

OpenText Documentum Life Sciences Solution Suite – Quality and Manufacturing

fme's Offering

Regardless whether it's ISO 9001, EU GMP, 21 CFR Part 11 or another standard – the necessity of self-governing regulations concerning the handling of records (e.g. documents) has grown steadily over recent years. Nevertheless, the information for critical core processes still plays a secondary role in many companies. Lapses in this area can result in significant sanctions. In the life science industry these range from restrictions on production or marketing permits to the closure of entire production facilities. The economic impact often ranges in the multi-million dollar region. The OpenText Documentum Life Sciences Solution Suite Quality and Manufacturing (LSQM) module provides you with an efficient means for the electronic management of controlled documents. As OpenText Documentum partner specialized in the life sciences industry we provide you with highly qualified industry consulting and implementation services around this solution. In addition we offer support and maintenance to help you benefit from the OpenText Documentum LSQM module.

Even in regulated areas, such as pharmaceutical and medical device industries, many companies are still documenting their processes using paper and antiquated IT solutions. Such solutions based on file servers or internally developed databases are often severely limited in terms of functionality and performance. Authoring processes cannot be implemented in a controlled manner and the traceability of individual processing steps is not ensured. This will lead to duplicate data storage and long release cycles. It is intrinsically important, and often a legal obligation, to continuously regulate the entire life cycle of a document and to maintain traceability, particularly for controlled documents.

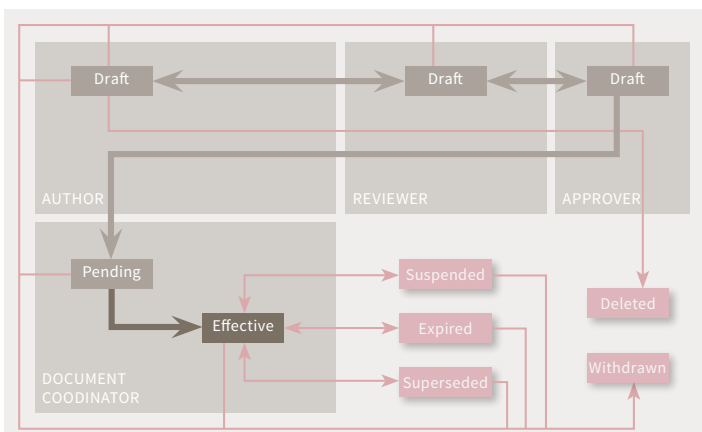
The OpenText Documentum LSQM module allows you to keep firm control over all of the steps in the document life cycle within one IT solution! At the same time it also enables you to reduce cost for document change and distribution control by up to 50 % and even shorten the lead times of your review and approval processes by up to 90 %.

Quick Facts

LSQM, the document management solution from OpenText Documentum, serves for the administration of controlled documents and assists you in fulfilling official standards and guidelines. At the same time the solution offers you extensive functionality, which enables you to significantly shorten the lead times of your processes.

Benefit

- Reduction of costs for SOP administration by more than 50 %
- Shortening of process turnaround times by up to 90 %
- Fulfillment of legal and compliance requirements
- Rapid implementation time and cost savings thanks to out-of-the-box, configurable software components and packaged validation documentation



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Range of Functions

The extensive and precisely tailored function spectrum of the solution includes elements such as

- Controlled, configurable filing structures
- Configurable workflows
- Watermarks and time stamps on documents
- Electronic signature processes
- Controlled distribution of documents
- Controlled printing of documents
- Management of the revision process
- Management of change requests

Fields Of Application

Management of Quality and Manufacturing (QM) documents

Do your day-to-day activities involve the compilation, review, approval, distribution and withdrawing of documents that are relevant to QM? Regardless whether these tasks revolve around SOPs, working instructions or specifications, using OpenText Documentum LSQM enables and enhances your ability to manage and control your regulated content. This allows you to ensure that all personnel involved in the production process always have the appropriate approved version of the relevant document. Other features, such as controlled distribution with corresponding confirmation messages, controlled printing and notification messages to the persons responsible for the document are also guaranteed before the end of the validity period.

Management of change requests

Compile, classify and evaluate change requests with electronic support. You are in control of managing the resulting tasks for manufacturing or inspection processes. The solution allows you to simultaneously monitor and document a collection of tasks. These range from the modification of specifications to actual implementation, including the corresponding tests. OpenText Documentum LSQM supports the entire process to ensure you never lose track of individual steps.

Management of corrective actions

Do you not only have to ensure that your process procedures are fully and properly documented, but also have to deal with any necessary corrective actions on request? OpenText Documentum LSQM supports you in compiling and subsequently tracking such measures. The system then automatically distributes the documents to the relevant decision maker. This ensures that you always assign the correct persons for evaluating and tracking the measures, thus allowing your company to respond appropriately to the necessary corrections.

Implementation

The OpenText Documentum LSQM module, the solution for document management of critical core processes will be delivered together with highly qualified consulting and implementation services by fme. Adaptation to the requirements of your company, as well as detailed validation documentation is a key component of this offering. Our certified product migration-center will help you migrate your content efficiently, compliant and without system downtimes from various source system into LSQM. Moreover, the auditable and customer-audited software development process of fme ensures that the application is also acceptable under GxP conditions.

Technology

- The OpenText Documentum Life Sciences Solution Suite LSQM module is seamlessly integrated in the Documentum Server Platform
- The solution utilizes the generic functionality provided by the respective environment. No additional platforms and infrastructures are necessary.
- The solution is consequently intranet-compatible and requires the Microsoft Internet Explorer web browser as the client

We would be happy to provide you with further information and give you a demonstration of the OpenText Documentum Life Sciences Solution Suite LSQM module, OpenText's solution for controlled documents. We look forward to hearing from you!