



✓ 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 and Personnel
- Purchasing and Supplier Controls
- Internal Quality Audits
- Laboratory Controls
- Management Review
- Deviation Management
- Customer Complaints and Post Market Adverse Event Reporting
- Production and Process Controls
- Product Recall
- Field Alert Report
- Stability Program
- Product Return and Reprocessing
- Validation Program
- Validation of Software and Spreadsheets
- Product Identification and Traceability
- External Audits
- Component Handling, Storage, and Distribution
- Equipment Calibration and Maintenance
- Labeling and Packaging
- Finished Product Release
- Final Acceptance Inspection
- Out of Specification (OOS)
- Supply Chain Management for Pharmaceuticals
- Good Documentation Practices
- Pharmaceutical Outsourced Operations
- Facilities Management
- Annual Product Review / Product Quality Review
- Clinical Risk Management
- Quality Control
- Waste Disposal
- Corrective and Preventive Action (CAPA)
- Subcontracting
- Corrective and Preventive Action (CAPA)
- Creation of a Complaint
- Creation of Event Change Request
- Create and Edit Training Plans
- Perform an Extension Request
- Management of Supplier Files in Qualio
- Creation of a Supplier Corrective Action Record (SCAR)
- Creation of Out of Specification (OOS)
- Quality Policy
- QMS to Regulation Matrix - Cosmetic and Nutraceuticals

Document templates

- Annual Product Review
- Batch Release Record
- Certificate of Analysis
- Certificate of Compliance
- Clinical Risk Management Plan
- IND Document Index
- External Audit
- Employee File
- Equipment List
- Equipment Record
- Event Risk Analysis Record
- Internal Audit File
- Internal Audit Schedule
- Management Review Minutes and Action Items
- Management Review Sign-In Sheets
- Policy
- Product Requirements
- Product Release Form
- Quality Manual
- Quality Record
- Qualio Validation Document
- Regulatory Document
- Risk Management File
- Risk Management Plan
- Risk Management Report
- Regulatory Record
- Supplier Audit Form
- Supplier Audit Schedule
- Signature Matrix
- Standard Operating Procedure
- Training Record
- Validation Master Plan
- Visitor Sign-In Form
- Work Instruction

Event templates

- Change Request
- Complaint
- Corrective and Preventive Action
- Deviations
- Extension Request
- Internal Audit Report
- Incident Report
- Nonconformance Report
- Out of Specification / Out of Trend
- Post Change Evaluation
- Recall
- Supplier Corrective Action Record