

Qualio Premier content: SaMD pathway



✓ Audit-tested

✓ 90% pre-built: ready for tailoring by you

✓ Built on best practice + industry expertise

Quality system content

- Quality Manual
- Electronic Records and Signatures
- General Change Procedure
- Document Control
- Risk Management
- Control of Quality, Regulatory and Product Records
- Training
- Internal Quality Audits
- Good Documentation Practices
- Nonconformance Process
- Design Controls
- Validation of Software and Spreadsheets
- Management Review
- Corrective and Preventive Action
- Purchasing and Supplier Management
- Analysis of Data
- Statistical Techniques
- Customer Communications and Feedback
- Customer Complaints
- Adverse Event, Vigilance and Incident Reporting
- User, Market, and Product Requirements
- Technical Files & Regulatory Controls
- Product Recall, Field Correction, and Advisory Notices
- Development of Product Labeling
- Software Validation Procedure (IQ/OQ/PQ)
- Product Identification, Traceability and Unique Device Identifier (UDI) Management
- Product Order Processing
- Software Development Processes
- Software System Verification and Validation
- Device Master Record
- Software Standard Coding Practices
- Clinical Evaluation Reporting
- Post-Market Surveillance
- UK Technical Files and Regulatory Controls
- Quality Policy
- Product Recall, Field Correction & Advisory Notices
- Management of Supplier Files in Qualio
- Creation of a Non-Conformance Report (NCR)
- Creation of a CAPA
- Creation of a Complaint
- Qualio's Design Controls Configuration
- Creation of a Supplier Corrective Action Record (SCAR)
- Perform an Extension Request
- Create and Edit Training Plans
- Creation of Event Change Request
- QMS Document to Regulation Matrix - SaMD

Document templates

- Design Development Plan
- Design History File Index
- Device Master Record
- Design Master Record Index
- Design/Process Change Review
- Design Traceability Matrix
- Internal Audit File
- Internal Audit Schedule
- Management Review Minutes and Action Items
- Management Review Sign-in Sheet
- Employee File
- Policy
- Quality Manual
- Quality Record
- Qualio Validation Document
- Risk Analysis
- Risk Management File
- Risk Management Plan
- Risk Management Report
- Standard Operating Procedure
- Work Instruction
- Bug Tracker
- CE Marked Product List
- Clinical Evaluation Plan
- Clinical Evaluation Report
- Cybersecurity Measures
- Design History File
- Device History Record
- External Audit
- Field Safety Corrective Action Report
- Field Safety Notice
- GSPR Checklist
- Health Hazard Evaluation
- Hazard Traceability Matrix
- Instructions for Use
- EU MDR Technical Documentation
- Organization Chart
- Product Requirements (Software)
- Periodic Safety Update Report
- QMS Documents to Regulation Matrix
- Quality Objectives
- Quality Plan
- Regulatory Document
- Regulatory Standards Log
- Software Detailed Design
- Software Development Plan
- Software Design Specifications
- Signature Matrix
- Supplier Periodic Review
- Software Requirements Specification
- Training Record
- UKCA/UKNI Market Product List
- User Manual
- User Requirements
- Validation Protocol
- Validation Report
- Verification Protocol
- Verification Report
- Validation Master Plan

Event templates

- Corrective and Preventive Action
- Internal Audit Report
- Incident Report
- Nonconformance Report
- Change Request
- Complaint
- Extension Request
- Supplier Corrective Action Record