

## Infor EAM for Life Sciences



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### Do business better.

The stringent regulations imposed on life sciences companies are in place for a good reason—to reduce the health, safety, and security risks faced by consumers of pharmaceutical, medical device, and biotechnology products. There's no real debate about the overriding rationale of the regulations. But for the life sciences companies that must comply, the regulations themselves pose a risk. If they fail to meet regulations such as those issued by the US Food and Drug Administration (FDA), life sciences companies face fines, delays in getting products to market or having the sale of a product blocked. The adverse impact on the bottom line can be dramatic.



In this environment, it's easy to grasp the importance of manufacturing and delivering safe, high-quality consumer products while complying with stringent government regulations. What can be elusive, however, is finding an efficient and cost effective way to simultaneously meet the challenges of product innovation and quality, and strict compliance with government regulations.

### Leverage experience.

Infor™ life science experts have been helping companies in the industry meet complex and constantly changing business and regulatory requirements for decades. This proven technical expertise and industry insight have been applied to produce Infor EAM for Life Sciences, an industry-leading asset performance management solution. Infor EAM for Life Sciences has been designed to help life sciences companies maximize their asset value, meet compliance standards, reduce expenses including energy costs, and increase the return on investment of their assets. As a result, Infor EAM for Life Sciences helps companies make great strides in improving their operational efficiency and uncovering hidden profits.

With Infor EAM for Life Sciences, Infor delivers specific capabilities to help life science companies meet the requirements of 21CFR (Title 21 of the Code of Federal Regulations), a far-reaching set of regulations for monitoring production of pharmaceuticals, medical products, food and beverages, and personal care products.

### Get business specific.

Infor EAM for Life Sciences helps pharmaceutical, biotech, and medical device companies address the unique asset management challenges of their industry. The solution features advanced capabilities for improving asset and work management, calibration processes, asset sustainability, and the security of electronic records and signatures.

**Achieve operational excellence.** Infor EAM for Life Sciences features rich functionality to meet the diverse EAM requirements of life sciences companies. Infor EAM for Life Sciences helps companies:

- Better identify, track, locate, and analyze physical assets.
  - Track all aspects related to work performed on assets.
  - Implement more flexible preventive maintenance (PM) programs.
  - Implement real-time performance-based maintenance programs that notify operations of potential problems before they disrupt production.
  - Streamline the budget management process by automating budget set up and the subsequent capture, monitoring, control, and analysis of associated maintenance expenditures.
  - Improve the efficiency of call center operations by centralizing incoming maintenance requests and empowering operators and customer service representatives by providing fast access to information needed to handle maintenance, service, and asset management requests.
  - Automatically generate corrective work orders when an inspection result exceeds preset limits.
  - Improve materials management with capabilities to monitor and control storeroom inventories, manage materials using tools for determining economic order quantity (EOQ), class classifications, and assignments.
  - Automate complex or simple projects from initiation to completion.
  - Ensure the right parts are ordered and that delivery times, vendor performance payments, and goods receipts are monitored.
- More efficiently generate reports using predefined reports for assets, materials, purchasing, schedule, work, budget analysis, projects, and commercial services.



**Meet 21 CFR 11 requirements.** To help life sciences companies comply with 21 CFR 11, Infor EAM for Life Sciences delivers industry-specific capabilities to monitor electronic records for invalid and unauthorized tampering, safeguard the validity of electronic signatures, and ensure the overall integrity of electronic records processes. 21 CFR 11 requirements addressed by Infor EAM for Life Sciences include:

- *Ensuring electronic signatures are unique, secure, and valid.* Infor EAM for Life Sciences implements electronic signatures through a pop-up screen whenever an action, such as a work or purchase order acceptance or rejection, requires a signature. The signature procedures in Infor EAM for Life Sciences enable companies to document who altered a document and show when it was altered, giving FDA inspectors a clear audit trail to observe. Infor EAM for Life Sciences has an extensive network of overlapping security controls that prevent unauthorized users from electronically signing a record, accessing functions outside their job, or altering records.
- *Providing easy access for FDA inspectors.* Infor EAM for Life Sciences makes it easy for you to give FDA inspectors access to critical records such as repair logs, inspection results, and preventative maintenance accounts.
- *Supporting audit trails.* Life sciences companies using Infor EAM for Life Sciences have access to extensive auditing tools for recording selected database entries, changes, and deletions. The solution also offers an audit record capability that enables companies to track user IDs; altered fields; any changes to values; the date and time of change; and whether it was a data insertion, update or deletion.
- *Maintaining document control.* The document control capabilities of Infor EAM for Life Sciences control distribution rights and the ability to revise documentation of protocols and procedures. Administrators can specify multiple staff members who must approve changes to procedures such as calibrations or inspection tasks.

**Maintain precise equipment and instrument calibration.**

Precise calibration of equipment and instruments is critical for life sciences companies that must document how they perform, trace, and achieve consistency in products. Infor EAM for Life Sciences features capabilities that meet stringent federal requirements for standardizing and managing calibration information and procedures; scheduling and executing calibrations; and integrating calibrations with asset, work management, and other enterprise systems.

The solution helps life sciences companies:

- *Establish a calibration preventive maintenance program for all equipment.* The solution provides life sciences companies with calibration instructions, approved calibration procedures, original equipment manufacturer (OEM) specifications, process control limits, and standard procedures for performing the calibration. Companies can establish calibration PM based on fixed calendar days, on usage, or on the results of previous calibrations.
- *Track calibration results.* With Infor EAM for Life Sciences, companies can track results including calibration sequences, test-point data, tolerances, process control limits, “As Found” results, “As Left” results, action taken, and calibration status. With Infor EAM for Life Sciences, companies can track corrective action procedures and root-cause analysis related to out-of-tolerance work orders. The solution supports effective traceability by enabling users to quickly determine when and where a calibration has been erroneous so potentially affected products can be segregated.
- *Search and view all calibration results.* With the calibration capabilities in Infor EAM for Life Sciences, users can search and view all calibration results for a selected piece of equipment by equipment class, department, or date range.
- *Enable mobile entry of calibration data.* Infor EAM for Life Sciences enables mobile employees to use a hand-held device to record, view, edit, and transfer calibration information to and from a central database.

**Asset Sustainability.** Compliance with environmental regulations and reducing energy and resource consumption are critical success factors for life sciences companies. Infor EAM for Life Sciences features asset sustainability capabilities to help life science companies easily and effectively comply with environmental regulations as well as reduce their overall consumption of water, air, gas, electricity, and steam. With Infor EAM for Life Sciences, you can:

- Compare the performance of an asset with the energy it consumes to help identify, optimize, and automate proactive maintenance.
- Incorporate energy, and other operating and environmental parameters into the maintenance decision process at the asset level.
- Make design and configuration changes in your asset infrastructure that help reduce energy consumption, lower emissions, and save money.

- Integrate energy metrics with other asset performance data to determine whether a piece of equipment should be repaired or replaced.
- Monitor and control your company's emissions of greenhouse gases such as CO<sub>2</sub>, as well as fugitive emissions such as refrigerants.
- Monitor and control the discharge of water and material by-products from your operations.

## See results now.

In the life sciences industry, managing assets to optimize operational efficiency and decision making is critical, but not enough to ensure success. Life sciences companies also must efficiently and effectively comply with stringent government regulations. Infor EAM for Life Sciences helps life sciences companies meet compliance obligations in ways that turn compliance from a complication into a competitive advantage. Companies using Infor EAM for Life Sciences have:

- Reduced their compliance cost
- Increased their operational efficiency by improving their asset management
- Enhanced their bottom line performance by uncovering and leveraging hidden profit potential
- Improved their ability to produce high-quality products
- Avoided costly fines and plant closings due to compliance problems

## About Infor.

Infor acquires and develops functionally rich software backed by thousands of domain experts and then makes it better through continuous innovation, faster implementation options, global enablement, and flexible buying options. In a few short years, Infor has become the third largest provider of business software. For additional information, visit [www.infor.com](http://www.infor.com).

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