

Implementing a globally compliant content management solution with OpenText Documentum for Life Sciences Quality and Manufacturing



Client

A leading global biopharmaceutical company manufacturing plasma-derived and recombinant therapeutic products. With a 100+ year legacy, the company delivers life-saving medicines for patients with rare diseases and other unmet medical needs.

Challenge

The client was in need of a unified global compliant content management solution. Getting to market quickly is critical to the success of their business. They need to run lean, efficiently, and have uninterrupted manufacturing production at the lowest possible cost.



The client also needed to control its critical quality documentation, streamline and automate processes, and enable compliance. The strategy was to provide access to a single source of truth for controlled documents, consolidate their disparate quality systems towards common global systems and integrate collaboration and document management solutions.

Solution

A global quality program was established to set up a unified document management platform for Good Manufacturing Practices (GMP) documentation. The decision was to invest in the OpenText Documentum for Life Sciences Quality and Manufacturing module, based on D2.

By leveraging OpenText Documentum for Quality and Manufacturing, we establish streamlined, auditable processes that support

Benefits

-  The OpenText Documentum Quality and Manufacturing solution platform provides a chain of custody and single source of truth improving Compliance, Security, Transparency and Visibility
-  The OpenText Documentum Quality and Manufacturing solution platform addresses a large global implementation without effects on performance.

global compliance with Good Manufacturing Practices (GMP) standards across all manufacturing locations.

With Documentum for Quality and Manufacturing, the client was able to clearly demonstrate that it was 21 CFR Part 11 compliant due to extensive audit trails, access controls (including approvals with e-signature support), and document distribution, version control, and lifecycle management.

Another key characteristic of the solution is the ability to support print and export control services and preconfigured, dynamic watermarking, and overlays to ensure document security.

By investing in the OpenText Documentum Quality and Manufacturing solution, the client is now able to achieve unprecedented efficiency, agility, document control, and compliance that is key to getting products to market ahead of the competition.

Results

The client is seeing positive results across its operation:

- The OpenText Documentum Quality and Manufacturing solution platform provides a chain of custody and single source of truth
- The OpenText Documentum Quality and Manufacturing solution platform addresses a large global implementation without a negative impact on performance.

Further information on www.fme-us.com