Infor EAM for Life Sciences

Protect your bottom line

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. But for the companies that must comply, the regulations themselves pose a risk. Firms that fail to meet regulatory requirements face fines, delays in getting products to market, or having the sale of a product blocked. The harm to a company's bottom line can be dramatic.

Infor can help

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, to help life sciences companies meet the requirements of 21CFR (Title 21 of the Code of Federal Regulations), a far-reaching set of regulations for monitoring industries that produce pharmaceuticals, medical supplies and devices, food and beverages, and personal care products.

Improve regulatory compliance and operational efficiency with Infor EAM for Life Sciences.

Address industry-specific challenges

Infor EAM for Life Sciences is a web-based, enterprise asset management (EAM) solution offering advanced capabilities for asset and work management, calibration processes, asset sustainability, and full support for the security of electronic records and signatures. The solution helps life sciences companies address critical industry-specific challenges.

Achieve operational excellence with enterprise asset management

Infor EAM for Life Sciences features rich functionality to meet the diverse EAM requirements of life sciences companies. Core capabilities include:

- **Asset management**. Identify, track, locate, and analyze physical assets. Facilitate metered usage measurement and automatic usage value transmission to sub-components. Define time, material, and labor costs in cost-charging arrangements. Track asset costs and movement using an easily configured "family tree" that forms relationships between equipment, systems, and locations.
- **Work management**. Track all aspects related to work performed on assets.
- **Preventive maintenance (PM)**. Base preventive maintenance tasks on a fixed date, flexible time period, or metered usage, letting the solution adjust schedules to compensate for early or late work completion.
- **Performance-based maintenance**. Notify operations of potential problems before they disrupt production through real-time monitoring, analysis of asset performance, and alert management.
- **Budget management**. Automate budget set-up and the subsequent capture, monitoring, control, and analysis of associated maintenance expenditures.
- **Call center management**. Centralize incoming maintenance requests and empower operators and customer service representatives by giving them fast access to all the information needed to handle maintenance, service, and asset management requests.
- **Inspection management**. Automatically generate corrective work orders when an inspection result exceeds preset limits.
- **Materials management**. Monitor and control the inventories of storerooms. Materials management tools include economic order quantity (EOQ), and class classifications and assignments. The module also supports management of parts receipts, issues, returns, and cycle counts.
- **Project management**. Automate complex or simple projects from initiation to completion.
- **Purchasing management**. Ensure the right parts are ordered and monitor delivery times, vendor performance payments, and goods receipts.
- **Reports**. Select from a variety of predefined reports including assets, materials, purchasing, schedule, work, budget analysis, projects, and commercial services.

Achieve safety and efficiency

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.

Meet 21 CFR 11 requirements

- **Print and electronically transfer records**. Print and export records in multiple formats, including Microsoft® Excel spreadsheets and Adobe® Acrobat® PDF files. Plus, compile a record library that keeps track of progressive changes so inspectors can see each alteration of a record. FDA inspectors will be able to easily access critical records such as repair logs, inspection results, and preventative maintenance accounts.
- **Manage system access**. Set parameters to ensure password and ID integrity, such as the number of days a user can keep the same password. An extensive network of overlapping security controls prevents unauthorized users from electronically signing a record, accessing functions outside their job, or altering records. These authority checks provide controls to ensure stability and meet or exceed the provisions of 21 CFR 11.
- **Support audit trails**. Independently record selected database entries, changes, and deletions with extensive auditing tools. Plus, track user IDs, altered fields, changes to values, the date and time of a change, and whether the change was a data insertion, update, or deletion.
- **Maintain document control**. 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.
- **Support electronic signatures**. Ensure that each electronic signature is unique, secure, and valid. Plus, keep track of when and by whom a document was altered, so FDA inspectors get a clear audit trail to observe. The solution implements electronic signatures through a pop-up screen whenever an action, such as a work or purchase order acceptance or rejection, requires a signature.

Improve asset sustainability

Infor EAM for Life Sciences helps life sciences companies more easily and effectively comply with environmental regulations as well as reduce their overall consumption of energy and other natural resources, including water, air, gas, electricity, and steam. The solution integrates energy efficiency with overall asset management. With 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 CO2, as well as fugitive emissions such as refrigerants.
- Monitor and control the discharge of water and material by-products from your operations.

Maintain precise equipment and instrument calibration

The advanced calibration module in Infor EAM for Life Sciences helps companies meet the stringent monitoring of federal agencies. Precise calibration of equipment and instruments is critical for life sciences companies that must document how they perform, trace, and achieve consistency in products. This documentation also helps ensure that companies meet cGMP (current good manufacturing practice).

Boost accuracy

Easy-to-use screens and menus allow companies to standardize and manage calibration information and procedures; schedule and execute calibrations; and integrate calibrations with asset, work management, and other enterprise systems.

Specific calibration capabilities include:

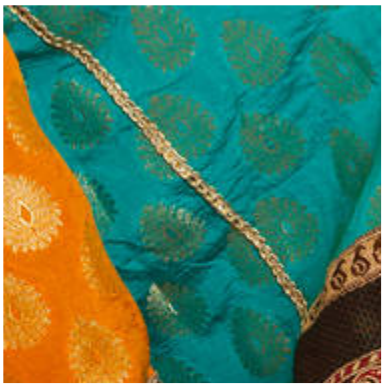
- **Calibration preventive maintenance**. Establish a calibration PM program for each piece of equipment. Each calibration PM contains calibration instructions, approved calibration procedures, original equipment manufacturer (OEM) specifications, process control limits, and standard procedures for performing the calibration. You can establish calibration PM based on fixed calendar days, on usage, or on the results of previous calibrations.
- **Track calibration results**. Track results including calibration sequences, test-point data, tolerances, process control limits, “As Found” results, “As Left” results, action taken, and calibration status. Each calibration work order is linked to a specific piece of equipment, making it easy to roll up costs and maintain historical tracking of all equipment information based on parent equipment, department, or organization. The solution also tracks corrective action procedures and root-cause analysis related to out-of-tolerance work orders.
- **Traceability**. Quickly determine when and where a calibration has been erroneous so you can segregate potentially affected products.
- **Calibration history and reports**. With the calibration module, users can search and view all calibration results for a selected piece of equipment by equipment class, department, or date range. The solution provides several standard calibration reports, including the frequency and date of last calibration and the next scheduled date of calibration. You can directly export calibration data to Excel and other programs for ongoing analysis and reporting.
- **Mobile entry of calibration data**. Use a hand-held device to record, view, edit, and transfer calibration information to and from a central database.

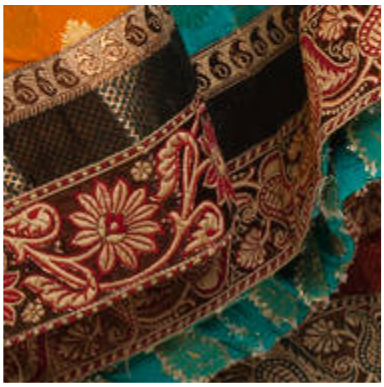
See results now

In the life sciences industry, managing assets to optimize operational efficiency and decision making is critical, but not enough to ensure success. You also must efficiently and effectively comply with stringent government regulations.

Infor EAM for Life Sciences helps you to:

- Reduce the cost of compliance.
- Increase operational efficiency through improved asset management.
- Enhance bottom-line performance by uncovering and leveraging hidden profit potential.
- Produce high-quality products.
- Avoid costly fines and plant closings associated with compliance problems.





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