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Epicor for Medical Device

MANUFACTURING

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. These include FDA 21 CFR Part 11 compliance, ISO13485, and cGMP in the United States and Regulation 2017/745/EU in Europe.

With increasing pressure to reduce prices in a business climate of expanding raw material costs, transportation costs, and reduced labor availability, businesses like yours need to streamline and adopt new technology to automate processes, gain competitive lead times, and reduce 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 enables 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
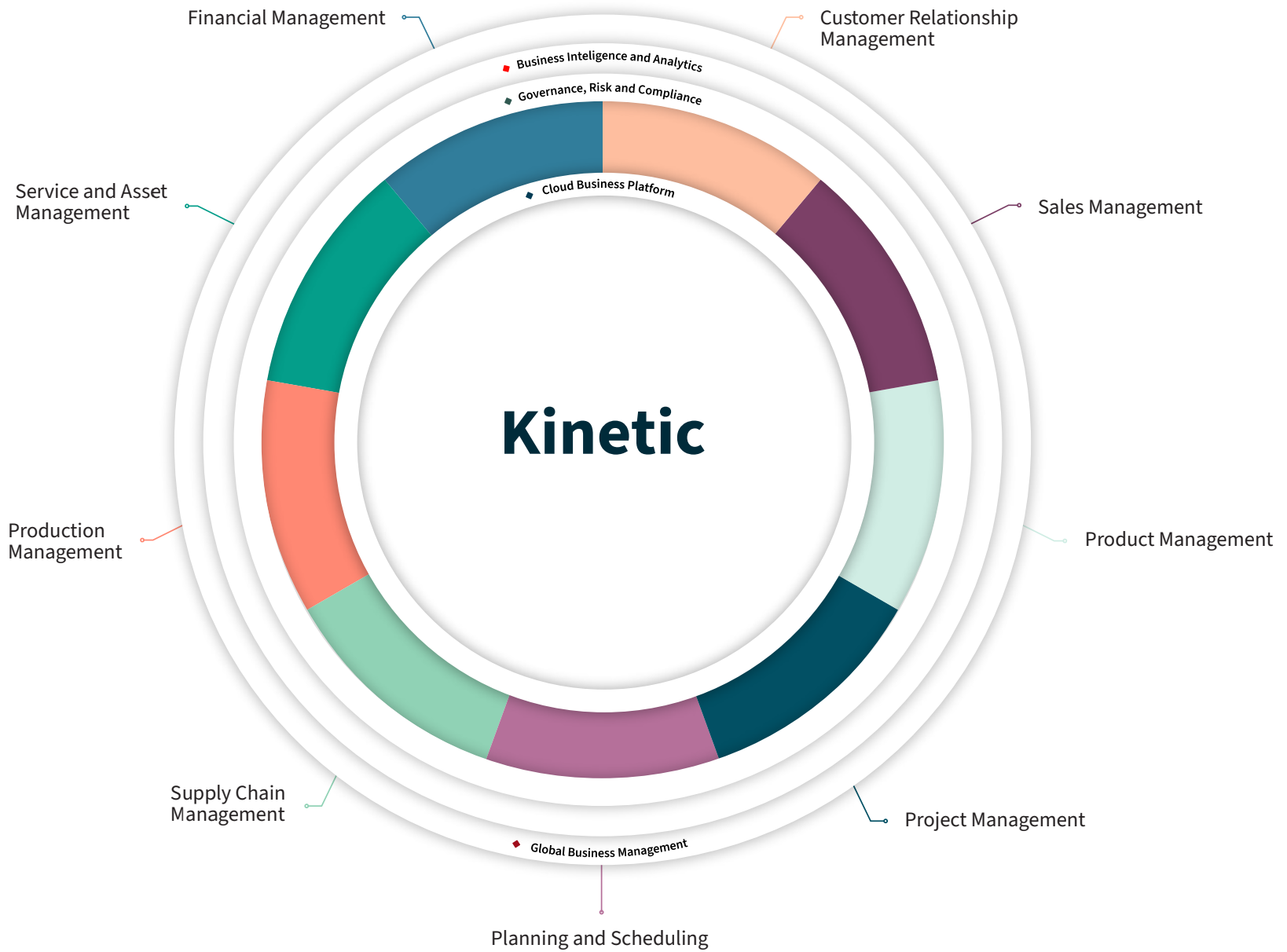- Rapid configuration and Product Lifecycle Management (PLM)

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 Device 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 ensure a seamless implementation 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 the innovative techniques and technologies that drive the industry. Responding with agility and speed to customer demands helps you preserve a competitive advantage. Customers may come to you with a wide range of understanding of medical devices. Our solutions empower your workforce to address a wide range of use cases: 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 the device 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 offers a centralized customer repository alongside comprehensive help desk functionality. Customer service details are streamlined to enable rapid responses 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 and resources.

You can respond more efficiently to escalations by using the Collaborate platform. These collaborative social tools allow engineering, production control, quality and compliance, and service to subscribe to escalation groups and communicate quickly on problem resolution and next steps. They can even facilitate direct collaboration with customers via Microsoft Teams® integration.

Financial Management

Customer Relationship Management

Sales Management

Product Management

Project Management

Planning and Scheduling

Supply Chain Management

Production Management

Service and Asset Management

Business Inteligence and Analytics

Governance, Risk and Compliance

Cloud Business Platform

Global Business Management

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Meet Strict Guidelines for Product Data and Quality

Product- and program-specific data guidelines for medical devices are especially stringent. There are governmental and industry standards for recording products at the design, production, sourcing, and delivery stages. Maintaining stringent product traceability, product documentation, revision change control, and electronic signature is at the core of the system. Epicor extends product data with end-to-end quality procedures, including online test results for easier audits. Our solutions support these high-quality standards and traceability with full non-conformance management, corrective actions, and preventative maintenance.

Additionally, the robust Epicor 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 and submission, through production, fulfillment, and delivery, through service and finance, you get complete visibility into the entire product history.

Product Traceability

In all regulated life sciences sectors, the need for traceability is critical. Epicor for Medical Device features strong, cradle-to-grave control and visibility over lot-tracked and serial-tracked parts, 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 help 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—enabling you to track products in-process alongside raw material inventory, finished goods, and supplied products. Epicor understands that complete traceability throughout helps provide clarity and quick resolution in the event of audit or recall.

Collaborate is a unique solution that allows stakeholders to work together electronically on product design and product issues. For added security, these interactions 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. At Epicor, we understand this and can guide you on the services needed to assist your company in complying with validation requirements for your installation, including business processes as they fit within your business framework. One of the challenges for businesses under validation requirements is keeping current with the latest technology. In addition, updates to software require risk analysis and re-validation. Epicor Life Sciences Cloud solutions help provide the necessary infrastructure, along with an upgrade cadence that not only supports the initial validation but ongoing validation requirements as well.

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/date stamps, business process management that can deliver approval criteria for key processes, and a 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 may erode 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 you a comprehensive approach to automating this compliance process while reducing the risk of warning, recall, and customer issues.

Software Validation Partner

Epicor has partnered with IZiel Healthcare, a proven industry expert, to allow comprehensive validation support. IZiel Healthcare can streamline software validation for the initial go-live, as well as establish a comprehensive software validation process for ongoing management.

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 remaining confident that your critical business systems are secure and ready when you need them. The solution delivers pragmatic innovation and the latest industry functionality, to help ensure you stay one step ahead of the competition.

Epicor for Medical Device empowers every employee to learn the solution easily, thanks to an easy-to-use, intuitive cloud-based user experience and embedded learning guides.

Made with manufacturers, for manufacturers, Epicor combines deep industry capabilities withgreat user experiences and the innovative technology to help you grow.

Epicor for Medical Device comes with a suite of essential web services tools including 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—you can use it during any process to gain additional information, 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) helps you meet the immediate requirement for scalability while supporting an open philosophy in the event your business strategy changes. SOA offers a simplified infrastructure that helps make any future mergers and acquisitions more streamlined.

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 can support you not only in doing business locally but doing business between countries, including meeting classification requirements of the Uniform Code Council (UCC).

Epicor for Medical Device offers comprehensive multi-site capabilities coupled with a 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—is possible with the right technology. The Epicor industry solution streamlines intra- and inter-company processes and helps companies communicate quickly and accurately.

Synchronization of the 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.

Flexible Cloud Options

Leadership in global cloud ERP is in the DNA of Epicor. Meeting the changing needs of your business with flexible cloud solutions delivers on business growth today and wherever the future may take you. Kinetic is ERP lets you choose your deployment: 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 uses the same technology, regardless of cloud or on-premises, businesses can also choose to self-host the solution or work with a third 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.

Industry Leading Services and Support

Epicor is committed to offering industry-leading services and support for cloud-based solutions to help meet the dynamic needs of businesses as they navigate industry changes, customer demands, and competitive landscapes. Understanding the unique challenges of medical device manufacturers, Epicor has partnered with Iziel Healthcare to offer specialized support for software validation, helping to ensure compliance with regulatory standards such as the FDA in the United States and EMA in Europe. The Epicor Life Sciences Cloud solution provides support for ongoing validation activities with documentation and annual upgrades that keep your business up to date with the latest industry functionality to help your business grow.

Epicor for Life Sciences Cloud

The availability of secure, critical business systems in the cloud improves your ability to compete and innovate with agility. The Life Sciences Cloud supports compliance requirements with software validation on an ongoing basis. This solution includes four cloud instances, combining regulatory documentation with an upgrade cadence designed to meet strict life sciences regulatory requirements.

EPICOR

We're here for the hard-working businesses that keep the world turning. You're the companies that make, move, and sell the things we all need. Trust Epicor to help you do business better. Your industry is our industry, and we understand you better than anyone. By working hand-in-hand, we get to know your business almost as well as you do. Our innovative industry solution sets are carefully built to fit your needs and respond flexibly to your fast-changing reality. We accelerate ambitions, whether you want to grow and transform, or simply become more productive and effective.

That's what makes us the essential partner to the world's most essential businesses.

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