Qualio Premier content: hardware + SaMD + ISO 27001 pathway

- Audit-tested
- 90% pre-built: ready for tailoring by you
- Built on best practice + industry expertise

Quality system content

- Quality Manual - ISO 27001
- Quality Manual - SaMD
- 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
- Management Review
- Nonconformance Management
- Good Documentation Practices
- Corrective and Preventive Action
- Design Control
- Software System verification and Validation
- Analysis of Data
- Statistical Techniques
- Customer Communications and Feedback
- Customer Complaints
- Medical Device Reporting, Vigilance, and Incident Reporting
- Product Recall, Field Correction, and Advisory Notices
- User, Market, and Product Requirements
- Design Verification and Validation
- Software Validation Procedure (IQ/OQ/PQ)
- Software Development Processes
- Software Standard Coding Practices
- 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
- Validation of Software and Spreadsheets
- Post-Market Surveillance
- Validation Program
- Clinical Evaluation Reporting (MDR)
- Technical Files & Regulatory Controls (UK MDR)
- Deviation Management
- System Recovery from Backup
- Security Incident Response Plan
- Data Protection Impact Assessments (DPIA)
- Clinical Trial Risk Management
- Good Practice for Digital and Data-Driven Health Technologies
- External Audits
- Development of Product Labeling
- Information Security Policy
- Internal Privacy Policy
- Employee Cybersecurity
- Business continuity, Disaster Recovery and contingency planning
- Vendor/Third-Party Access Policy
- Systems Password and Access Policy
- Threat & Vulnerability Management Policy
- Bring Your Own Device (BYOD) Policy
- IT Asset Management Policy
- Technology Controls and Endpoint Security Policy
- Data protection
- Software Licensing Policy
- Validation Policy
- Incident Management Policy
- Clean Desk and Clear Screen Policy
- Software development life cycle
- Data security, backup & redundancy
- Infrastructure Specification: Details the system landscape and installed software components
- General Data Protection and Privacy Policy
- Network Security Policy
- Cable Security Policy
- Cryptography and Cryptographic Key Management 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
- Creation of Deviations
- Managing Risk with Qualio Design Controls
- Use of Gitlab
- Use of Bitbucket
- QMS Documents to Regulation Matrix - HW
- QMS Documents to Regulation Matrix - ISO 27001:2022

Document templates

- Design Development Plan
- Design History File Index
- Device History Record
- Device Master Record Index
- Design/Process Change Review
- Design Review Record
- Design Validation Protocol
- Design Validation Report
- Design Verification Protocol
- Design Verification Report
- Management Review Minutes and Action Items
- Management Review Sign-in Sheet
- Employee File
- Internal Audit File
- Internal Audit Schedule
- Policy
- Risk Analysis
- Quality Record
- Qualio Validation Document
- Risk Management File
- Risk Management Plan
- Risk Management Report
- Standard Operating Procedure
- Work Instruction
- Asset Management Log
- Australian (TGA) Declaration of Conformity
- Bill of Materials
- CE Marked Product List
- Clinical Evaluation Protocol
- Clinical Evaluation Report
- Cable Inspection Checklist
- Cybersecurity Measures
- Certificate of Analysis
- Certificate of Conformance
- Design History File
- Device Master Record
- Data Protection Impact Assessment
- 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
- Information Security Record
- Label Specification
- Market Assessment
- EU MDR Technical Documentation
- Manufacturing Plan
- Organization Chart
- Organizational Content Matrix
- 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
- Quality Manual
- QMS Documents to Regulation Matrix
- Quality Objectives
- Quality Plan
- Regulatory Document
- Regulatory Standard Log
- Register of Data Processing Activities (GDPR Inventory)
- Research Protocol
- Supplier Audit Form
- Supplier Audit Schedule
- Software Detailed Design
- Software Development Plan
- Software Design Specifications
- Statement of Applicability
- Software Requirements Specification
- Signature Matrix
- Security Risk Register
- Technical File Index
- Traceability Matrix (Design)
- Training Record
- Usability Engineering File
- UKCA/UKNI Market Product List
- User Requirements
- Validation Protocol
- Validation Report
- Verification Protocol
- Verification Report
- Validation Master Plan
- Work Order

Event templates

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

Qualio