Epicor Brochure

Epicor for Medical Device
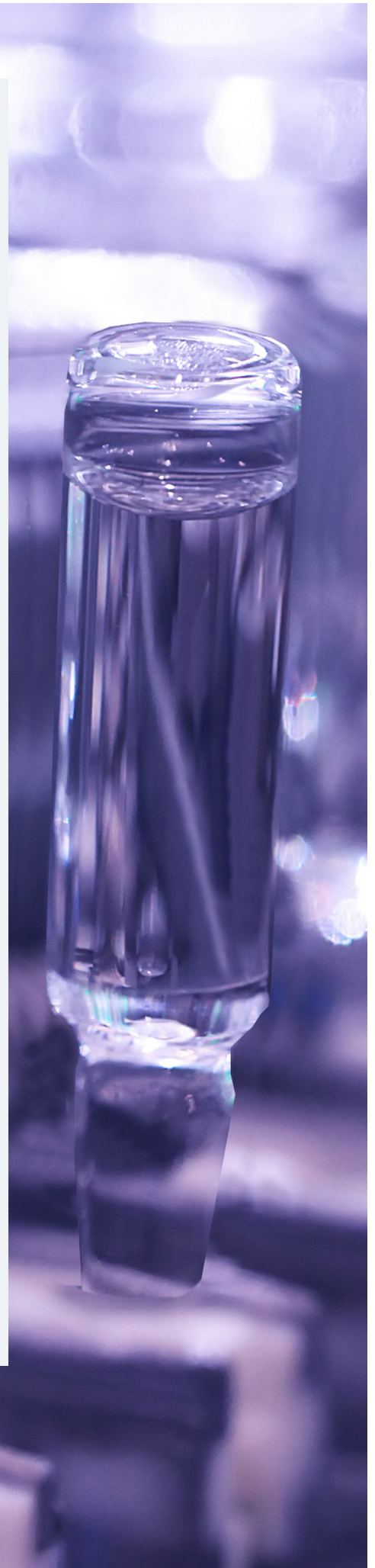
EPICOR

Introduction

Meeting the Challenges for Medical Device Manufacturers

Epicor understands that businesses manufacturing medical devices face a unique set of challenges. Whether your business is built on the creation of a single successful device or OEM manufacturers depend on you for components in their end devices, providing the latest innovative technologies alongside long product development cycles and complex traceability requirements inherently introduces business risk. Demographics are on your side. With today's aging population, a 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.

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 Device is a global, cloud-based enterprise resource planning (ERP) software solution designed for manufacturing and distribution organizations that supply products and services to the Medical Device industry. Epicor for Medical Device provides a comprehensive framework for managing product innovation with solid product data management, document control, quality process controls, and cradle-to-grave product traceability.

Functionality

- Global operations
- Quality Management System (QMS), traceability and audits
- Cost management
- Rapid configuration and Product Lifecycle Management (PLM)
- Document control and regulatory compliance
- FDA, cGMP, ISO, SOX

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 Device has the integrated tools to assist in your initiatives to grow your business profitably while improving operational visibility and efficiency.

To help the pain of your first ERP for startup Medical Device manufacturers, cloud solutions like Epicor for Medical Device provide the end-to-end capabilities needed to manage business needs now and quickly scale as your business grows and needs change.
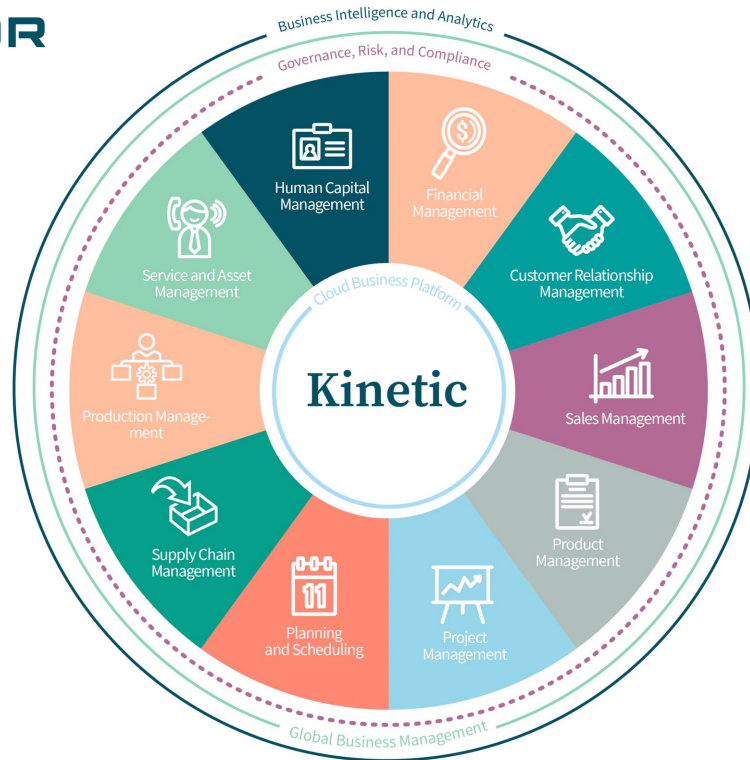
Putting Your Customer at the Center of Your Business

For medical device businesses, customers are central to the development of new innovative techniques and technologies that drive the industry. Responding with agility and speed to customer demands preserves a 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 Tier 1 or Tier 2 medical device manufacturers looking for reduced cost and improved quality.

The Epicor embedded CRM functionality enables a centralized customer repository alongside comprehensive help desk 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.

Escalations can be responded to more efficiently by social teams using Collaborate. Collaborative social tools allow engineering, production control, quality and compliance, and service to subscribe to escalation groups and communicate on problem resolution and next steps. It can even collaborate directly with customers via Microsoft Teams® integration.

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Meet 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 enable 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 Device 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 Device 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 Device supports reference designator and manufacturers' part cross reference requirements for tracking electronic devices.

Supporting the need for enhanced traceability, Epicor delivers wireless 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. Collaborate is a unique solution that allows stakeholders to collaborate electronically on product design and product issues. In particular, as these interactions are stored in a repository, all data related to success and failure are stored in a secure cloud location.

Regulatory Compliance

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. One of the challenges for businesses under validation requirements is in keeping current with technology. Updates to software require risk analysis and re-validation of software. Epicor introduces services and solutions to simplify not only initial validation but ongoing validation requirements.

Epicor for Medical Device offers a robust framework in support of FDA 21 CFR Part 11 certification and audit including; comprehensive change logs with time and date stamps and business process management that can deliver approval criteria for key processes as well as request password validation for system-wide electronic signature capabilities.

Software Validation

On top of the other challenges facing medical device organizations is a 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.

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 Device 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 Device can help you achieve maximum efficiencies across your globally extended enterprise.

Cloud Business Platform

Epicor delivers a scalable, cloud solution with a focus on agility so that you can adapt to the changing business climate while doing so with the peace of mind that your critical business systems are secure and ready when you need them. The solution delivers pragmatic innovation on a regular basis to keep your business up to date with the latest industry functionality that keeps you highly competitive. Enable every employee, regardless of tenure or experience with an easy-to-use intuitive cloud-based user experience and embedded learning guides.

Made with manufacturers, for manufacturers, Epicor combines deep industry capabilities, great user experiences expected by today's workforce, and innovative technology to help you grow.

Epicor for Medical Device is uniquely positioned on this technology today and comes with a suite of web services tools such as Epicor Service Connect, Business Process Management (BPM), and Epicor Mobile Access that make internal and external collaboration a reality. BPM, in particular, introduces granular control of business processes and can be invoked on any process to; for example, require additional information on, validate authorization against login, or automate operational steps to eliminate the risk of error.

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.

Flexible Cloud Options

Leadership in global cloud ERP is in the DNA of Epicor and meeting the changing needs of your business with flexible cloud solutions delivers on business growth today and into the future - wherever that growth takes you. Kinetic is cloud ERP with deployment choice of public cloud, on premises, or hybrid cloud. Hybrid cloud allows businesses to step into the cloud with extensions without running their entire ERP in the cloud. As the solution offered uses the same technology, regardless of cloud or on premises, businesses can also choose to self-host the solution or work with a 3rd party. Multinational organizations benefit from additional flexibility as distributed business units have deployment choices across the enterprise with some sites choosing cloud and others choosing on premises deployment. The latter because of the region or remote geography challenges for cloud.

Cloud Validation Bundle for Life Sciences

The availability of critical business systems in the cloud improves your ability to compete. Cloud enables both business agility and the increased speed at which technology is delivered to better meet business needs for innovation. Additionally, the Epicor Cloud Validation Bundle for Life Sciences offers a cloud solution designed to reduce the risk of compliance with support for the software validation needs of FDA-regulated businesses. The solution couples regulatory documentation with an upgrade cadence designed for Life Sciences and the need to meet FDA requirements.

Industry Leading Services and Support

Epicor has over 50 years of experience delivering industry focused, world-class solutions, and ongoing customer care and service to over 21,000 customer installations. It is a true global solutions partner with support offices all over the world. The key vehicle that transforms Epicor for Medical Device into a successful business solution is its rapid implementation methodology. Epicor delivers among the most cost-effective and efficient techniques to plan, design, validate and deploy your Epicor solution. Staffed with direct employees around the globe who are properly trained and equipped with a world-class methodology designed specifically around Epicor software and our customers. The end result is an on-time, on-budget implementation of your Epicor solution that allows your company to quickly begin using Epicor for Medical Device in day-to-day operations. Epicor for Medical Device saves your company time and money by providing broad functionality at a lower total cost of ownership.