) that streamlines document lifecycle management, training, and regulatory compliance for life sciences. This paper details Helyx Quality's security framework, ensuring data confidentiality, integrity, and availability in compliance with GxP regulations and industry best practices.

Key Security & Compliance Highlights:

- Secure Cloud Architecture – Layered defenses, data encryption (in transit and at rest), and robust access controls.
- Compliance-Driven – Built for 21 CFR Part 11, Annex 11, and global GxP standards.
- Scalable & Resilient – High availability, multi-region backups, and real-time monitoring ensure adaptability.
- Continuous Improvement – Regular security audits, vulnerability testing, and compliance updates.

Helyx Quality helps biotech companies maintain regulatory readiness and protect intellectual property by embedding security and compliance at every stage.

2. Introduction

2.1 Industry Context & Challenges

Biotech companies in R&D and clinical stages face challenges in:

- Developing novel treatments while ensuring regulatory compliance.
- Managing quality systems efficiently as they scale.
- Meeting GxP standards without impeding innovation.

2.1.1 Early-Stage Challenges (R&D & Preclinical)

Small teams, limited resources, and manual document controls often lead to:

- Version control issues.
- Incomplete audit trails.
- Inability to scale.

2.1.2 Clinical-Stage Challenges

- Increased regulatory scrutiny (GLP, GCP, GxP).
- Outdated legacy document management systems create inefficiencies.
- Coordination issues across internal teams, CROs, and external labs.

All life sciences companies, regardless of their current stage, require clear, traceable, and compliant documentation to avoid delays, warnings, or financial risks.

3. The Helyx Quality Solution

Helyx Quality centralizes quality management, providing a scalable, cloud-based solution tailored to evolving biotech needs.

3.1 Right-Sized Workflows for Growing Teams

- Simple, adaptable workflows for small teams that scale with growth.
- User-friendly interface reduces onboarding time.

3.2 Streamlined Compliance Management

- 21 CFR Part 11 & GxP-ready e-signatures, audit trails, and version control.
- Automated compliance checks reduce regulatory risks.

3.3 Enhanced Operational Efficiency

- Eliminates paper-based processes, reducing errors and approval delays.
- Real-time collaboration & notifications improve coordination.

3.4 Integrated Compliance Training

- Customizable training modules aligned with GxP.
- Built-in tracking & reporting ensures audit readiness.

3.5 Scalability & Future Readiness

- Adapts as companies move from preclinical to clinical to manufacturing.
- Supports integrations and future enhancements (e.g., analytics).

4. Security Architecture

Helyx Quality employs a layered security model to protect data from application interfaces to infrastructure and processes.

4.1 Access Management & Controls

- Role-Based Access Control (RBAC) – Restricts user permissions by role.
- Multi-Factor Authentication (MFA) – Adds an extra layer of login security.
- Single Sign-On (SSO) – Integrates with enterprise authentication systems.
- Audit Logs – Tracks logins, edits, and approvals for forensic analysis.

4.2 Enforced Security Policies

- Strict password policies with complexity rules and session timeouts.
- Regular security policy reviews to adapt to emerging threats.
- Ongoing employee security training to reinforce best practices.

4.3 Data Backup & Recovery

- Daily & incremental backups to prevent data loss.
- Geographically redundant storage for disaster resilience.
- Routine recovery drills to validate backup integrity.

4.4 Security Monitoring

- Security Information & Event Management (SIEM) for real-time threat detection.
- Automated incident response with containment & remediation.
- Regular vulnerability scanning & patching to eliminate risks.

4.5 Performance & Reliability

- Scalable cloud infrastructure adapts to user load.
- Load balancing & monitoring prevent slowdowns.
- Proactive capacity planning ensures smooth growth.

5. Compliance & Regulatory Framework

Helyx Quality aligns with GxP standards (GLP, GCP, GMP) to ensure:

- Data accuracy.
- Traceability.
- Accountability.

5.1 GxP-Aligned Platform Features

- 21 CFR Part 11 & Annex 11 compliance – Secure e-signatures & audit trails.
- Validated workflows – Aligns with IQ/OQ/PQ requirements.
- Audit-ready documentation – Auto-generated logs for compliance reviews.

5.2 Ongoing Compliance Management

- Regular internal audits to maintain compliance.
- Dedicated regulatory team tracks evolving industry standards.

6. ISO 27001:2022 Certification

6.1 Commitment to International Security Standards

Celito is actively pursuing ISO 27001:2022 certification, reinforcing our commitment to global best practices in information security.

6.2 Alignment with Existing Security Controls

- Risk assessments, access management, and incident response already align with ISO 27001 standards.
- Ongoing gap analysis ensures we exceed compliance requirements.

6.3 Certification Roadmap

- Internal audits & readiness reviews to verify security controls.
- Formal certification process to enhance regulatory credibility.

6.4 Customer Benefits

- Increased trust in data security practices.
- Easier vendor audits & regulatory inspections.
- Stronger data protection for research & clinical data.

By integrating ISO 27001:2022 with GxP compliance, Celito enhances security, reduces risk, and simplifies regulatory processes for biotech organizations.

7. Conclusion

7.1 Key Takeaways

- End-to-End Security – Protects data at every level.
- Regulatory Compliance – Meets GxP, 21 CFR Part 11, and ISO 27001 standards.

- Operational Efficiency – Streamlined workflows and real-time monitoring.
- Scalability & Resilience – Cloud-based infrastructure adapts to business needs.

7.2 Future Outlook

Helyx Quality will continue to evolve, with planned releases and enhancements. We remain committed to achieving ISO 27001:2022 certification, reinforcing our dedication to continuous security improvements.

8. Call to Action

Ready to optimize quality management while ensuring compliance?

- Request a personalized demo today.
- Explore how Helyx Quality can secure your data, streamline workflows, and accelerate biotech innovation.

Contact us to get started.