Qualio Add-on content: clinical pathway

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

Quality system content

- QMS to Regulation Matrix - ICH E6 Good Clinical Practice
- Receipt, Storage, Handling, and Disposal of Samples
- Deviation Management
- Transfer of Regulatory Obligations
- Pre-Qualifying and Selecting Clinical Investigators
- Generation and Review/Approval of Protocols and Amendments
- Managing CRO
- Management of Financial Disclosure Documents
- Study Specific Training
- Generation and Review/Approval of Regulatory Submissions
- Development of Informed Consent Form
- Development of Investigator's Brochure
- Study Start-Up
- Management of Serious Adverse Events
- Monitoring of Clinical Trials
- Management of Investigational Product
- Clinical Vendor Selection and Oversight
- Trial Master File Management
- Clinical Data Management
- Security Incident Response Plan
- Clinical Risk Management
- System Recovery From Backup
- Archiving of Clinical Trial Data and Essential Documentation
- Case Record Form (CRF) Design
- Trial Closure
- Creation of Deviations

Document templates

- Case Record Form Approval
- Clinical Training Record
- Financial Disclosure Documents
- IB Annual Review Form
- Trial Master File Index
- Trial Master File Plan

Event templates

- Deviation