SimplerQMS

SimplerQMS

Fully validated, cloud-based Electronic Quality Management Software (eQMS) for Life Science companies to simplify compliance and streamline quality processes.

https://simplerqms.com

Overview

SimplerQMS is a fully validated, cloud-based Electronic Quality Management System (eQMS) purpose-built for regulated Life Science industries, including Medical Devices, MedTech, Pharmaceuticals, Biotech, IVD, and CROs. The software is designed to help small to medium-sized organizations achieve and maintain regulatory compliance while automating core quality processes.

Key Features and Capabilities

SimplerQMS offers a comprehensive, all-inclusive suite of QMS modules, eliminating the need for separate systems. Key modules include Document Control, CAPA Management, Training Management, Change Control, Design Control, Risk Management, Supplier Management, Audit Management, and Electronic Batch Records (EBR). The system streamlines workflows for document authoring, review, and approval, ensuring version control, automated audit trails, and 21 CFR Part 11 compliant electronic signatures.

Technology and Integration

The platform is built on trusted Microsoft Azure and M-Files technologies, providing enterprise-level security and scalability. A key differentiator is the seamless integration with Microsoft Office 365 (Word, Excel, PowerPoint, and Outlook), allowing users to edit documents directly in the cloud environment without manual download and upload. SimplerQMS also offers an open API for integration with other enterprise solutions such as ERP, PLM, CRM, LMS, WMS, Azure DevOps, and Jira.

Compliance and Validation

SimplerQMS is fully validated according to GAMP5 (Category 4) and provides continuously updated validation evidence (IQ, OQ, PQ documentation), significantly reducing the validation burden for customers. It supports compliance with a wide range of global standards and regulations, including FDA

21 CFR Part 11, FDA 21 CFR Part 820 (QSR), ISO 13485:2016, EU MDR, EU IVDR, GxP, EU GMP Annex 11, ISO 9001:2015, and ICH Q10.

Pricing and Support

The software is offered via an all-inclusive annual subscription with transparent pricing and no hidden fees. The subscription covers all modules, full system implementation (typically 5-6 weeks), unlimited user training, system validation, hosting, and 24/7 expert support via email, phone, video calls, and a knowledge base. A free 'Viewer' license is available for unlimited auditors and collaborators with read-only access.

Key Features

- Document Control
- CAPA Management
- Training Management
- Change Control
- Design Control
- Risk Management
- Supplier Management
- Audit Management
- Electronic Batch Records (EBR)

Pricing

Model: subscription

All-inclusive annual subscription with flexible license types (Viewer, Light, Standard, Full). The Starter plan is for up to 15 users, starting from USD 15,000 annually. Viewer licenses are FREE for invited auditors/collaborators with read-only access.

Starting at: USD $15000

Target Company Size: small, medium, enterprise

Integrations

Microsoft Office 365, Microsoft Entra ID (Azure AD), ERP, PLM, CRM, LMS, WMS, Azure DevOps, Jira

Compliance & Certifications

FDA 21 CFR Part 11, FDA 21 CFR Part 820, ISO 13485:2016, EU MDR, EU IVDR, GxP, GAMP5, EU GMP Annex 11, ISO 9001:2015, ICH Q10