

# Qualio Core content: ISO 9001 pathway



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

## Quality system content

- Quality Manual ISO 9001
- Electronic Records and Signatures
- General Change Procedure
- Document Control
- Risk and Opportunities Management
- Control of Quality, Regulatory and Product Records
- Training
- Purchasing and Supplier Evaluation
- Internal Quality Audits
- Management Review
- Nonconformance Management
- Good Documentation Practices
- Corrective and Preventive Action
- Design and Development Procedure
- Validation of Software and Spreadsheets
- Analysis of Data
- Statistical Techniques
- Customer Communications and Feedback
- Customer Complaints
- Service and Product Requirements
- Design Verification and Validation
- Process Validation Procedure
- Product Identification and Traceability
- Production Work Environment
- Equipment Calibration and Maintenance
- Release of Products and Services
- QMS to Regulation Matrix - ISO 9001
- Management of Supplier Files in Qualio
- Creation of a Nonconformance Report (NCR)
- Create and Edit Training Plans
- Creation of Event Change Request
- Perform an Extension Request
- Creation of a CAPA
- Creation of a Complaint
- Creation of a Supplier Corrective Action Record (SCAR)
- Quality Policy

## Document templates

- Employee File
- Internal Audit File
- Internal Audit Schedule
- Management Review Minutes and Action Items
- Management Review Sign-in Sheet
- Policy
- Quality Manual
- Quality Record
- Risk Management Plan
- Standard Operation Procedure
- Work Instruction
- Design and Development Plan
- Design Review Record
- Design Validation Protocol
- Design Validation Report
- Design Verification Protocol
- Design Verification Report
- Equipment List
- Equipment Record
- Organizational Chart
- Product Requirements
- Part Specification
- QMS Documents to Regulation Matrix
- Qualio Validation Document
- Risk Management Report
- Risk Management File
- Training Record
- User Requirements

## Event templates

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