SYSPRO™
Simplifying your Success

Medical Device

SYSPRO provides affordable, industry- focused solutions to facilitate and alleviate the operational bottlenecks and issues facing the Medical Device Manufacturer.

Leveraging SYSPRO Enables You To:

- ❖ Reduce costs of compliance related to manufacturing in a regulated environment
- ❖ Facilitate meeting regulations, laws and guidelines laid out by the FDA and other regulatory bodies
- ❖ Improve customer satisfaction through faster, efficient responses and order tracking
- ❖ Increase market share and revenues through operational efficiencies
- ❖ Control, minimize and track operating expenses
- ❖ Shorten order-to-delivery cycle times
- ❖ Reduce costs to convert raw materials to finished goods
- ❖ Lower capital expenditures via reduced work in process and inventory levels
- ❖ Improve yield and product quality while conforming to specifications
- ❖ Increase the accuracy of plant floor data
- ❖ Provide traceability from source to ultimate destination
- ❖ Improve overall asset utilization
- ❖ Improve supply chain integration with disparate internal and external systems

Medical Device Manufacturing Software

As a medical device manufacturer, your success depends on your ability to efficiently manufacture superior products. Your business must follow closely controlled processes to develop and manufacture products that meet the strictest quality standards, while providing documentation to substantiate all procedures.

SYSPRO understands that meeting these standards can be a difficult, daunting task. The SYSPRO solution is designed and constructed to help medical device manufacturers address these issues and manage the five key components of a medical manufacturing business: Design, Manufacture, Distribution, Maintenance and Service. With award-winning integrated applications, SYSPRO for Medical Devices is a powerful, yet flexible business software solution that provides the tools and scalability you need to grow your company.

SYSPRO goes beyond traditional enterprise resource planning (ERP) to provide Medical Device Manufacturers with financial management, product management, customer relationship management (CRM), supply chain management (SCM) and more.

Functionality Tailored to Fit Your Needs

- ❖ Trace a product's life cycle—from design through manufacture to post-sale
- ❖ Integrate our medical device ERP solution with 2-D CAD, 3-D CAD, and E-CAD solutions
- ❖ Rely on a solid foundation for compliance with regulatory and industry standards, including the FDA (21CFR Part 11) requirements
- ❖ Provides electronic signatures with transaction audit traceability
- ❖ Enable sophisticated pricing and contract management
- ❖ Leverage sub-contracted operations and supply chain control
- ❖ Utilize extensive device history
- ❖ Strengthen inventory and warehouse management with the use of barcode technology
- ❖ Improve visibility with a comprehensive end-to-end solution

"SYSPRO helps our executives make key day-to day business decisions. We get real-time access, and we can quickly see any and all operations. SYSPRO has made a tremendous difference in freeing up our head of Quality to focus more on continuing to improve our TQM system instead of having to spend countless hours updating logs."

- Russell Ziegler, President, Acro Associates

Meeting the Challenges of the Medical Device Industry

In addition to other challenges facing medical device organizations is a set of governmental and industry mandated regulatory requirements that demand tight control of the manufacturing process and traceability. Accessing information required for government reporting (like ISO 13485,cGMP 820, 21 CFR Part 11, and validation) is a time consuming, laborious task. SYSPRO helps companies comply by providing a convenient and efficient way to gather and monitor relevant process information by eliminating manual procedures throughout the manufacturing process.

The SYSPRO solution, coupled with the Advanced Quality Management suite, offers an integrated approach to enforcing inspections that assure item conformance to any required characteristics, operational tolerances or expected results. Automating the compliance process- reduces the risk of warning, recall, or customer issues. Failure to comply with FDA 21 CFR Part 11 could seriously damage brand image or financially cripple an organization. Management of electronic data is critical. SYSPRO for Medical Devices offers a robust platform in support of certification and audit controls including: comprehensive audit and change logs with time and date stamp, authenticated user's electronic signature, and approval criteria for key processes.

Companies can also benefit from automation of the business processes delivered via SYSPRO Workflow Services, a tool used to automate processes. By enabling the application of rules-based control over business processes, status and performance information can be tracked and monitored through the workflow monitor. Using the tracking data, workflow processes can be analyzed to alleviate bottlenecks and streamline business processes.

> "Our previous system gave nothing back. In order to get information, you had to know the dictionary items and create the proper sentences. Individuals needing data from the system actually had to ask the IT department to get it. When researching new systems, we made the software selection a team effort and we involved representatives from every department. We decided to go with SYSPRO because it had more of the features every department was looking for, plus it was the most user friendly system."
>
> -Petra Adamson, IT Manager
> World Precision Instruments

Controls for Compliancy

Laws, regulations and guidelines require that medical device manufacturers establish and maintain controls and procedures from the design phase through to the delivery of finished goods. The level and stages of controls must satisfy the safety and performance needs of a specific manufacturer, product and user-market.

SYSPRO Engineering Change Control (ECC) module enforces controls in product design with a user-defined workflow that can supplement or replace the paper trail that usually accompanies any product design or changes to product design. Groups or individuals are electronically notified of required actions, accompanied by instructions, comments, documents and drawings. Specific actions or responses are required before the change order can move to the next step in the design and ultimate approval process. Existing orders (sales, purchase or work orders) can optionally be locked by the system, when a change order request is accepted. Prior revisions of an item are archived and can be accessed for manufacturing or investigative purposes.

The increasing demands of CAPA (Corrective and Preventive Action) in the medical device industry have caused organizations to refocus their efforts to include CAPA capabilities within their enterprise business systems. The need for real-time information and analysis is critical to an organization's ability to respond to situations within minutes or hours, and issues can be identified, analyzed and addressed from any location.

Traceability Across the Extended Supply Chain

The need for product traceability is critical in a compliance-regulated environment, lot traceability for medical device manufacturers is a supply chain issue, not just a manufacturing issue. SYSPRO provides a comprehensive framework for managing product innovation with solid product data management, quality process controls and cradle-to-grave product traceability.

SYSPRO allows medical device manufacturers to assign both lot and serial numbers to one item for more efficient traceability. If required, SYSPRO addresses the requirement for pre-allocating component lots/serials to work-orders to adhere to strict specifications. Likewise, lot/serial numbers for medical devices may be determined when a work order is created or upon receipt into inventory.

SYSPRO offers inspection at the time of receipt from either a purchase order or work order. Non-conforming parts failing inspection from a supplier may be tracked using the Return to Vendor capability. Likewise, non-conforming parts that have failed inspection in Work in Progress (WIP) may be rejected or sent back to the same job or a new job for rework. If applicable, the part could be received into a different warehouse or even received into inventory as a different product.

SYSPRO supports multi-warehouses, providing the option to create a quarantine warehouse that may have different levels of security to prevent the incorrect usage of the items placed in this location. Through pro-active exception inquiries, reporting and automatic notification functionality, both operational and management personnel have full visibility throughout the supply chain.

Customers Are the Focal Point of Your Business

For medical device businesses, customers are essential to the development of new innovative techniques and technologies that drive the industry. The ability to respond to changing customer demands preserves an organization's competitive advantage. Understanding customers and their needs can be a challenge. It can mean helping a doctor with the implanted device, responding to questions from healthcare workers servicing or using the medical device, or providing education to hospital personnel. SYSPRO Customer Relationship Management (CRM) functionality provides a centralized customer repository alongside all-inclusive helpdesk functionality. Customer service details are simplified for rapid response to inquiries as they happen. Implementing automated processes for issue escalation and resolution, along with full document control and audit trial, maximizes efficiency.

Audit Trail, Documentation Reporting and Metrics

Regulations and guidelines by the governing bodies require that medical device manufacturers have audit trails for every step of their procedures. SYSPRO eases this process by providing detailed audit reports for all transactions, including changes to static data. The operator making the change is recorded, along with the old and new value of the changed information. SYSPRO provides multiple facilities for additional notes, and the technology platform facilitates the fluid development of custom requirements.

SYSPRO Reporting Services allows for the archival of all documents generated, and the SYSPRO XML Document viewer can be utilized to view these archived documents at a later time in the event of an audit. A detailed history log displays elements of maintenance performed on the document templates.

SYSPRO Analytics is based on the Microsoft Business Intelligence stack and uses data warehousing functionality, which allows tracking of trends and performing data mining and analytics in all areas of the business. SYSPRO Analytics is an end-to-end solution which comes standard with the most common Key Performance Indicators (KPI) ready to use in an internal viewer. SYSPRO Analytics is designed to facilitate easy customization of the existing KPIs and with OLAP or MDX knowledge, the generation of additional KPIs.

SYSPRO Executive Dashboards provide businesses with a visual presentation of real-time data in their ERP solution. Business process management and what-if analysis tools enable executives to leverage strategic advantage of their ERP investment.

Security

Security is important to medical device manufacturers, and SYSPRO offers multiple levels of security to control and limit access to the system based on user responsibilities. Security can be configured at system, company, group, and role or operator level.

Access to the system is granted with a unique user name. The password is linked to a user name providing a unique combination, and an additional alternate password can be associated with transactions for authentication in the event of an audit. Passwords are rules-based and can force change after a pre-defined period, limit number of retries when logging in and auto-logout users when they are dormant.

The user interface (UI) can be personalized to a particular industry or role within an organization. Authorized users can add, remove, and edit fields, labels, and complete screens without having to call on IT for help. With SYSPRO technology, personalizing the system is simple, cost-effective and version independent.

How SYSPRO Helps Meet the Needs of the Medical Device Industry

Comply with Medical Safety Regulations

- Security configured at system, company, group, and role or operator level
- Electronic Signatures for record binding and operator authentication
- Provide full bi-directional traceability from source to consumption
- Close the gap between ERP and your quality system Manage all steps in the nonconformance process and generate corrective actions and other workflows that link right to the original nonconformance
- Quality Records are the documented evidences that processes are executed according to the quality systems plan
- Produce detailed audit trails of all transactions Manage the investigation and resolution of customer complaints in compliance with FDA guidelines Authenticate operators for specific transactions Support FDA 21 CFR Part 11 and Good Manufacturing Practices (GMP) requirements

Accurately Manage Design Process

- Eliminate redundant data entry with real-time integration to CAD
- Control design and release process with Engineering Change Control
- Eliminate paper trail with user defined approval process
- Electronically notify of required actions, accompanied by instructions, comments, documents and drawings
- Define all the production resources, including raw materials, machines, labor and quality variables Provides a 'replace component where-used' facility that enables the quick replacement of one item with a valid substitute item
- Track variances and defects
- Manage subcontract operations to suppliers
- Allow contract manufacturers to fulfill their requirement without access to the main system

Production Management

- Monitor production processes and track exceptions with notifications when a job has been assigned for rework or scrap
- Utilize job classifications to track all rework due to quality issues for trending and analysis
- Complete audit trail of who worked on what and when and reporting is produced as part of history record
- Reserve lots and/or serials for parent parts and components for correct issuance of materials for Finished Goods
- Deny operators access to making changes to a job or material allocations
- Issue lots/serials based on expiration dates Detailed work instructions, training records and videos can be associated to each job
- Final inspection prior to acceptance to determine scrap, rework, downgrade or accept

Integrated Quality Capabilities

- Quality Records are the documented evidences that processes are executed according to the quality systems plan
- Perform supplier ratings to measure, evaluate and improve supplier performance
- Manage all steps in the nonconformance process and generate corrective actions and other workflows that link right to the original nonconformance. Automate the process of auditing including internal audits and customer satisfaction surveys
- Manage the creation, approval, distribution and archiving of all controlled documents
- Manage the identification, responsibilities, authorities, training and certification requirements for each employee
- Schedule and record the results of all your calibration activities and costs

Optimize Materials Planning & Visibility

- Optimize inventory levels with accurate forecasting to minimize forecast errors and improve order fulfillment performance
- Place stock codes, lots and bins on hold to prevent usage of discrepant material
- Define restrictions by user to either deny access or limit access to a warehouse
- Monitor transfers between multiple warehouses to provide complete visibility
- Manage purchasing process with the requisition approval workflow
- Expedite the purchasing process by creating and submitting RFQ to prospective suppliers
- Control the return and exchange of items bought from suppliers

Control Costs to Increase Profitability

- Provide accurate costing with real-time tracking Monitor production processes and track exceptions
- Track selling prices, discounts and deductions
- Record gains or losses on currency fluctuations for foreign trading partners
- Track true landed cost for imported components

Improve Customer Satisfaction

- Deliver 360^0 view of customer history with CRM
- Identify and track different types of returns, the reason for the return, and generate non-con formances and other workflows that link directly to the original return
- Establish and maintain procedures for receiving, reviewing, and evaluating complaints of a designated unit
- Offer flexible pricing options
- Track promotions and deductions
- Effectively plan and manage delivery schedules

Manage by Exception

- Notification alerts to predefined events that monitor information as certain transactions occur
- Monitor production processes and track exceptions
- Analyze data for effective decision making
- Use standard KPIs or create custom views
- Provide detailed and summary reports with drill down capability
- Convenient scheduling of standard or custom report

SYSPRO ERP Creates

Growth Path for Bodypoint, Inc.

The Company

Bodypoint, Inc, is a Seattle-based designer and manufacturer of high quality posture support products and wheelchair accessories. The company holds their products to the highest standards and believes that every device they make, no matter how simple, should deliver the highest level of comfort, safety, fit, performance and aesthetics.

The Challenge

Prior to SYSPRO, Bodypoint was running their daily operations on multiple, disparate systems. In order to keep up with their rapid growth and customer demand, Bodypoint President David Hintzman knew the company needed a single fully-integrated solution that could bring advanced financial and operational efficiency as the company grew. "Our financing system didn't speak to our invoicing system, which didn't speak to our manufacturing system and it caused us to do a lot of 'work arounds' and a lot of extra work," Hintzman remembers.

Additionally, during their search, the company also had to keep one principle in mind: quality. As a player in the medical device industry, Bodypoint is subjected to stringent quality control regulations and is required to report to the regulating agencies. Thus, finding an ERP solution that could match their needs in scalability and performance while also maintaining an accurate, visible account of their quality was imperative.

While several ERP solutions were studied, SYSPRO ERP was short listed and out of three finalists, was the choice for Bodypoint. "The SYSPRO solution had outstanding references, was very flexible and user-friendly and, most importantly, was a single source solution, not a kluge of third party packages," notes Hintzman.

The Solution

The SYSPRO software implementation integrated all Bodypoint departments, including, sales, accounting, manufacturing, purchasing, inventory and shipping, under 'one IT umbrella.' With all company departments fully integrated, company management had the ability to make rapid, effective decisions utilizing real-time data.

The Result

The SYSPRO ERP system now allows Bodypoint to have the ability to deliver product in a way the customer wants it. SYSPRO ERP enables Bodypoint to offer complex pricing and discounting methods. In addition to the ability to resolve compliance issues using SYSPRO ECC (Engineering Change Control)

Bodypoint has deeper process integration and visibility. Integrated accounting has reduced errors and increased capacity. The company's reporting has greatly improved, and its shipping is more accurate, adding customer value with shipping notifications through the SYSPRO integrated shipping solution.

SYSPRO also allows Bodypoint to meet the needs of international markets that require complex product instructions in multiple languages with the ability to print product instructions for packaging on demand by product and country.

Most importantly, SYSPRO has helped the company to enhance operational efficiencies resulting in a 300% increase in new market growth and a revenue increase of 20% without the need to add headcount. Another result -- Bodypoint was the recent winner of the Manufacturing Leadership Award. "We were voted one of one hundred companies to receive this award. We received our particular award in Information Leadership. A lot of it is a result of how we have used SYSPRO to increase our productivity, to increase our customer responsiveness and also to improve our production processes."

About SYSPRO

SYSPRO is an internationally-recognized, leading provider of enterprise business solutions. Formed in 1978, SYSPRO was one of the first software vendors to develop an Enterprise Resource Planning (ERP) solution. Today, SYSPRO is a global business solutions vendor, represented on six continents and by more than 1600 channel and support partners. Over 15,000 licensed companies across a broad spectrum of industries in more than 60 countries trust SYSPRO as the platform on which to manage their business processes.

Customer focus is a core component of SYSPRO's corporate culture and is one of the key reasons why SYSPRO maintains a strong leadership position in the enterprise application market. By focusing on people and building lasting relationships with customers and partners, SYSPRO consistently excels at guiding customers through all aspects of their implementation and ongoing utilization. SYSPRO's mission is to deliver world-class software that gives customers the control, insight and agility they need for a competitive advantage in a global economy. As such, SYSPRO provides a unique combination of robust, scalable technologies that ensure minimal risk and a high return on investment.

The release of SYSPRO 7 is the next evolution of the company's commitment to helping clients make their businesses more agile. SYSPRO 7 provides powerful enterprise processing enhancements for higher transactional throughput building on SYSPRO's commitment to being scalable for small through to large enterprises. The SYSPRO 7 mobile platform, SYSPRO Espresso, enables easy, enhanced access to information anywhere, anytime.

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