SimplerQMS

SimplerQMS Audit Trail

A fully validated, cloud-based eQMS solution for life science companies, featuring a secure, time-stamped, and 21 CFR Part 11 compliant audit trail.

https://simplerqms.com/21-cfr-part-11-audit-trail/

Overview

SimplerQMS is a comprehensive, cloud-based Electronic Quality Management System (eQMS) specifically designed for life science companies, including those in medical devices, pharmaceuticals, biotech, and clinical laboratories. The software is sold as an all-inclusive solution, with the **Audit Trail** being a core, compliant feature.

Key Features and Capabilities

The system is fully validated according to GAMP5 Category 4 standards, ensuring continuous compliance with major regulatory requirements. The cornerstone feature is the **21 CFR Part 11 Compliant Audit Trail**, which is secure, computer-generated, and time-stamped. It automatically captures and records all actions and changes made to electronic records, including user identity, date and time of changes, and the type of change, providing complete traceability for audits.

Other integrated QMS modules include:

Document Control: Robust features for version control and document access management.
Electronic Signatures: 21 CFR Part 11 compliant digital signatures for legally binding approvals.
Training Management: Assign training activities, track progress, and automate reminders based on job roles.
CAPA Management, Change Management, Nonconformance/Deviation Management, Audit Management, Risk Management, and Supplier Management.

Technology and Integration

SimplerQMS is a cloud-based SaaS solution hosted on Microsoft Azure and M-Files technology, offering enterprise-grade security and data encryption. A key differentiator is the seamless integration with **Microsoft Office 365**, allowing users to edit documents in familiar applications like Word and

Excel directly in the cloud, with changes automatically logged in the audit trail. The platform also offers an open API for custom integrations.

Target Users and Benefits

The software targets companies of all sizes (startup, small, medium, enterprise) within the life science sector. Its primary benefit is simplifying compliance, achieving audit readiness in a short timeframe (5-6 weeks), and reducing the time and cost associated with manual, paper-based quality management systems.

Key Features

- 21 CFR Part 11 Compliant Audit Trail
- Electronic Signatures
- Full GAMP5 Validation
- Seamless Microsoft Office 365 Integration
- Document Control and Versioning
- CAPA, NC, and Deviation Management
- Training Management and Matrix
- 24/7 Customer Support

Pricing

Model: subscription

Subscription-based, priced per user on a recurring yearly basis. The minimum annual subscription is USD 15,000, which covers up to 15 users. Pricing is all-inclusive, covering all modules, full implementation, system validation, unlimited training, hosting, and 24/7 support. A free 'Viewer' license is available for read-only access for auditors and external collaborators.

Starting at: USD $15000

Target Company Size: startup, small, medium, enterprise

Integrations

Microsoft Office 365, Microsoft Entra ID (Azure AD), Jira, ERP, CRM, PLM, LIMS, MES, WMS

Compliance & Certifications

FDA 21 CFR Part 11, ISO 13485, EU MDR, EU IVDR, GxP, GAMP5, ISO 9001, ISO 27001, ISO 27018, FDA 21 CFR Part 820, GDPR