OpenText Documentum for Life Sciences – Turn-Key Solutions

Unified processes and seamless information sharing

The OpenText Documentum for Life Sciences is a basic framework for document management applications that optimizes access, management, and exchange of information in life sciences companies, making information silos a thing of the past. The pre-configured, integrated solutions are based on best practices for this industry branch and are available as specific business modules for standardized business processes for the business areas of quality assurance, clinical and non-clinical research, and regulatory issues. OpenText Documentum for Life Sciences solutions harness an information architecture based on the Drug Information Association (DIA) Electronic Document Management (EDM) and Trial Master File (TMF) Reference Models.

Are you looking for a holistic Life Sciences solution to meet regulatory compliance requirements, increase efficiency and productivity, balance access, control and localization as well as securely collaborate across the enterprise? Then the Documentum D2 based purpose-built solutions are the proper choice for your company. You may either use off the shelf business modules or even establish your own business logic by means of configuration. With our 360° fme Professional Service, we ensure a seamless implementation of the OpenText Documentum for Life Sciences solutions and support you with the alignment on the business process – also on a global scale!

Our Offering

Looking back at 15+ years of experience in ECM for Life Sciences with global clients as well as mid-size manufacturers we developed the 360° fme Professional Services. With our industry and content migration expertise and proven Prince 2-based project management methodology as well as our Roll Out Support (module-by-module vs. all solutions at once) we will make your project a success. No matter if on-premise or off premise (as private, public or hybrid cloud), fme is your partner of choice.

Full Lifecycle Service

We support you throughout the whole life cycle: from Process Analysis & Solution Design and Installation & Configuration through to Customization & Integration as well as 24/7 Global Operation & Support.

Content Migration Service

Our migration-center is the bridge between your content in file or legacy systems and the OpenText for Life Sciences solution. Understanding the target OpenText Documetum

fme Start-up For OpenText Documentum For Life Sciences Solutions

Set-up

- Demo with focus on one specific module
- Matching customer requirements with D2 features
- Identification of module for »Ramp-up stage«
- Decision about on-premise or off-premise
- Outlining of potential project scope

Ramp-up

- 2 days consulting package to discuss existing processes
- Brief analysis of existing data (source, format, etc)
- Installing the module and setting up first workflows
- Manual creation of small amounts of data to visualize the process
- Workshop to handover PoC
- Project budget calculation
- Documentation of results

Take-off

- Project kick-off
- Deep analysis of existing processes and content
- Finding workshop
- Multi-side installation of the D2 modules (Dev/Test/Prod)
- Configuration
- Migration of existing content
- Roll-out including training
- Hypercare support
- Up to 24*7 support

object design based on the principles of the DIA reference model is one of the core expertise areas of fme. Further, fme's migration-center software, certified for OpenText Documentum and OpenText, combined with best practice experience qualifies fme as first choice for Life Sciences companies to support complex and critical migration projects. For specific migration paths with the target of D2 based systems, migration-center supports a so called in-place migration to streamline the process. Object IDs and audit trail entries remain during this conversion. fme also offers a migration-center Validation Package consisting of two basic components. One component is a collection of needed document templates. The other component is a consulting service to adapt the individual client validation needs to these templates.

Benefit

- Improved business productivity and efficiency
- Integrated, easy to configure purpose-built solutions with intuitive user interface
- A trusted, compliant and scalable ECM platform that is cloud ready
- A committed, single-source vendor with 15+ years experience in Life Sciences and Documentum projects

Extensible With fme And 3rd Party Extensions

Although OpenText Documentum for Life Sciences offers complete solutions, there are many extensions. These extensions come from fme and fme partner and include widgets (e.g. Dimension Viewer & Simplified User Interface) as well as an integration of Microsoft SharePoint, Extedo eSUBmanager and Sparta Trackwise.

OpenText Documentum for Life Sciences – Solution Module Overview

OpenText Documentum Electronic Trial Master File
Effectively plan, collect, track and maintain essential GCP-compliant clinical trial documentation.

OpenText Documentum Research and Development
Manage the creation, review and approval of regulatory submission documentation.

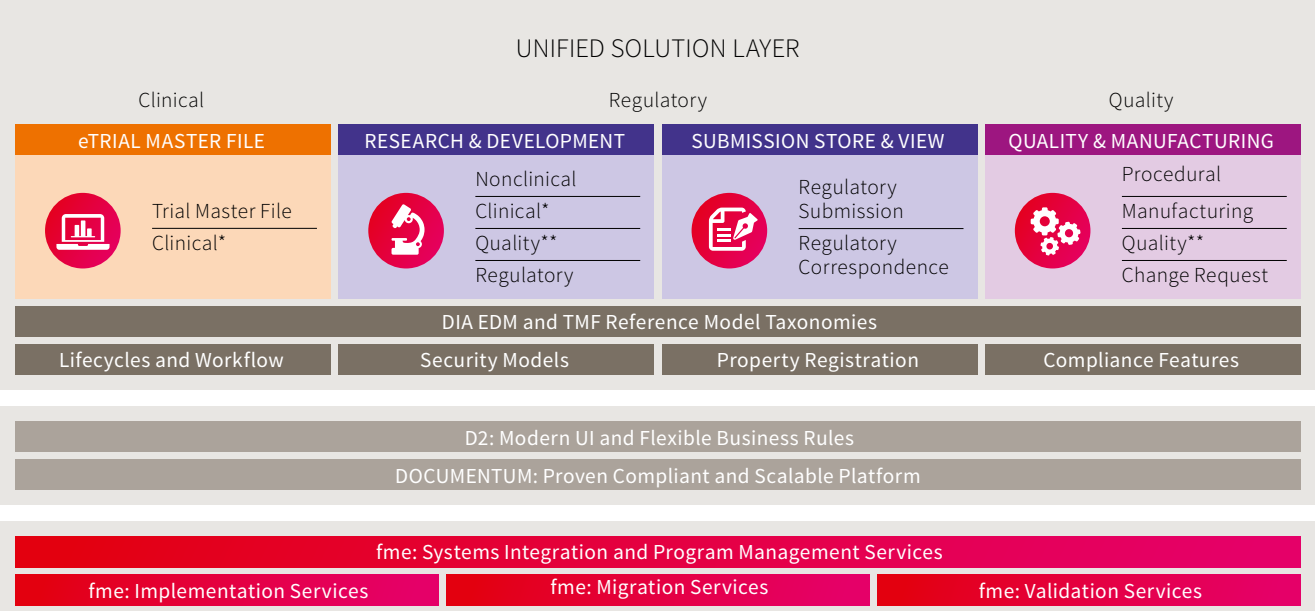
OpenText Documentum Submission Store and View
Simplify the search and retrieval of archived submissions and associated correspondence, while improving security and compliance.

OpenText Documentum Quality and Manufacturing
Control quality and manufacturing documents, auto mate workflows and ensure GMP compliance.

A Strategic Partner To Ensure Your Success

As Life Sciences companies transform, they require a partner who addresses pressing needs such as IDMP, Labeling, and HTA. Someone who supports a long-term vision and who can deliver the complete content solution. The Life Sciences organization at fme leverages the entire OpenText Documentum portfolio of offerings, including Records Management, Analytics, Archiving, Mobile Apps, and more. Our products and solutions are designed to provide flexibility and scalability as your organizational needs evolve.

We look forward to your challenge!



* Clinical documents can be stored in either the eTMF or R&D Module ** Quality documents can be stored in either the Quality or R&D Module

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