OpenText™

OpenText Life Sciences Solutions

Ensure Compliance, Improve Efficiency, Speed Time to Market with a Range of OpenText Solutions

Life sciences business leaders are tasked with transforming their organizations into innovation centers while maintaining tight regulatory compliance with governmental guidelines such as the FDA's 21 CFR Part 11 and the EU's Annex 11. OpenText solutions for the Life Sciences industry support critical processes where compliant management of all paper and electronic records and documents is essential. Processes range from informal research collaborations to formal procedures like SOP review and approval, and may be limited to single departments, span the enterprise, or even include alliance partners, contractors, and consultants. CIOs must enable sharing of key information among team members and make the best decisions possible, while dealing with vast amounts of data and information often housed within legacy systems.

To help our customers in the life sciences sector meet these challenges, OpenText has developed a set of solutions that include:

- Regulated Information Management
- Enterprise Asset Management
- Governance for Microsoft SharePoint®
- Electronic Laboratory Notebook
- Quality Document Management

THE BROADEST RANGE OF ENTERPRISE SOLUTIONS FOR LIFE SCIENCES

OpenText Solutions for Life Sciences are being utilized at over 350 organizations worldwide in all lines of business including:

- *Research and Development*
- *Clinical Trials*
- *Manufacturing*
- *Legal*
- *Regulatory Affairs*
- *Operations*
- *Distribution and Logistics*

And enables compliance to dozens of global regulations and best practices such as:

- *Current Good Manufacturing Principles (cGMP)*
- *DIA eTMF/eCTD models*
- *EU Annex 11*
- *FDA 21 CFR Part 11*
- *FDA 21 CFR Part 211*
- *FDA 21 CFR Part 820*
- *Good Documentation Practices (GDocP)*
- *ISO 15378:2011*

OpenText solutions for Life Sciences are built upon a portfolio of Enterprise Information Management (EIM) products and services designed to improve information governance, increase compliance, optimize business processes, and drive innovation and profitability.

Regulated Information Management

Pharmaceutical organizations are subject to strict regulations that dictate how, when, and under what circumstances electronic documents can be authored, updated, approved, published, and archived. The drug development process requires compliance with 21 CFR Part 11 and other national and international regulations as an integral part of their document management and control processes to reduce risk and gain competitive advantage by bringing new products to market faster. Functions across the Life Sciences value chain, such as Regulatory Affairs, Quality, R&D, Commercial Operations & Marketing, Legal, Manufacturing, and Distribution, are all under strict directives to maintain documents and records of high integrity and careful compliance to GxP, ISO, USP and other standards and regulations.

Often, these records are managed in disparate information silos, slowing the flow of information among stakeholders and impeding time to market. In fact, poor documentation procedures are the most cited reason for receiving a 483 Warning Letter from the FDA. The OpenText Regulated Information Management solution consolidates and maintains business-critical documents in a manner which complies with your corporate and international regulatory guidelines and makes those documents available to the right internal and external stakeholders at the right time while accelerating time to market and reducing total cost of ownership.

Enterprise Asset Management

Life Sciences companies devote considerable resources to the design, construction, operations, and maintenance of their manufacturing infrastructure, not just the physical plant but also the manufacturing equipment, such as tablet presses, blister packaging machines, etc. To optimize production and maximize revenue, while maintaining quality and regulatory compliance, it is critical for organizations to consider the total lifecycle management of those assets and the challenges that may arise without effective information management and continuous process improvement.

Traditional enterprise asset management and maintenance management systems are rarely equipped to manage the challenging influx of information of your key assets, such as: work orders, maintenance records; vendor purchase orders; engineering drawings and specifications; CAPAs; incident reports and regulatory reporting. Also, they are often not designed to support GMP-compliant information management across the entire life of the asset–from capital project through decommissioning. The OpenText Enterprise Asset Management solution integrates best-practice processes to improve consistency and compliance, inherently supports secure collaboration and revision control, and links all this information–wherever it resides in the organization–back to the asset.

Governance for Microsoft® SharePoint®

As enterprise content grows exponentially, Life Sciences organizations are required to reconcile information across disparate systems to operate transparently, improve access to information for decision support, and ensure compliance with FDA, EMA, and other regulatory requirements—while staying within tight budgets. OpenText Governance for Microsoft SharePoint builds on your existing SharePoint base, making content accessible to your employees throughout its lifecycle to comply with regulations, improve system performance, reduce costs, and increase overall productivity. It reduces the risk of non-compliance and litigation through cost-effective, comprehensive information governance.

Electronic Laboratory Notebook

Capturing and managing the increasing volume of information in the laboratory is a challenge for any R&D organization. Managing information on paper no longer meets the day to day research requirements for any company. Effective information capture, reuse, collaboration, and knowledge management are impossible in a paper-based environment. Witnessing and signing a paper notebook is a manual process with limited visibility.

The OpenText Electronic Lab Notebook solution allows users to capture all R&D information electronically. Applicable to any scientific environment, its web-based interface allows scientists to enter information directly, or import existing data and files. Templates ensure consistency in how scientific information is captured and organized. Integration with scientific tools and equipment ensures all information is captured. At the conclusion of an experiment, the solution's One-Click Publishing feature automates the entire process of publishing, approving, and witnessing the experiment, archiving the experiment for use in future research.

Quality Document Management

Adhering to a high standard of quality in processes, products, and functions throughout a life sciences organization is a complicated and highly dynamic responsibility. Lack of visibility into the quality systems can lead to issues being overlooked or mishandled. Deviations from quality standards quickly affect the bottom-line performance of the organization and increases potential for non-compliance with regulatory guidelines.

The OpenText Quality Document Management System for Life Sciences helps achieve the highest product quality while maintaining compliance across all key processes and systems. Moving away from error-prone, paper-based systems and automating the manual review and approval methods greatly reduces the risk of non-compliance. OpenText electronic forms and workflows automate the entire process of creation, review, and approval of quality documents. CAPA's, NCP's, Deviations, Audits, and other quality processes can be managed in a single, integrated solution that is easily accessible from any web browser. On demand reports that provide up to the minute details and visual indicators on the status of all quality tasks, processes, and documents can be readily generated. Furthermore, detailed audit trails, easy retrieval of information, and electronic signatures ensure the rapid availability and traceability of all the information required to respond to any inquiries.

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