OpenText Documentum for Quality and Manufacturing

Control critical, quality documentation and streamline and automate processes while ensuring compliance


Using cloud-native technologies for on-premise or cloud deployment, the solution is built on OpenText™ Documentum™, the industry’s leading and most scalable content management platform, and complies with the Drug Information Association (DIA) GMP Quality Systems reference model for consistent document modeling. This includes specifications, methods, labelling and master batch records, as well as procedures, governance, corporate policies, validation reports and many other document types. The solution expands upon the DIA reference model by supporting medical device documents, including collated Design History Files and Device Master Records.
Documentum for Quality and Manufacturing addresses the challenges of managing documents governing manufacturing, quality, compliance and other standard operating procedures. It provides prebuilt templates and lifecycles, automated workflows and support for parallel collaborative authoring and review, giving users consistent, accurate, compliant and quality documentation. This extensive out-of-the-box functionality, built on more than 25 years of experience in the Life Sciences industry, shortens implementation time while providing robust configuration capabilities. And, when a change to documentation is required, such as during a scheduled periodic review, the entire process is automated and tracked.

Uncompromised regulatory compliance

At any time, Life Sciences organizations can be called upon to demonstrate compliance with quality and manufacturing regulations. With Documentum for Quality and Manufacturing, organizations can clearly prove 21 CFR Part 11 compliance with extensive audit trails and access controls, including e-approval and e-signature support, document distribution, version control and lifecycle management.

Automatically distributed effective documentation

As an organization’s business network expands, it must harmonize data and procedures across geographically distributed sites, while still enabling localized productivity and efficiency. With Documentum for Quality and Manufacturing, users can automatically distribute documentation to employees and partners, both internally and externally. The solution automatically replaces previous versions with the latest approved documents, ensuring that
the most current version is in use across the extended enterprise. Users can also view controlled documents on mobile devices safely and securely.

**Provides mobile accessible and auditable actions**

Documentum for Life Sciences provides role-based, personalized views to enable employees to simply and efficiently complete routine tasks. Users can expect an intuitive, personalized experience. Easy-to-use, consumer-like mobile access on phones and tablets ensure that work continues on the go. External users review and approve content in the same compliant way as internal users. And, with watermark support and rights management capabilities, control over distribution and use of content has never been stronger.