Qualio Core content: 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
- Information Security Policy
- Employee Training and Development
- Document Management and Control
- Internal Privacy Policy
- Record Retention and Destruction
- Employee Cybersecurity
- Business continuity, Disaster Recovery and contingency planning
- Vendor/Third-Party Access Policy
- Systems Password and Access Policy
- Threat & Vulnerability Management Policy
- Supplier Management
- Bring Your Own Device (BYOD) Policy
- IT Asset Management Policy
- Technology Controls and Endpoint Security Policy
- Data protection
- Software Licensing Policy
- Change Management 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
- Cable Security Policy
- Cryptography and Cryptographic Key Management Policy
- System Recovery from Backup
- Security Incident Response Plan
- Network Security Policy
- Control of Quality, Regulatory and Product Records
- Electronic Records and Signatures
- General Change Procedure
- Document Control
- Risk Management
- Training
- Design Verification and Validation
- Internal Quality Audits
- Analysis of Data
- Statistical Techniques
- Management Review
- Nonconformance Management
- Customer Communication and Feedback
- Customer Complaints
- Corrective and Preventive Action
- Process Validation Procedure
- Good Practice for Digital and Data-Driven Health Technologies
- Data Protection Impact Assessments (DPIA)
- Validation of Software and Spreadsheets
- Design and Development Procedure
- Purchasing and Supplier Evaluation
- Clinical Trials Risk Management
- Management of Supplier Files in Qualio
- Creation of a Non-Conformance Report (NCR)
- Creation of a CAPA
- Creation of a Complaint
- Use of Gitlab
- Use of Bitbucket
- Creation of a Supplier Corrective Action Record (SCAR)
- QMS Documents to Regulation Matrix - ISO 27001:2022

Document templates

- Asset Management Log
- Cable Inspection Checklist
- Design Development Plan
- Data Protection Impact Assessment
- Design Review Record
- Design Validation Protocol
- Design Validiation Report
- Design Verification Protocol
- Design Verification Report
- Internal Audit Schedule
- Information Security Record
- Management Review Minutes and Action Items
- Organization Chart
- Organizational Content Matrix
- Policy
- Quality Manual
- QMS Documents to Regulation Matrix
- Quality Record
- Register of Data Processing Activities (GDPR Inventory)
- Regulatory Document
- SaMD
- Risk Management File
- Risk Management Plan
- Risk Management Report
- Signature Matrix
- Statement of Applicability
- Standard Operating Procedure
- Security Risk Register
- Training Record
- Work Instruction

Event templates

- Change Request
- Complaint
- Data Breach | Security Incident Response
- Corrective and Preventive Action
- Nonconformance Report
- Supplier Corrective Action Record