



Infor SyteLine ERP for Medical Devices

Stay current with the shifting standards of FDA compliance

For medical device manufacturers, advancing and maintaining information management solutions that are compliant with an evolving set of FDA regulatory standards is a constant challenge. As you strive to manufacture high-quality medical devices, you need an enterprise resource planning (ERP) solution that can help you minimize compliance risk, as you maintain profitability, drive efficiencies, and streamline all parts of your business.

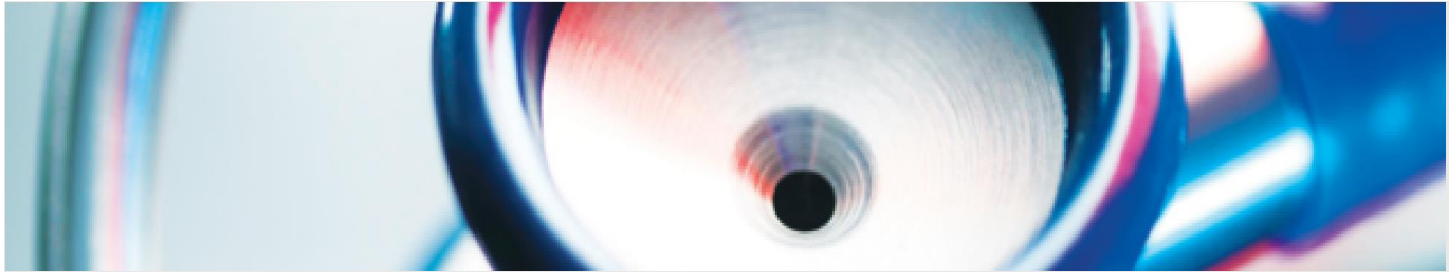
Improve your processes for developing product offerings

Infor SyteLine ERP for Medical Devices is built to specifically address the unique requirements of the medical device industry. The solution delivers advanced security, data auditability, electronic recording, and business intelligence capabilities mandated for FDA compliance. At the same time, SyteLine ERP for Medical Devices gives you the tools you need to help you mitigate compliance risk, while turning your developmental concepts into commercialized product offerings with greater efficiency.

Infor SyteLine ERP for Medical Devices gives you the tools you need to develop, evolve, and thrive in a regulated environment.

Meet regulatory requirements

SyteLine ERP for Medical Devices is delivered in an FDA compliant IT infrastructure. It is delivered with well-established protocols and validation scripts that meet regulatory requirements for computer systems in compliance with the FDA's 21 CFR Part 11. The latest set of FDA rules necessitates compliance from a systems-oriented approach, rather than isolated functional units.



Take a systems-oriented inspection approach to FDA compliance

Previous state

- Inability to identify improvements in manufacturing processes
- Time- and resource-consuming inspection intrusive to manufacturing process
- Compliance verification and validation for a wide pool of stand-alone systems
- Fragmented, hybrid compliance systems
- Isolated functional units

Future state

- Electronic records and visibility across all manufacturing processes facilitate true identification of compliance standards
- Real-time inspection
- Verification and validation of integrated systems
- Integrated compliance systems
- Regulatory compliance enforced with each quality system and integrated system-based approach to compliance

Maintain regulatory compliance

For medical device manufacturers, business process validation, inclusive of computer software, is a critical component of maintaining regulatory compliance. While validation ensures the software's intended use is substantiated and documented, this process can consume valuable resources, material costs, and expose a company to the risk of FDA audit non-compliance if not properly executed. Here's how Infor SyteLine ERP for Medical Devices can help.

Kick-start the validation process

The operational validation scripts, developed specifically for SyteLine ERP for Medical Devices, can help manufacturers reduce the effort, resources, and risk it takes to meet these stringent requirements. The proprietary protocols available to you in SyteLine ERP for Medical Devices include scripts and best practice templates to help you kick-start and facilitate the validation process.

Use integrated electronic records

Global regulatory agencies, including the FDA, define electronic records as the information created, stored, generated, received, or communicated by electronic means. With electronic records management, this information can be accurately perceived, reproduced, and distributed for further assessment. For medical device manufacturers, this information may be associated with various object types for engineering change management, audit trails, device history records (DHR), device master records (DMR), revision control, quality plans, and a range of other key areas of information management that are associated with FDA compliance.

SyteLine ERP for Medical Devices provides electronic records throughout the medical device manufacturing lifecycle from the creation of digital records through modification, storage, and records submission to FDA. This information includes the printed name of the signor, date, and time stamp, as well as the meaning associated with the signature. Extending the use of electronic signatures beyond specific requirements of the FDA to meet industry standard good manufacturing practices (GMP) further establishes a win-win proposition for medical device manufacturing organizations.

Uphold GMP quality standards

Ineffective enforcement of corrective and preventive action (CAPA) processes in fragmented compliance systems often leads to non-conformance to FDA regulations. To enable FDA compliance, you must integrate CAPA results into the information systems you use for quality planning. This is critical to improving manufacturing processes and leveraging electronic data recording and information management capabilities. Medical device manufacturing companies need this business system functionality to contain costs and tighten product and process control.

SyteLine ERP for Medical Devices gives you the tools you need to integrate CAPA results into quality planning, improvement, assurance, engineering, and control. That way you can create a centralized approach to master data management.

Deploy a complete solution for medical device manufacturers

From managing complex value chains and fast-paced product launches to shortening cycle times and easily managing product configurations, Infor gives medical device manufacturers like you advanced functionality that's backed by decades of practical application and relied upon by thousands of manufacturing customers worldwide.

With SyteLine ERP for Medical Devices, you get a complete solution for your industry with flexible deployment options, either through a subscription in the cloud or a traditional on-premise license option.



Reduce Compliance risks and improve your business

SyteLine ERP for Medical Devices is designed, developed and deployed specifically to address the nuances of a medical device enterprise with:

- Deep medical device functionality
- Packaged operational validation scripts
- Industry knowledgeable consultants
- Implementation Accelerator package
- Regular compliance

The fluctuating business environment is dangerous enough to manage. Controlling your business and conforming to strict regulations should not add to your challenges. With SyteLine ERP for Medical Devices, you can reduce these risks and make your business processes more efficient.

Learn more about our solutions for medical device manufacturers.

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