

# **SYSPRO**

## **FDA 21 CFR**

### **Compliance**

**OVERVIEW**

**Enterprise Software  
Solutions for Manufacturers  
and Distributors**

# SYSPRO Compliance and 21 CFR Compliance

## Simplifying your Success

### FDA 21 CFR Compliance

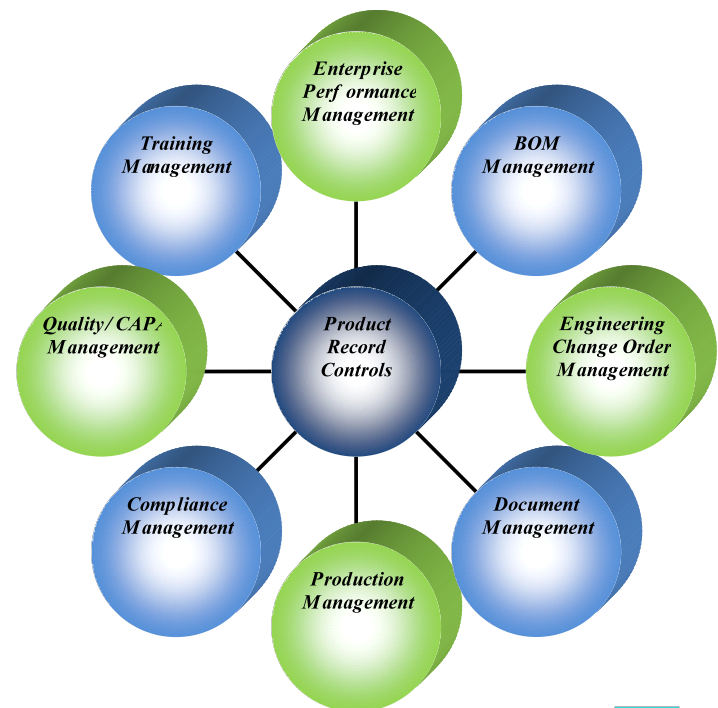
Manufacturers of medical devices are required to adhere to standards set forth by the FDA, particularly Title 21 of the Code of Federal Regulations (21 CFR). Complying with these regulations can determine the success or failure of a medical device company. With the increasing pressures of meeting FDA regulations many medical device manufacturers are turning to software solutions, such as SYSPRO, to ensure ongoing adherence to these guidelines from product development to manufacturing processes.

### FDA 21 CFR Part 11 Electronic Records and Electronic Signatures

Medical manufacturers who retain their documentation electronically, maintain records or submit information to the FDA are subject to the 21 CFR Part 11 regulations. In order to be compliant, medical manufacturers must meet the electronic records and electronic signature guidelines set forth by the FDA.

SYSPRO helps medical device companies manage product controls for these FDA regulations by providing features such as:

- ***Password-protected signoffs***
- ***Authorized electronic signatures***
- ***Amendment Journals and audit logs for electronic audit trails***



## **FDA 21 CFR Part 820 - Quality System Regulation - Current Good Manufacturing Practices**

Manufacturers of medical devices intended for distribution in the United States may be required to adhere to 21 CFR Part 820. This regulation requires device manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices.

SYSPRO provides controls medical device companies require to manage the product development process through the final retirement phase by providing features such as:

- **Quality for SYSPRO provides a Closed-loop Corrective and Preventive Action (CAPA) system**
- **Training records management**
- **Process Modeling**
- **Work Flow with Approval status**
- **Enterprise Performance Management (Analysis, Reporting, Dashboards)**
- **Role based security to control accessibility**

### **SYSPRO – Quality Focused on the Customer**

The customer is the ultimate judge of a company's values and products. The growing SYSPRO customer base and high customer retention rates are ongoing validations of the quality products and principles that have exemplified the company since its inception.

Our overriding goal is to simplify all aspects of administrating, integrating, deploying and using our software. Simplicity is a strategic objective supporting the SYSPRO promise to our customers.

SYSPRO remains a dedicated, independent company that continues to focus on customer satisfaction. Early on, SYSPRO realized that success is predicated on more than offering a leading edge product. Every member of the SYSPRO team is steeped in the traditions of honest and open communications, being proactive and reliable, and most importantly, responsive. SYSPRO is a "world-class" software provider – a designation earned through outstanding levels of service and ongoing innovation that positively impact the customer.

SYSPRO is distinguished by our commitment to providing enterprise software solutions that are established and proven, but at the same time are designed to support the vision into the future. This outlook is reflected in our customer landscape, which we've identified as a place in technology where the pragmatic meets the visionary, and it's where SYSPRO is focused.



Over the years, SYSPRO has gained industry recognition for expert knowledge and having one of the worlds most effective development teams. Consistent growth, upgrades, pertinent releases and a strong relationship with both customers and business partners, contribute to the company's high degree of financial stability. Customers buying SYSPRO solutions are buying technology and a long-term relationship that continues to provide significant value.

Through our 30-year relationship with thousands of customers in over 60 countries, SYSPRO has recognized that every customer is unique and has their own way of doing business. The result is a system that is extremely feature rich but also has the capabilities, configuration, customization and SYSPRO e.net solutions functionality to tailor the system for maximum effectiveness.

## **SYSPRO World Class**

### **AFFORDABLE SOLUTION**

Since its inception, SYSPRO has been dedicated to producing technologically superior business software and providing it at a cost that small and mid-market companies can afford. Today, more than 14,000 companies in 60 countries enjoy the benefits of the SYSPRO solution, which continues to fuse cost effectiveness with overall value.

Many of the world's leading business enterprises can testify to the true power of the pragmatic, yet visionary SYSPRO software, including the important role it plays in helping them compete successfully.

SYSPRO customers represent some of the world's most prestigious companies with highly challenging requirements. Established and emerging manufacturers and distributors continue to leverage the SYSPRO enterprise solution to further their growth and business objectives.

SYSPRO remains focused, responsive, reliable and dedicated. With offices around the globe catering to the local needs of geographically defined regions, serving manufacturing and distribution entities in the Medical Devices, Pharma and Food industries. SYSPRO software is offered through networks of highly qualified SYSPRO business partners and consultants, as well as through a collaborative, customer-focused, direct approach. SYSPRO's in-house intellectual capital and expertise on many levels serve to enhance the value of SYSPRO solutions.

SYSPRO is a well-established cornerstone of excellence, quality, functionality and customer satisfaction. SYSPRO is a company that listens and responds – a true long-term dependable supplier of software and services. SYSPRO is a company on which customers can rely.

