



# FourthShift Edition™ Medical Devices

SAP Business One



## The Right Treatment in Medical Device Manufacturing

Competition. It's a constant force in the medical device manufacturing industry. Whether it's getting innovations to market quickly, making the company attractive to acquisitions, or complying with FDA regulations to avoid shutdowns, scrapped production and recalls, your success depends on your ability to stay strong in your market.

FourthShift Edition for SAP Business One is designed to help you do just that. FourthShift Edition is SoftBrands' fully integrated ERP system built on the tools of SAP Business One, SAP's leading solution for more than 17,000 small and midsize businesses worldwide.

No matter if you're just launching your product or readying your company for a sale, FourthShift Edition for Medical Device Manufacturing provides you the power of SAP and the backing of more than 20 years

of industry experience to help achieve your business goals.

*"The commitment we saw from SoftBrands to make the implementation work, but also acknowledging the importance of validation, compared to what we saw with the competition was night and day."*

—Greg Manson,  
IT Director, TranS1

- Delivers Cradle-to-Grave Lot Traceability
- 21 CFR Part 11 Compliance
- Unique FDA Validation Service
- Effectively Manages Engineer Change Orders
- Easily Substitutes Components
- Accommodates Customer Requests
- Increases Purchasing Power
- Manages New Product Releases
- Supports Virtual Manufacturing
- Ensures HR Compliance

FourthShift Edition for Medical Devices is designed to help you comply with FDA regulations, including 21 CFR Part 11 and cGMP (current Good Manufacturing Practices). Use it to keep your operations running without interruption, to compete with other specialized manufacturers by bringing your products to market quickly, safely and effectively, and to position your company as a solid acquisition opportunity.

Validating your processes can be a painstaking and tedious procedure. Draining a company of people, resources, and money, it is often left incomplete.

**AT A GLANCE:  
FOURTHSHIFT  
EDITION FOR SAP  
BUSINESS ONE**



SoftBrands™  
www.fourthshiftdition.com



# How Can FourthShift Edition for Medical Devices Help You Achieve Success?

SoftBrands unique FDA Validation service includes a team that executes the protocols freeing the customer's team to focus on their normal routine. Most achieve validation in just a few weeks without disrupting their software implementation and with minimal staff time required.

FourthShift Edition for Medical Devices uses the same straightforward, intuitive user interface as Business One, eliminating the need for a custom system. It takes advantage of Business One's extensive library of business management applications, including Drag and Relate, Business One's intuitive query building tool, which makes business analysis a snap for busy executives. It also uses the same intuitive report building tools.

## WITH FOURTHSHIFT EDITION, YOU CAN:

- **Maintain compliance with traceability requirements.** Trace both components and finished goods with a cradle-to-grave serial number.
- **Maintain compliance with 21 CFR Part 11.** Harness the power of SAP Business One with audit trails that extend from manufacturing all the way back to the financial functions in the program.
- **Increase purchasing power.** Simplify the process of establishing purchasing contracts, allowing you to lock in component prices to meet cost requirements and maximize returns.
- **Maximize quality control.** Eliminate waste and unnecessary delays by managing the quality of components and raw materials.
- **View graphical scheduling.** Get the visuals to most effectively use available resources to meet key customer commitments and compete on more than price alone.

- **Receive alerts.** Know what's happening in your business with alerts that monitor conditions and notify you to take action before problems develop.
- **Collect data.** Utilize automated workflow processes to ensure that the appropriate data is collected from the shop floor.
- **FDA Validation.** SoftBrands consultants execute the protocol freeing the customer to focus on their normal routine.

*"Instead of weeks of dedicated time I spent 20 hours of review time. For me the validation process was a real positive experience. It was seamless."*

—Cheryl Wagoner,  
Quality Manger, TranS1

Along with the benefits of FourthShift Edition for Medical Devices, you get the backing of SoftBrands' experience, expertise and support. From a seamless implementation and beyond, SoftBrands is the partner your company needs to create efficient processes, comply with regulations and build a successful and profitable manufacturing enterprise.

## VALIDATION SERVICES

Implementing a new system is a great time to review your processes and procedures. However, it's often difficult to try to manage both projects at the same time. SoftBrands' team of experts can assist in reviewing your processes and documenting everything you need to remain in compliance with the FDA.

For more information, contact SoftBrands:  
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