COPLEY CONSULTING GROUP
A Judge Consulting Company

CASE STUDY

MEDICAL DEVICE MANUFACTURER SEEKING AN ERP SOLUTION OFFERING FDA VALIDATION

A medical device manufacturer specializing in aesthetic solutions faced a fundamental moment in their operational journey. Their existing processes were becoming increasingly outdated, posing challenges in efficiency and compliance. The company understood the critical importance of modernizing their operations with an ERP solution that could ensure strict adherence to FDA regulations.

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THE CHALLENGE:

Modernizing Processes in an FDA-Regulated Industry

The client, a company operating in a highly regulated industry, recognized the need for a comprehensive solution that would seamlessly integrate various aspects of their operations. Their existing processes relied on disparate tools: QuickBooks, Salesforce, and Excel spreadsheets. The disjointed nature of these systems hindered efficient communication and data flow across departments. Siloed information led to inefficiencies and errors. While these tools served specific purposes, they posed significant challenges.

Conducting business in an industry subject to stringent FDA regulations, compliance was critical. Their existing manual processes lacked an electronic trail for tracking and validation. The situation had reached a tipping point, prompting the client to recognize that modernization was long overdue. They needed a partner to advise and implement a solution that would streamline their operations, enhance compliance, and provide a robust audit trail.

THE SOLUTION:

Systems Assessment and Implementing Infor's SyteLine ERP Solution for Compliance and Validation

Copley Consulting Group, a division of Judge Consulting Group, was engaged to assess the current situation and systems and recommend a solution. After speaking with key stakeholders, reviewing systems and processes, and aligning with the business on the desired future state, Copley recommended implementing Infor's SyteLine ERP solution with a perpetual license and cloud hosting. This robust ERP system provided a unified platform for various business functions. The perpetual license ensured long-term access to the software, while cloud hosting offered scalability and flexibility.

Copley extended the Infor SyteLine product with their unique FDA solution to meet the FDA compliance requirements including Device Master Record (DMR) and Device History Records (DHR). DMR provides every detail related to building and testing a medical device and ensures it was meticulously recorded. 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. An Electronic Batch Records (EBR) facilitates paperless batch processing, ensuring accuracy and traceability. During implementation, the client made a strategic decision to retain Salesforce. Copley integrated Salesforce with Infor SyteLine where appropriate. This integration allowed seamless data exchange between the two systems, optimizing sales, customer management, and other processes.

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THE RESULT:

A Fully Integrated ERP Solution for FDA-Regulated Compliance

Following a highly successful go-live, the client has seen the true upside of Infor SyteLine. Improved financial reporting capabilities offered deeper insights into their financial performance enabling informed decision making. The solutions electronic trail facilitated comprehensive traceability. Every action, from manufacturing to quality control, has a digital footprint. This has enhanced compliance with FDA regulations and streamlined audits. By consolidating processes within Infor SyteLine, the client achieved operational efficiency. Siloed workflows were replaced with seamless integration, reducing manual effort and errors. Working alongside of SyteLine, the client was able leverage existing investments such as Salesforce. They have been able to benefit from both systems' capabilities, optimizing sales and customer management. The Copley solution is the only solution in the market that has the functionality to allow for a truly paperless DHR/EBR, which supports electronic FDA validation and maintains regulatory compliance.

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