EMC²
where information lives®

SOLUTION OVERVIEW

Solution for Plant and Asset Management

The Big Picture

- Enables companies to manage and maintain the integrity of engineering documentation within highly regulated environments
- Minimizes costly plant downtime
- Ensures the adherence to consistent business processes to mitigate the risk and cost of non-compliance
- Supports electronic signature validation to CFR 21 Part 11 standards
- Tracks collaboration on project documentation over long distances and across internal and external systems
- Enables management of engineering drawings and documentation for both engineering projects and asset operations

An integrated engineering documentation solution for the life sciences industry provided by McLaren Software and EMC

Life sciences organizations deal daily with many challenges and need to address a broad range of industry-specific regulatory issues, in addition to standard corporate governance—including risk and compliance demands. The life science industry has to ensure a competitive supply chain, promote customer confidence, and enable profitable growth. For life sciences organizations, failure to comply can be very costly, not just from expensive plant shut downs, but also criminal penalties.

To achieve these goals, it is vitally important that plant and asset documentation be tightly controlled to ensure that it complies with any necessary industry regulations and remains reliable and accurate. Effective operation of a pharmaceutical processing plant depends on up-to-date engineering or CAD drawings, related health and safety documents, maintenance manuals, SOPs, and as-built documents. Equally important to regulators is the ability to prove that both engineering project and asset documentation have followed an auditable set of business processes.

The complexity of managing engineering and asset documentation

Managing engineering documentation and business processes in the Life Sciences industry carries several unique challenges.

First, the sheer volume of engineering documentation that needs to be managed to maintain and operate a pharmaceutical processing plant is vast. A single asset can have hundreds of thousands of pieces of documentation with many cross references, making it extremely complex to manage.

Second, the ability to manage as-built documentation is invaluable. During an engineering project where a plant is refurbished or extended, the same engineering documents may be modified by different project and maintenance teams working in parallel. Not only are the existing documents being modified, but they are modified and extended in different ways. When they are brought together, they don't always fit neatly to provide a consistent view of a plant. Reconciling various changes is absolutely necessary so that the final document reflects all of the changes in the appropriate manner. The ability to synchronize documentation between concurrent project teams—referred to as concurrent project engineering—is crucial to reduce planned shut downs for engineering projects..

Third, industry regulatory bodies are mandating stronger documentation control and proof that appropriate business processes are being followed during the lifecycle of asset-related documentation. For the life sciences industry, this may require archiving documents for as few as twenty years or as long a hundred. If a plant shutdown is necessary, regulatory agencies require that all asset documentation be reviewed and approved prior to start up, which can be an arduous process. The documentation acts as a formal record and, if anything does go wrong; it must be easily accessible and accurate.

Finally, there are risks associated with using incorrect documentation. Doing so can create project delays and plant downtime, which reduces profitability, or compliance issues, which in turn could lead to fines, compensation payments, and potential bad press coverage and public relations—severely impacting shareholder confidence and stock value.

mclaren™ software

EMC and McLaren Software: Seamless management of life sciences documentation

The EMC® Documentum® platform and the McLaren Enterprise Engineer application suite together provide a complete solution for managing engineering documentation (engineering or CAD drawings, specifications, contracts, correspondence, etc.) in the context of enterprise business processes. The joint solution gives you enterprise-wide access to vital engineering information and ensures the right versions of the right documents are available to the right individuals throughout the design, construction, operation, maintenance, and decommissioning of plants and other large assets. Seamless management of engineering documentation allows you to ensure that consistent business processes are followed. As a result, your organization can increase productivity, reduce costs, and reduce the risk of non-compliance.

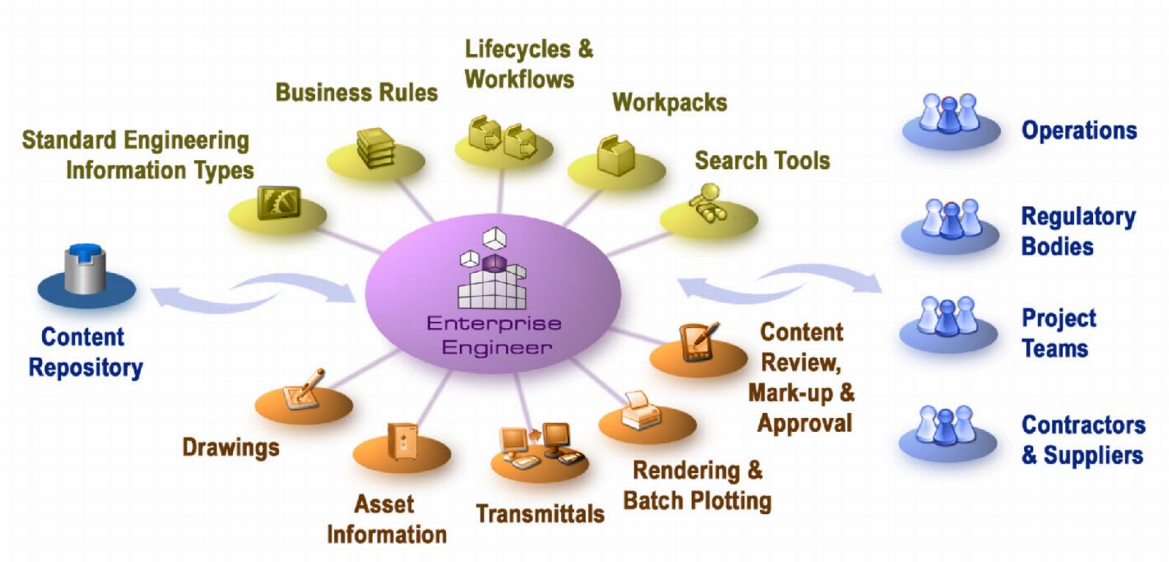
McLaren Enterprise Engineer leverages the power of the EMC Documentum enterprise content management platform, providing full access to all its functionality and co-existing with other EMC Documentum solutions. Enterprise Engineer combines EMC Documentum content services, such as workflows, lifecycles, and audit trails, with packaged business logic to deliver an engineering-specific solution. Enterprise Engineer also integrates with other EMC Documentum products to support the full range of customer requirements for managing engineering content, including EMC Documentum Records Manager and Content Storage Services. And because it's built on the EMC Documentum platform, Enterprise Engineer makes it possible to distribute engineering content in multiple languages, over long distances, and across internal and external systems.

Benefits of the EMC/McLaren solution for life sciences

EMC and McLaren's solution for plant and asset management brings plant and asset operators a clear choice for innovative management of engineering documents and plant operations. The combination of EMC and McLaren produces the only global solution provider that merges the industry-leading enterprise content management platform with the depth of asset management expertise needed to create an integrated and compliant environment to manage a wide range of engineering related challenges.

The chief benefits of the EMC and McLaren solution for plant and asset management solution include:

- Enterprise-wide management of all engineering documentation and associated business processes concerned with operating and maintaining large capital assets, including the operation of existing facilities, design and construction of new facilities, major modifications, refurbishments, and plant decommissioning
- Control over the creation, review and publication of all types of engineering content including CAD drawings, raster images, hybrid drawings, specifications, calculations, SOPs, MSDS sheets, project correspondence, work instructions, contracts, invoices, environmental analysis, inspection reports, and more



Powered by the EMC Documentum platform, McLaren Enterprise Engineer provides access to engineering content across the extended enterprise.

- Integration with Microsoft Office, Autodesk AutoCAD, and Bentley Systems MicroStation
- Reduced risk of plant downtime due to inaccurate asset documentation or noncompliance with industry regulations
- Support for electronic work packages and electronic signature CFR 21 Part 11 standards.
- Ease of access for consumers of engineering documentation via Microsoft SharePoint

A Designed for EMC accredited application

Enterprise Engineer carries the "Designed for EMC" accreditation. This accreditation ensures tight integration and product roadmap alignment between ISV applications and the EMC Documentum platform. Recognized as a Designed for EMC Offering of the Year and Best Vertical Offering, Enterprise Engineer requires minimal implementation and configuration. Together, EMC Documentum and McLaren Enterprise Engineer generate rapid return on investment by shortening time to deployment and replacing expensive customizations.

About McLaren Software

McLaren Software develops engineering-centric intellectual work management applications for the life sciences, pharmaceutical, oil and gas, manufacturing, utilities, and engineering, design, and construction sectors. McLaren helps organizations optimize their engineering design and asset change management processes to maximize the value in their engineering documentation while mitigating the commercial risk associated with their use.

About EMC Solutions

This solution is one of many content management solutions offered by EMC and our partners.

EMC and partner solutions help organizations solve business problems specific to their function or industry. Built on the EMC Documentum platform, and combining EMC and partner technologies and services, these solutions help organizations to streamline and automate processes, increase productivity of teams and individuals, address their information compliance and retention requirements, foster creative work, and lower the cost of operations.

EMC and partner content management solutions are designed to shorten deployment cycles as well. These solutions encompass a full range of integrated EMC products and professional services, combined with EMC-certified partner technologies and professional services. The combined industry experience and process expertise of EMC and our partners help you achieve maximum value in minimum time.

About EMC

EMC Corporation (NYSE: EMC) is the world's leading developer and provider of information infrastructure technology and solutions that enable organizations of all sizes to transform the way they compete and create value from their information. Information about EMC's products and services can be found at www.EMC.com.

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Take the next step

To learn more managing engineering documentation and reducing the risk of non-compliance, visit **www.EMC.com** or call **800.607.9546** (outside the U.S.: +1.925.600.5802).

Published in the USA. 9/08 Solution Overview H4554