

Qualio Premier content: hardware + 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
- Purchasing and Supplier Controls
- Internal Quality Audits
- Design Control
- Analysis of Data
- Statistical Techniques
- Management Review
- Nonconformance Management
- Good Documentation Practices
- Validation of Software and Spreadsheets
- Customer Communications and Feedback
- Customer Complaints
- Corrective and Preventive Action
- Medical Device Reporting, Vigilance, and Incident Reporting
- Product Recall, Field Correction, and Advisory Notices
- User, Market, and Product Requirements
- Design Verification and Validation
- Software System verification and Validation
- Software Validation Procedure (IQ/OQ/PQ)
- Software Development Processes
- Software Standard Coding Practices
- Process Validation Procedure
- Device Master Record
- Product Identification and Traceability
- Unique Device Identification
- Production Work Environment
- Production Work Order and Device History Record
- Storage, Handling, and Distribution
- Receiving of Purchased Materials
- Equipment Calibration and Maintenance
- Technical Files & Regulatory Controls
- Labeling and Packaging
- Product Order and Shipping
- Final Acceptance Inspection
- Sterilization of Product
- Contamination of Product
- Post-Market Surveillance
- Clinical Evaluation Reporting (MDR)
- Technical Files & Regulatory Controls (UK MDR)
- Deviation Management
- Development of Product Labeling
- Clinical Trials Risk Management
- Quality Policy
- Employee Cybersecurity
- 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)
- Creation of Extension Request
- Create and Edit Training Plans
- Creation of a Change Request
- Creation of Deviations
- Managing Risk with Qualio Design Controls
- QMS Document to Regulation Matrix - HW
- QMS Document to Regulation Matrix - SaMD

Document templates

- Design Development Plan
- Design History File Index
- Device History Record
- Device Master Record
- Device Master Record Index
- Design/Process Change Review
- Design Review Record
- Design Validation Protocol
- Design Validation Report
- Design Verification Protocol
- Design Verification Report
- Employee File
- Internal Audit File
- Internal Audit Schedule
- Policy
- Management Review Minutes and Action Items
- Management Review Sign-In Sheet
- Quality Manual
- Quality Record
- Risk Management File
- Risk Management Plan
- Standard Operating Procedure
- Risk Analysis
- Risk Management Report
- Work Instruction
- Australian (TGA) Declaration of Conformity
- Bill of Materials
- CE Marked Product List
- Clinical Evaluation Protocol
- Clinical Evaluation Report
- Cybersecurity Measures
- Certificate of Analysis
- Certificate of Conformance
- Design History File
- Design Risk Analysis
- Design Transfer Checklist
- External Audit
- End-of-Life Notification
- Equipment List
- Equipment Record
- Feedback Form
- Field Safety Corrective Action Report
- Field Safety Notice
- GSPR Checklist
- Health Hazard Evaluation
- Traceability Matrix (Harzard)
- Instructions for Use
- Label Specification
- Market Assessment
- EU MDR Technical Documentation
- Manufacturing Plan
- Organization Chart
- Product List
- Process Master Validation Plan
- Product Requirements
- Product Requirements (Software)
- Part Specification
- Periodic Safety Update Report
- Process Validation Protocol
- Quality Inspection Record
- Quarantine Log
- QMS Documents to Regulation Matrix
- Quality Objectives
- Quality Plan
- Qualio Validation Document
- Regulatory Document
- Regulatory Standard Log
- Research Protocol
- Supplier Audit Form
- Supplier Audit Schedule
- Software Detailed Design Plan
- Software Development Plan
- Software Design Specifications
- Software Requirements Specification
- Signature Matrix
- Technical File Index
- Traceability Matrix (Design)
- Training Record
- Usability Engineering File
- UKCA/UKNI Market Product List
- User Requirement
- Validation Protocol
- Validation Report
- Verification Protocol
- Verification Report
- Validation Master Plan
- Work Order

Event templates

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