

# Qualio Premier content: combination products pathway



Audit-tested

90% pre-built: ready for tailoring by you

Built on best practice + industry expertise

## Quality system content

- Quality Manual
- Quality Policy
- Electronic Records and Signatures
- General Change Procedure
- Document Control
- Risk Management
- Control of Quality, Regulatory and Product Records
- Training
- Laboratory Controls
- Internal Quality Audits
- Analysis of Data
- statistical Techniques
- Management Review
- Nonconformance Management
- Corrective and Preventive Action (CAPA)
- Good Documentation Practices
- Customer Communication and Feedback
- Customer Complaints
- Deviation Management
- Medical Device Reporting, Vigilance, and Incident Reporting
- Product Recall, Field Correction, and Advisory Notices
- Design Control
- Product Identification and Traceability
- Unique Device Identification
- Storage, Handling, and Distribution
- Labeling and Packaging
- Final Acceptance Inspection
- Sterilization of Product
- Contamination of Product
- Validation Program
- Receiving of Purchased Materials
- Product Order and Shipping
- Production and Work Environment
- Production Work Order and Device History Record
- Equipment Calibration and Maintenance
- Device Master Record
- Validation of Software and Spreadsheets
- Post-Market Surveillance
- External Audits
- UK Technical Files and Regulatory Controls
- User, Market, and Product Requirements
- Product Return and Servicing
- Clinical Evaluation Reporting (MDR)
- Out of Specification (OOS)
- Facilities Management
- Production and Process Controls
- Field Alert Report
- Finish Product Release
- Pharmaceutical Outsourced Operations
- Annual Product Review/Product Quality Review
- Technical Files and Regulatory Controls (EU MDR/IVDD/IVDR)
- Purchasing and Supplier Evaluation
- Design Verification and Validation
- Stability Program
- Software Development Process
- Process Validation Procedure
- Supply Chain Management for Pharmaceuticals
- Product Recall, Field Correction, and Advisory Notices
- Management of Supplier Files in Qualio
- Creation of Non-Conformance Report
- Creation of a CAPA
- Creation of a Complaint
- Qualio's Design Control Configuration
- Creation of a Supplier Corrective Action Record (SCAR)
- Creation of Deviations
- Perform an Extension Request
- Create and Edit Training Plans
- Creation of Event Change Request
- Creation of Out of Specification (OOS)
- Managing Risk with Qualio's Design Controls
- Organization Chart
- QMS Documents to Regulation Matrix - Device HW
- QMS Documents to Regulation Matrix - Pharma

## Document templates

- Annual Product Review
- Bill of Materials
- Batch Release Record
- CE Marked Product List
- Certificate of Analysis
- Certificate of Conformance
- Clinical Risk Management Plan
- Design Development Plan
- Design History File
- Design History File Index
- Device History Record
- Device Master Record Index
- Design/Process Change Review
- Design Risk Analysis
- Design Review Record
- Design Transfer Checklist
- Design Validation Protocol
- Design Verification Protocol
- Design Verification Report
- External Audit
- Employee File
- Equipment List
- Equipment Record
- Event Risk Management Plan
- Feedback Form
- Health Hazard Evaluation
- Harzard Traceability Matrix
- Internal Audit File
- Internal Audit Schedule
- Inspection Plan
- Label Speciafication
- Market Assessment
- Manufacturing Plan
- Management Review Minutes and Action Items
- Management Review Sign-In Sheet
- Organization Chart
- Product List
- Policy
- Product Requirements
- Product Release Form
- Product Specifications
- Part Specification
- Purchase Specifications
- Process Validation Protocol
- Process Validation Procedure
- Quarantine Log
- Quality Manual
- QMS Documents to Regulation Matrix
- QMS Master List
- Quality Objectives
- Quality Plan
- Quality Record
- Qualio Validation Documents
- Regulatory Document
- Regulatory Standard Log
- Risk Management File
- Risk Management Plan
- Risk management Report
- Supplier Audit Form
- Supplier Audit Schedule
- Signature Matrix
- Standard Operating Procedure
- Supplier Quality Management
- Technical File Index
- Traceability Matrix (Design)
- TMF Plan
- Training Record
- Validation QMS
- Validation Master Plan
- Work Instruction
- Work Order

## Event templates

- Change Request
- Complaint
- Deviation
- Corrective and Preventive Action
- Internal Audit Report
- Incident Report
- Nonconformance Report
- Out of Specification/Out of Trend (OOS/OOT)
- Supplier Corrective Action Record