BROCHURE

FDA Extended ERP Solution based on Infor CloudSuite Industrial

FDA compliance and the shifting standards

As a medical device manufacturer, you face an evolving set of FDA regulatory standards to comply with. FDA-regulated manufacturers strive for high-quality service. With the proper enterprise resource planning (ERP) solution, you can advance and maintain information management solutions that are FDA-compliant and minimize compliance risk while maintaining profitability, driving efficiencies, and streamlining all aspects of your business.

Improve processes for developing product offerings

The medical device industry has a unique set of requirements. The Copley FDA Extended Solution, based on Infor CloudSuite™ Industrial, is built to specifically address those requirements. Created by The Copley Consulting Group as part of Infor's micro-vertical specialization program, the solution delivers advanced security, data auditability, electronic recording, and business intelligence capabilities mandated for FDA compliance. Turning your developmental concepts into commercialized product offerings with greater efficiency, Copley's FDA Extended Solution gives you the tools you need to help mitigate compliance risk.

The tools you need to help mitigate compliance risk

Meet and maintain regulatory compliance

In an FDA-compliant IT infrastructure, Copley's FDA Extended Solution is delivered with well-established protocols and validation scripts developed by Copley Consulting that meet regulatory requirements for computer systems in compliance with the FDA's 21 CFR Part 11. Rather than acting as isolated functional units, the latest set of FDA rules necessitates compliance from a systems-oriented approach.

PREVIOUS STATE	FUTURE STATE
• Inability to identify improvements in manufacturing processes • Time- and resource-consuming inspections that are intrusive to the manufacturing process • Wide pool of stand-alone systems • Fragmented, hybrid compliance systems • Isolated functional units	• Electronic records and visibility across all manufacturing processes facilitate the true identification of compliance standards • Real-time inspection • Verification and validation across integrated systems • End-to-end compliance across systems • Regulatory compliance enforced with each quality system and an integrated, system-based approach to compliance

Maintain regulatory compliance

A critical component of maintaining regulatory compliance for medical device manufacturers is the business process validation of software systems. The software's intended use is substantiated and documented by the validation process; however, this can consume valuable resources, material costs, and expose a company to the risk of FDA audit if not properly executed. The Copley Extended FDA Solution can help.

Starting the validation process

The Copley Consulting Group has developed operational validation scripts specifically to help manufacturers reduce the effort, resources, and risk required to meet these stringent requirements.

Scripts and best practice templates are included in the proprietary protocols of your ERP solution to help facilitate the validation process.

Use integrated electronic records

Worldwide regulatory agencies, including the FDA, define electronic records as information created, stored, generated, received, or communicated by electronic means.

Electronic records management ensures this information is accurately perceived, reproduced, and distributed for further assessment. For medical device manufacturers, this information might 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 data associated with FDA compliance.

Throughout the medical device manufacturing lifecycle, the Copley FDA Extended Solution facilitates the flow of electronic records from the creation of digital records through modification, storage, and records submission to the FDA. Record types include the printed name of the signer, date and time stamp, as well as the meaning associated with the signature.

Medical device manufacturing organizations can also extend the use of electronic signatures beyond specific requirements of the FDA to meet industry standards of good manufacturing practices (GMP).

Uphold GMP quality standards

Fragmented compliance systems often lead to non-conformance with FDA regulations, causing ineffective enforcement of corrective and preventive action (CAPA) processes. You must integrate CAPA results into the information systems you use for quality planning to enable FDA compliance. This step is critical to improving manufacturing processes and leveraging electronic data recording and information management capabilities. This business system functionality is needed for medical device manufacturing companies to contain costs and tighten product and process control.

To create a centralized approach to master data management, the Copley FDA Extended Solution based on Infor CloudSuite Industrial gives you the tools you need to integrate CAPA results into quality planning, improvement, assurance, engineering, and control.

Go-live quickly with Copley Implementation Accelerator

Copley Implementation Accelerator makes it possible for medical device manufacturers to implement the Copley FDA Extended Solution quickly and without major modifications, while still benefiting from the solution's flexibility and scalability for long-term, continuous improvement.

Streamline the implementation process

The Copley Implementation Accelerator is a packaged set of well-defined deliverables that allows for the successful deployment of the Copley FDA Extended Solution on an aggressive timeframe. The Copley Implementation Accelerator can decrease the risk to your budget parameters and go-live expectations by reducing the downtime for your critical functions and increasing your technology ROI.

Sensitive to GMP practices, the Copley Implementation Accelerator enables us to deliver solutions tailored to your company's unique validation, quality, compliance, and regulatory requirements. The methodology optimizes your resources and streamlines your implementation process, with the flexibility of deploying in the cloud or on-premises while ensuring the same high degree of success.

Deploy a complete solution for medical device manufacturers

The Copley Consulting Group and Infor provide medical device manufacturers like you with advanced functionality backed by decades of practical application and relied upon by thousands of manufacturing customers worldwide.

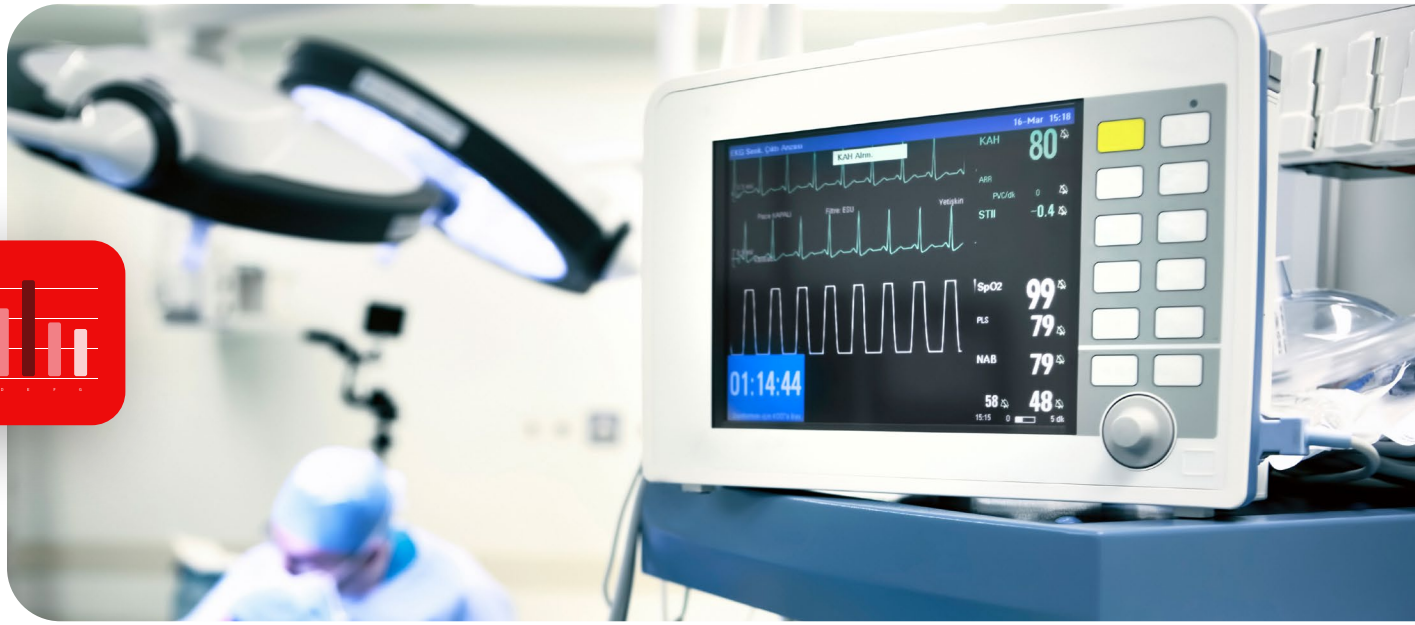
Starting with managing complex value chains and product launches to shortening cycle times and easily managing product configurations, with the Copley FDA Extended Solution based on Infor CloudSuite Industrial, you get a complete solution for your industry with flexible deployment options, either through a subscription in the cloud or a traditional on-premises license option.

Reduce compliance risks and improve your business

The Copley FDA Extended Solution is designed, developed, and deployed specifically to address the unique needs of a medical device enterprise with:

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

The ever-changing business environment can be tough to manage. Conforming to strict regulations and controlling your business should not add to your daily challenges. Let Infor help reduce these risks and make your business processes more economical and efficient.



About Copley

Copley Consulting Group, a division of The Judge Group, is a recognized leader in the strategy and implementation of Infor solutions. We pair small- to mid-size manufacturers and distributors with the foremost experts in software development and project management for the modernization and growth of organizations. Rivaling Copley's expertise is its ability to implement solutions flexibly and affordably given each organization's needs. We bring expertise in business systems, collaboration, and project management with technical application support. Working with our customers to complete their project on time and on budget is always one of our top goals. We work closely with each customer to determine their current needs and forecast future needs for them to grow with the platform. Copley customers have seen benefits such as increased revenue, decreased operating costs, and shorter production cycle time.

About Infor

Infor is a global leader in business cloud software products for companies in industry-specific markets. Infor builds complete industry suites in the cloud and efficiently deploys technology that puts the user experience first, leverages data science, and integrates easily into existing systems. Over 67,000 organizations worldwide rely on Infor to help overcome market disruptions and achieve business-wide digital transformation.

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Learn more about Infor CloudSuite Industrial ERP

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