Merit for Life Science GxP Documents

Toss the paper. Keep the compliance.
Gain a better way of working together.

BUILT FOR CONTROL. DESIGNED FOR COLLABORATION.

Merit for Life Science GxP Documents is a complete document management and control solution that supports the comprehensive document lifecycle—from creation, development, review, and publishing to change management and archival. Gain control of quality SOPs, validation documents, compliance documents, process specific instructions, analytic procedures, and more. All while amping up the secure, controlled collaboration your business requires. Work securely with both internal teams and external partners following GxP guidelines and regulations, ISO standards, and maintaining 21 CFR Part 11 compliance.

INTEGRATE WITH YOUR SYSTEM OF RECORD.

Merit for Life Science GxP Documents works seamlessly with Merit for Life Science – Operations and also works well with any ERP or operational system, further advancing your organization's ability to streamline, automate, and securely manage and control critical documents as part of your complete digital solution. It is also available as a standalone solution.

UNLIMITED USE CASES.

There are limitless applications for Merit for Life Science GxP Documents because the solution not only works for all internal team members, but also enables you to securely collaborate with external partners—one of the biggest challenges facing life science organizations.

Here are a few of the ways different departments within life science organizations are using it today:

FINANCE & LEGAL

- Contracts and other legal documents
- Sarbanes Oxley (SOX) and Sunshine Reporting
- 10K, shareholder presentations and other reporting narrative aids

HUMAN RESOURCES

- On-boarding, training, and cross-training
- Separation/exit
- Job descriptions, salary and level templates, promotion form templates
- Company handbook and other employee policy information

CUSTOMER RELATIONS

- Customer technical specifications intake forms and surveys
- Customer [or partner] project deliverables
- Sales and marketing collateral

RESEARCH & DEVELOPMENT

- Research findings
- Internal and external peer review
- R&D collaboration
- Collaborative documentation, approvals and reviews with trial sites, CDMOs (contract development and manufacturing organizations), cell banks and other partners

SUPPLY CHAIN PLANNING

- Supplier CMO/CDMO contracts
- Vendor certifications
- Vendor Audit history/results
- Vendor delivery commitments / schedules

QUALITY/REGULATORY COMPLIANCE

- Standard operating procedures (SOPs)
- Employee certification requirements
- Complaints
- Investigations and CAPAs (Corrective Action Preventive Actions)
- Electronic systems independent verification and validation (IVV)

SOURCING, PROCURMENT & MATERIALS MANAGEMENT

- Material inspection records
- Material COAs
- Material specifications
- Batch track and trace records
- Approved Supplier Lists
- Supplier Qualifications
- Material receipt records
- Batch Release history
- Employee training history
- Internal Audit history
- Supplier audit history
- Material Testing / Inspection documents
- Analytics methods standards

MANUFACTURING EXECUTION

- Material Testing / Inspection documents
- Analytics methods standards
- Employee training documentation
- Batch Production Records
- Equipment validation records
- Equipment maintenance records
- Equipment specifications and audits
- Environmental controls logs and history
- Non-conformances, Deviations, Corrections, Investigations
- Batch Release history

INVENTORY & WAREHOUSING

- Material inspection records
- Material COAs
- Material specifications
- Batch track and trace records
- Dispensing records
- Shipping records
- Material receipt records
- Batch Release history