



Meeting the Challenges for Medical Devices

Epicor understands that businesses manufacturing and/or distributing medical devices face a unique set of challenges. Whether your business is built on the creation of a single successful device, or other manufacturers depend on you for parts or components in their end devices, or you procure and supply end medical devices directly; the drive for providing the latest innovative technologies alongside long product development cycles and complex traceability requirements inherently introduces risk. Demographics are on your side. With today's aging population, tremendous opportunity is available to successful medical device businesses who can manage growth, while responding to market changes and adhering to the rigorous demands of the industry; namely FDA 21 CFR Part 11 compliance, ISO13485, and cGMP.

EPICOR.

Gold Partner

With increasing pressure to reduce price in a business climate of expanding raw material cost, transportation cost, and reduced labor availability, businesses like yours are streamlining and adopting new technology to automate business processes for more competitive lead times and reduced waste. Epicor for Medical Devices is a global enterprise resource planning (ERP) software solution designed for manufacturing and distribution organizations who supply products and services to the Medical Devices industry. Epicor for Medical Devices provides a comprehensive framework for managing product innovation with solid product data management, quality process controls and cradle-to-grave product traceability.

Managing Rapid Growth

For many businesses, taking stock of core business operations in an integrated fashion is the initial step in improving bottom line revenues through greater visibility into office, warehouse, and plant floor operations. Epicor for Medical Devices is a completely integrated solution for managing your business. From initial concept and design through test plans, submissions, marketing and sales, production and planning, sourcing and procurement, quality and delivery, and finally financial recognition, Epicor for Medical Devices has the integrated tools to assist in your initiatives to grow your business profitably, while improving operational visibility and efficiency.

Putting Your Customer at the Center of Your Business

For medical device businesses, customers are central to development of new innovative techniques and technologies that drive the industry. Responding with agility and speed to customer demands preserves competitive advantage. Customers can have a wide range of understanding of medical devices and meeting the needs of the customer can be multifaceted. It can mean helping a patient with an implanted device, working with an in-home care worker who services or uses the medical device, responding to a surgeon or doctor with questions, educating and deploying via a global multinational channel, or responding to the demands of a Tier 1 or Tier 2 medical device manufacturer looking for reduced cost and improved quality.

The Epicor embedded Customer Relationship Management (CRM) functionality provides a centralized customer repository alongside comprehensive helpdesk functionality. Customer service details are streamlined for rapid response to inquiries as they happen. Embedded workflow for issue escalation and resolution, along with full document control and audit trail, maximizes your use of time.

Meeting Strict Guidelines for Product Data and Quality

Product and program specific data for medical devices is especially stringent due to governmental and industry standards for recording products at the design, production, sourcing, and delivery stages. Support for stringent product traceability, product documentation, revision change control, and electronic signature are core to the system. Epicor extends product data with end-to-end quality procedures, including online test results for easier audits. Full nonconformance management and corrective actions, preventative maintenance and workflow support high quality standards and traceability. Additionally, the Epicor robust Product Lifecycle Management (PLM) is a complete end-to-end solution developed to manage all aspects of a product's lifecycle, as well as enabling enterprises to control the enormous amount of electronic documentation that they produce. From engineering to submission to production, to fulfillment and delivery, to service and finance, complete product history and visibility is available.

Product Traceability

In all regulated life sciences sectors, the need for traceability is critical. Epicor for Medical Devices features strong control and visibility over lot tracked and serial tracked parts from cradle-to-grave, including serial genealogy of component products. Additionally, Epicor for Medical Devices offers strong fulfillment processes to allocate parts directly to customer orders, including serial and lot designations. These strict disciplines for traceability ensure customer and industry requirements are met—all while streamlining the shipping process. Additionally, Epicor for Medical Devices supports reference designator and manufacturers' part cross reference requirements for tracking of electronic devices.

Supporting the needs for enhanced traceability, Epicor delivers full Radio Frequency (RF) capability in the warehouse and on the plant floor that can track products in process alongside raw material inventory, finished goods, and supplied products. Epicor understands that complete traceability throughout provides for relief in the event of audit or recall.

Regulatory Compliance

On top of the other challenges facing medical device organizations is a new set of governmental and industry mandated regulatory requirements that demand tight control of manufacturing process and traceability. From FDA 21 CFR Part 11 compliance to ISO 13485 and cGMP 820, today's medical device manufacturer is faced with challenges that erode the bottom line of their profits. Distributors of medical device products see similar challenges, including meeting strict requirements of the RoHS directive.

The Epicor robust infrastructure, coupled with its Quality Management suite, offers a comprehensive approach to automating the compliance process and reduces the risk of warning, recall, and customer issues. Furthermore, for companies looking to comply with FDA 21 CFR Part 11, management of electronic data is critical. Epicor for Medical Devices offers a robust framework in support of certification and audit including; comprehensive change logs with time and date stamp and business process management that can deliver approval criteria for key processes as well as request password validation for system wide electronic signature capabilities. Additional benefit from automation of business processes is delivered via Epicor Service Connect, an orchestration tool used to automate processes, reducing time to delivery by eliminating human intervention.

Validation Services

Companies regulated by the FDA are required to validate their business systems. This validation needs to include the business processes deployed by your company within the selected application. Epicor understands this and can guide you on the services needed to assist your company in complying with validation requirements for your Epicor installation, including business processes as they fit within your business framework.

Supporting Extended and Global Operations

The market for most medical devices is a global one. Epicor understands the requirements of the global marketplace and can meet the requirements for doing business on a global scale. Whether your business represents a single entity, multiple entities within the same geography, or ranges across multiple countries worldwide, Epicor meets the global requirements for not only doing business locally, but doing business between countries, including meeting classification requirements of the Uniform Code Council (UCC).

Epicor for Medical Devices offers comprehensive multisite capabilities coupled with global presence to meet your company's requirements for local support. Competing globally and domestically—bridging geographic and strategic diversity and eliminating supply chain inefficiencies—can be accomplished with the right technology. The Epicor industry solution streamlines intra- and inter-company processes and helps companies communicate quickly and accurately. Synchronization of complex relationships which determine supply, demand and fulfillment is the means to reaching new, industry-leading levels of business performance. Epicor for Medical Devices can help you achieve maximum efficiencies across your globally extended enterprise.

Robust Technology Framework

Epicor is uniquely positioned with a complete suite of applications based on 100% Web services technology, protecting your investment in software and services well into the future. Why are Web services so important to businesses, particularly in medical devices? Outside of all the reasons organizations look to Web services for deployment; speed, stability, reusability, and more; for midsize businesses, the incentive is imminent to drive electronic collaboration more firmly into their supply chain. Web services collaboration is fast becoming a necessity to doing business.

Epicor for Medical Devices is uniquely positioned on this technology today and comes with a suite of Web services tools such as Epicor Service Connect and Epicor Mobile Access that make internal and external collaboration a reality.

Supporting your business strategies with applications built on a service-oriented architecture (SOA) keeps the door open for medical device businesses by meeting both the immediate requirement for scalability while supporting an open philosophy in the event your business strategy changes. SOA simplifies the coming together of established infrastructures to make acquisition and merger less painful—attractive to companies looking to acquire.

Industry Leading Service and Support

Epicor has over 40 years of experience delivering industry focused, world-class solutions, and ongoing customer care and service to over 20,000 customer installations. It is a true global solutions partner with support offices all over the world. The key vehicle that transforms Epicor for Medical Devices into a successful business solution is its Signature Implementation methodology. Signature allows Epicor to provide consistent, customer-focused implementations that deliver added value because it provides a controlled environment. It is a highly structured, proven implementation methodology that successfully guides you and your company through a six-step process, from an in-depth analysis of your business requirements all the way to the hand over, enabling your company to quickly begin using Epicor for Medical Devices in day-to-day operations. Signature and Epicor for Medical Devices save your company time and money by providing broad functionality at a lower total cost of ownership.

Force 9 Business Solutions Ltd
2 Wheatstone Court
Waterwells Business Park
Quedgeley
Gloucester GL2 2AQ
United Kingdom

Contact us for more information on Epicor Products and Services

08704 104 149

info@f9solutions.com

www.f9solutions.com



The contents of this document are for informational purposes only and are subject to change without notice. Epicor Software Corporation makes no guarantee, representations or warranties with regard to the enclosed information and specifically disclaims, to the full extent of the law, any applicable implied warranties, such as fitness for a particular purpose, merchantability, satisfactory quality or reasonable skill and care. This document and its contents, including the viewpoints, dates and functional content expressed herein are believed to be accurate as of its date of publication, September, 2012. The usage of any Epicor software shall be pursuant to the applicable end user license agreement and the performance of any consulting services by Epicor personnel shall be pursuant to applicable standard services terms and conditions. Usage of the solution(s) described in this document with other Epicor software or third party products may require the purchase of licenses for such other products. Epicor, Business Inspired, and the Epicor logo are registered trademarks of Epicor Software Corporation in the United States, certain other countries and/or the EU. All other trademarks mentioned are the property of their respective owners. Copyright © 2012 Epicor Software Corporation. All rights reserved.