FDA Extended ERP Solution based on Infor CloudSuite Industrial

FDA compliance and the shifting standards

As a medical device manufacturer, you are faced with an evolving set of FDA regulatory standards with which to comply. 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, as you maintain profitability, drive efficiencies, and streamline 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 (CSI) 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 necessitate compliance from a systems-oriented approach.

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

To find out more about the Copley FDA Extended Solution, contact us at **sales@copleycg.com.**

Maintain regulatory compliance

A critical component of maintaining regulatory compliance for medical device manufacturers is 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 it takes 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 the information created, stored, generated, received, or communicated by electronic means.

Electronic records management assures 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 that are 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 FDA. Record types include the printed name of the signor, 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 allow for the successful deployment of the Copley FDA Extended Solution on an aggressive timeframe. 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, 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 give medical device manufacturers like you advanced functionality that's 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 CSI, 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 distinctions of a medical device enterprise with:

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

The always changing business environment can be tough to manage. Conforming to strict regulations and controlling your business should not add to your daily challenges. Let the Copley Consulting Group reduce these risks and make your business processes more economical and efficient.

For more information on the Copley FDA Extended Solution, contact us at sales@copleycg.com.

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