



Matrix One & Matrix Quality eQMS

Matrix One (<https://matrixone.health>) is headquartered in Germany and specializes in providing compliant SaaS software system solutions for the biopharma, medical device, and life science sectors. With presences in France, the United States, Switzerland, and Israel, its core mission is to automate and digitize highly complex and high-risk medical regulatory compliance (such as FDA, EU MDR/IVDR, ISO 13485, GxP, etc.) business processes. This boosts corporate productivity and efficiency, helps shorten time-to-market, and mitigates regulatory risks.

Matrix Quality eQMS is a cloud-based Quality Management System built on the Salesforce platform, offering QMS functions and modules including: Document Control, Training Management, Quality Event Management (Deviation, CAPA, Change Control, Complaints, OOS, etc.), Audit Management, Supplier Management, Electronic Trial Master File (eTMF), Design Control (DHF/DMR), and Risk Management.

Matrix Quality compliance Information

FDA 21 CFR Part 11	✓	Built-in electronic signatures, complete audit trail, access control, and data integrity mechanisms compliant with Part 11
EU Annex 11	✓	Provides a validation framework and cloud data security control compliant with EU computerized systems regulations
ISO 13485	✓	Provides default workflow templates (CAPA, Change Control, Document Management, etc.) compliant with the ISO 13485
GxP (GMP/GLP/GCP)	✓	Includes TMF management, Batch Records and Deviation Management, and Validation-ready modules

Matrix Quality core features

Key Factor	MQ eQMS Feature	Competitors Model	MQ eQMS Benefits & Business Value
Pricing	✓ Monthly fee includes all system functions	✗ Modules are split for billing or sales	• All-inclusive pricing • Precisely budget cap control & financial forecasting
Self-Service	✓ Self-service implementation ready	✗ Designated consulting & fee models	• No extra or potential hidden costs
Configuration	✓ 24/7 online support for change requests	✗ Highly reliant on external resource & availability	• Fast support of change requests • Avoids project delays due to waiting in line for external resources
Expansion	✓ No extra service fee for any new module implementation	✗ Every newly implementation requires separate fees	• Low cost for future expansion • Maximizes system utility and long-term value
CSV Validation	✓ Online validation module ready	✗ High-cost & time-consuming validation process	• Faster project go-live • New module implementation does not require re-validation of the entire system
AI Features	✓ Built-in AI tool module, no extra cost	✗ Requires additional fees or upgrade to premium license	• Provides AI functions such as data query, problem analysis, report writing assistance, and chatbot, significantly increasing productivity and efficiency at no extra cost



Matrix One & Matrix Quality eQMS

Matrix Quality subscription fees

Type	Monthly / Seat	Applicable Roles and Access Level
Light Users	\$15 USD	Beginner Users: general viewing of SOP, WI, GMP/GLP/GCP documents, receiving training notifications, completing training & confirmations
Light Plus	\$45 USD	Advanced Review/Collaboration Users: applicable to personnel who need to participate in reviews or execute specific data recording
Full Access	\$90 USD	QA, RA, Audit or Dept. Head Users: process permissions for document creation, drafting, signing, & CAPA, Change Control, Deviation creation
Admin	\$125 USD	System Admin (IT / QM Head): Responsible for system settings, field/workflow configuration, user access control, and audit trail monitoring

Customer Reference

Matrix Quality eQMS has been adopted by over 200 companies globally, with implementation spanning pharmaceuticals, medical devices, drug development, CDMO, and digital health companies. Most customers have successfully passed regulatory audits. Here is some customer references :

- **Ionetix** : an MIT spin-out US company engaged in superconducting cyclotron and technology development, providing comprehensive radioisotope production, and end-to-end radiopharmaceutical R&D and manufacturing. **Passed US FDA audits.**
- **CellVec** : a Singapore-based GMP-certified gene therapy CDMO company, specializing in providing customized viral vectors for preclinical and clinical applications. **Passed the Singapore HSA GMP audit** in 2020.
- **Baccinex** : an established European CDMO company headquartered in Switzerland, holding **EU GMP certification** (EudraGMDP registration), and possessing clinical and commercial sterile filling capabilities. **Passed US FDA audits.**
- **Xbrane Biopharma** : a biopharmaceutical listed company (Ticker: XBRANE). Its Ranibizumab biosimilar (Ximluci) officially obtained EMA EU Marketing Authorization (MAA) in November 2022. Its manufacturing supply chain **passed the EU pre-approval inspection and GMP audit.**
- **Nanox** : an innovative medical tech company headquartered in Israel and listed on Nasdaq (Ticker: NNOX). Passed the European Notified Body quality system **ISO 13485 audit** in 2020. Its core products (semiconductor X-ray technology + AI technology) obtained **US FDA 510(k)** clearance for marketing in 2021 and **EU CE certification** (MDR/MDD) in 2022.



Quillaya | QualityScape



Quillaya partners with QualityScape in Singapore. Our team possesses diverse technical backgrounds and rich practical experience in QMS system implementation. If needed, we provide customized partial or comprehensive full-scale assistance for Matrix Quality eQMS consulting and implementation services.

- ✓ Gap Analysis / Project Planning
- ✓ CSV / CSA Services - URS, RA, VP, CS/FRS, RBAC, TM, IOPQ, VSR
- ✓ Onsite Implementation - PM, DMP/DMR, Training, 或 SOP revision
- ✓ Continuous Validation & Audit Readiness