

# Qualio Core content: medical device hardware 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
- Corrective and Preventive Action (CAPA)
- Validation of Software and Spreadsheets
- Good Documentation Practices
- Management Review
- Design Control
- Nonconformance Management
- 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
- 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
- Clinical Trials Risk Management
- 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)
- Create and Edit Training Plans
- Creation of Event Change Request
- Creation of Deviations
- Managing Risk with Qualio Design Controls
- Perform an Extension Request
- Quality Policy
- Employee Cybersecurity
- QMS Document to Regulation Matrix - Hardware



## Document templates

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



## Event templates

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