

# Qualio Core content: **therapeutics 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
- Control of Quality, Regulatory and Product Records
- Training and Personnel
- Purchasing and Supplier Controls
- Internal Quality Audits
- Management Review
- Corrective and Preventive Action (CAPA)
- Deviation Management
- Validation of Software and Spreadsheets
- Good Documentation Practices
- Risk Management
- Laboratory Controls
- 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
- 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
- Pharmaceutical Outsourced Operations
- Facilities Management
- Annual Product Review / Product Quality Review
- Clinical Risk Management
- Quality Policy
- Corrective and Preventive Action (CAPA)
- Creation of a Complaint
- Perform an Extension Request
- Management of Supplier Files in Qualio
- Creation of a Supplier Corrective Action Record (SCAR)
- Creation of Event Change Request
- Create and Edit Training Plans
- Creation of Deviation
- Creation of Out of Specification (OOS)

## **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
- Qualio Validation Document
- Risk Management File
- Risk Management Plan
- Risk Management Report
- Standard Operating Procedure
- Work Instruction
- Annual Product Review
- Batch Release Record
- Certificate of Analysis
- Certificate of Compliance
- Clinical Risk Management Plan
- IND Document Index
- External Audit
- Equipment List
- Equipment Record
- Event Risk Analysis Record
- Product Requirements
- Product Release Form
- Regulatory Document
- Regulatory Record
- Supplier Audit Form
- Supplier Audit Schedule
- Signature Matrix
- Training Record
- Validation Record
- Validation Master Plan
- Visitor Sign-In Form

## **Event templates**

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