

Qualio Core content: ISO 15189 pathway



✔ Audit-tested

✔ 90% pre-built: ready for tailoring by you

✔ Built on best practice + industry expertise

Quality system content

- Quality Manual - ISO 15189
- 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
- Service Agreements
- Examination Process
- Quality Control
- Screening and Testing of Donors
- Decision Rules
- Reporting of Test Results and Release of Certificate of Analysis
- Receipt, Storage, Handling, and Disposal of Samples
- Sampling
- Measurement Uncertainty
- Laboratory Reagents and Consumables
- Equipment Calibration and Maintenance
- Test and Calibration Methods and Method Validation
- Deviation Management
- Facility Maintenance and Environment
- Release of Products and Services
- Management of Supplier Files in Qualio
- Creation of a Nonconformance Report (NCR)
- Creation of Event Change Request
- Creation of Deviations
- Create and Edit Training Plans
- Perform an Extension Request
- Creation of Out of Specification (OOS)
- Creation of a CAPA
- Creation of a Complaint
- Creation of a Supplier Corrective Action Record (SCAR)
- Quality Policy
- QMS to Regulation Matrix - ISO 15189

Document templates

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

Event templates

- Change Request
- Complaint
- Corrective and Preventive Action
- Deviation
- Extension Request
- Internal Audit Report
- Incident Report
- Supplier Corrective Action Record
- Out of Specification/ Out of Tolerance/Trend
- Nonconformance Report