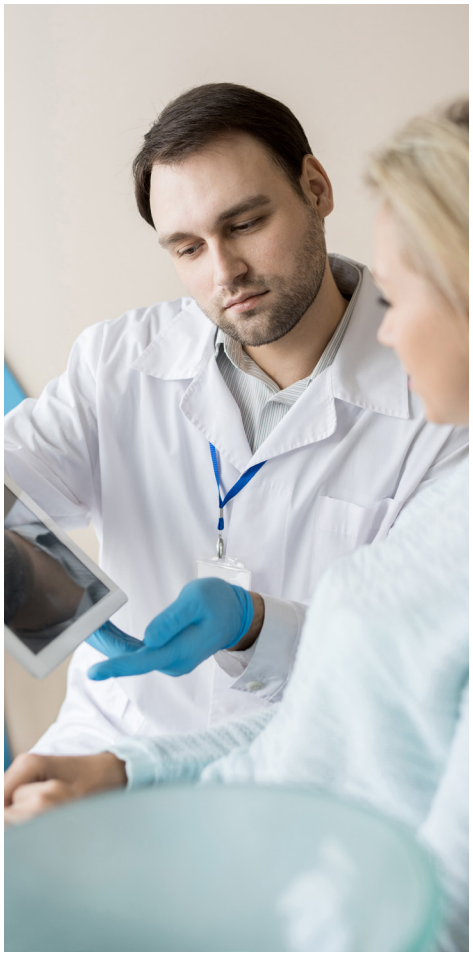
Case Study

COPLEY CONSULTING GROUP
A Judge Consulting Company

Medical Device Manufacturer Looks to Copley Consulting Group for ERP Solution that Meets Strict FDA Requirements



A medical device manufacturer specializing in diagnostic tools that test patient's immune activation levels for sepsis gained full FDA approval on their testing device. Being new to the world of FDA regulations, the company needed an ERP solution that can be fully validated to adhere to all FDA requirements.

THE CHALLENGE
A Strategic Solution to Obtain FDA Compliance

As a newly FDA-approved medical device manufacturer, the client recognized the need for a comprehensive solution that would seamlessly integrate into various aspects of their operations. Their existing processes were built and based on disparate tools including QuickBooks, Salesforce, and excel spreadsheets. These systems did not communicate well together and restricted the flow of data between departments. While these tools served specific and individual purposes, they posed significant challenges as a cohesive system.

Conducting business in an industry - subject to strict FDA regulations, compliance, and traceability - was necessary for a successful operation. Their existing processes did not have an electronic trail for tracking and validation. This required a strategic partner with experience and expertise to advise and implement an ERP solution that offered seamless FDA validation, data integrity, traceability, and scalability, all while supporting the company's commitment to delivering high-quality diagnostic tools for sepsis testing.

THE SOLUTION
Infor SyteLine ERP with Copley's FDA Extended Solution

Copley Consulting Group, a division of Judge Consulting Group, met with key client stakeholders and assessed the current systems and processes to provide a recommended solution. The recommendation? To implement Infor SyteLine ERP solution in a hybrid hosting environment, that would be capable of handling complex data management, quality control, and manufacturing processes.

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Additionally, Copley recommended their FDA extended solution to ensure the system is fully aligned and capable of meeting the regulatory requirements. This ERP system would provide a unified platform for various business functions. The licenses provide long-term access to the software, while cloud hosting offers scalability and flexibility.

SyteLine, in combination with the Copley FDA extended solution, would provide the FDA compliance outlined by the client during discovery. FDA requirements including Device Master Record (DMR) and Device History Records (DHR) that provide every detail related to building and testing a medical device and ensures it was thoroughly documented. The electronic DMR guarantees compliance with industry-specific standards. The DHR contains material evidence proving device compliance. It includes records of testing, manufacturing, and quality control. The Electronic Batch Records (EBR) facilitates paperless batch processing, ensuring accuracy and traceability.

THE RESULT

Obtaining Operational Efficiency and FDA Compliance with Infor SyteLine and Copley's FDA Extended Solution

After implementing SyteLine using Copley's rapid "FastLine" methodology, the client was able to realize immediate return. The "FastLine" approach is ideal for start-ups or small organizations who intend to leverage Infor's core applications. The improved financial reporting capabilities provides deeper insights into financial performance, supporting c-level decision-making. The solution's electronic trail facilitated comprehensive traceability, with all actions from manufacturing to quality control having a digital footprint. The trackability and reporting provided aligns with the strict FDA compliance requirements and helps streamline audits.

By working with Copley to select and implement Infor SyteLine, the client has improved their operational efficiency and met compliance standards in a highly-regulated industry. Siloed workflows were replaced with seamless integration, reducing manual effort and errors. The Copley FDA extended solution stands out as the only solution offering a truly paperless DHR/EBR, supporting electronic FDA validation while retaining regulatory compliance.

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Visit CopleyCG.com to learn more about Copley's ERP solutions and implementation services.