

# OpenText in Life Sciences: Asset Management

Effective Information Management ensures maximum uptime of your assets

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.

Too often, companies overlook the benefits of integrated information and business processes, or simply lack the tools to handle them. Information management is typically fragmented across the lifecycle of the asset, with a large effort being dedicated to the commissioning of operations and maintenance systems, and the handover of information from the EPC contractors and equipment vendors to the owner-operators. 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.

Companies need a comprehensive solution that 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.

## Eliminating silos and contextualizing asset technical documentation

The vast majority of asset technical documentation and information is unstructured and

## ENHANCE STRATEGIC PLANNING AND RISK MANAGEMENT THROUGH ACCESS TO BETTER QUALITY ASSET INFORMATION

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*All organizations with multiple assets at the heart of the business realize that an efficient asset management system yields benefits in a number of areas beyond site operations, such as Quality, Human Resources, Sales & Marketing, Finance, and Corporate Governance.*

*A robust Asset Management solution optimizes the efficiency of your assets' technical documentation and maintenance activities. It also integrates and extends your Enterprise Asset Management (EAM), ECM and Enterprise Resource Planning (ERP) systems to improve quality, consistency, and compliance of your plant and equipment maintenance projects, change management and asset documentation.*

unclassified. While this can apply to physical documentation, the digital age amplifies the problem, especially for rich media such as images, audio and video. To complicate the issue, unstructured content, which often exists in multiple versions, is sometimes handled by different individuals, housed in disparate systems and siloed in various departments. For companies with numerous, dispersed global assets, this creates challenges that extend beyond central business processes and operations and can make it difficult to establish a single point of truth from which all organizational information can be viewed.

A comprehensive asset information management solution can eliminate silos and help contextualize assets by integrating all documents, in all file formats, into your organization's established work processes and make these documents available whenever they are required. The result is a single, authoritative GMP and 21 CFR Part 11-compliant repository for storing and organizing electronic documents and leverage powerful tools that encourage collaboration amongst all parties involved.

### Managing collaboration and concurrent revision control

Because information must be readily available to plant personnel, engineers and vendors, effective collaboration is critical to working efficiently. Otherwise, unexpected delays or downtime can create a number of ongoing problems, such as unfulfilled contracts, profit loss and environmental incidents. On the backend, documents must be revised to reflect all maintenance procedures, technological updates and equipment changes.

The vast majority of FDA 483 warning letters are directly attributable to issues during the manufacturing process. Thus, efficient asset information management, collaboration and integrated best-practice workflows will improve your execution on major and routine maintenance activities, reduce the downtime of your facilities, support technical and process innovation, and mitigate your compliance and reputational risk.

### Ensure compliance through the total lifecycle management of assets

Poor information management can create health, safety, environmental and business risks. In the complex and evolving world of operations and maintenance, companies must accurately document, transmit and report their complete history of asset maintenance, inspections and changes in order to remain compliant with FDA and international regulations. Standards and regulations, such as GMP, ISO 55001, ICH Q9 and Q10, clearly define processes and best practice for managing the life cycle and validation of assets.

With a capable asset information management solution, being compliant can be transparent, consistent and automated. Risks are reduced when you are able to track, capture and manage the flow of information. Having the correct information at the correct time is critical to making informed decisions, and mitigating risks.

### The OpenText Approach: OpenText Asset Management

OpenText has extensive experience in efficiently managing high volumes of technical drawings, contracts, documents and records

## The Benefits of Integrated Asset Information Management

The right asset management solution can help take your assets successfully from the capital projects and handover phases, through a long lifecycle of efficient operations, and ultimately through decommissioning. With the right solution, your organization will be better able to:

- Embed compliance and risk management in your plant asset management system
- Streamline and reduce the efforts tied to existing manual processes for document control, information handover and commissioning
- Link documents and business processes to your assets to improve productivity
- Improve knowledge-sharing and collaboration through organization-wide access to information
- Strengthen your compliance posture with consistent, secure information governance across all data and processes
- Leverage real-time access to structured and unstructured data to realize commercial and strategic advantages
- Respond quickly and effectively, and with all critical information at hand, to avert unplanned downtime and manage reputational risk

across multiple sites using an Enterprise Content Management (ECM) solution that has now been channeled into the complex world of Asset Management. While owner-operators are looking for a single source of truth to properly manage their assets, stakeholders across the entire value chain are looking for increased transparency and compliance.

For organizations that already have investments in other purpose-built applications, the OpenText Asset Management solution offers integration to these applications to encourage user adoption as well as to ensure minimal business interruption. The integration between Asset Management and, for example, SAP® Plant Maintenance or Oracle® Enterprise One, enables a full information governance and process management controls, that underpin all maintenance activities.

The Asset Management solution from OpenText optimizes the efficiency of your asset technical documentation and maintenance activities. It also integrates and extends your Enterprise Asset Management (EAM), ECM and Enterprise Resource Planning (ERP) systems to improve quality, consistency, and GMP compliance of your maintenance projects, management of change (MoC) and asset documentation.

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