



USING CLOUD ERP TO ACCELERATE THE MEDICAL DEVICE INNOVATION CYCLE

*An Axendia Insight Brief on
the Epicor Medical Device ERP platform*



Introduction

High growth Medical Device companies are looking for ways to accelerate innovation across the product lifecycle to support patient needs. They are also seeking to improve product quality and manage costs to support financial growth.

Until recently, companies have had to implement multiple on-premises point solutions such as ERP, PLM, MES, and QMS to achieve these goals. Today, these Medical Device organizations are looking for enterprise-wide cloud native platforms that support improved outcomes across the entire product lifecycle.

This insight brief is based on Axendia's research and conversations with the following Medical industry thought leaders from Epicor:

Christine Hansen

Director of Product Marketing Manufacturing

Trevor Steel, Sr.

Principal Solution Engineer

Andrew Dancan

Sr. Solution Engineer



The Time for Transformation is Now

Traditionally, Medical Device ERP systems focused on financial transactions, tracking business resources and the status of business commitments. In addition, various departments implemented point solutions to support their respective needs. Compounding this challenge, many device manufacturers struggle with outdated on-premises systems they find difficult and costly to upgrade. As a result, sharing data to achieve visibility, control and collaboration required the creation of spreadsheets, reports and “swivel chair integration” between these standalone systems.

Leveraging a modern cloud platform, companies can improve visibility, control, collaboration, and innovation, from development to approval.

76% of industry respondents to a recent Axendia poll shared that Black Swan events are accelerating digital transformation in their organizations. See: [Using Connected Manufacturing to Overcome a Disruption in Life-Sciences - A “Straight from the Source” Webinar](#)

Modern cloud ERP provides a platform to support Digital Transformation and accelerate the Medical Device innovation cycle. Today, high growth Medical Device organizations are looking for platforms that provide visibility across:

- ▶ The value network from raw material to patient
- ▶ The organization from shop floor to top floor
- ▶ The product lifecycle from ideation to retirement

The transition to value-based healthcare models is also adding price pressures, affecting the life sciences and healthcare ecosystem. See: [The Value of Analytics in Healthcare](#)

This transition is especially evident in high growth Medical Device companies, where stakeholders want to focus resources on bringing innovative products to market, not on IT infrastructure and services. As a result, cloud offerings, such as SaaS, PaaS and IaaS have become the preferred implementation in this segment. See: [The 5 Essential Characteristics of Cloud](#)

In addition, regulators are incentivizing industry to transition their focus from checking regulatory compliance boxes to improving product quality and patient outcomes.

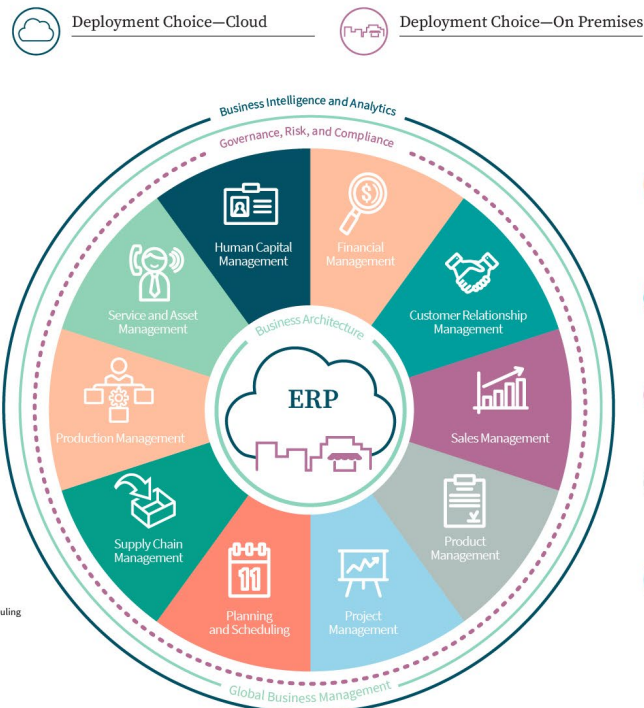
The use of an integrated cloud platform should support accelerated innovation, improved product quality and patient outcomes while managing profitability and value. A cloud platform that supports more agile upgrades ensures that systems are always current to meet the ever-changing business, technology, and regulatory requirements of high growth Medical Device companies.

The Modern ERP Platform for Medical Device Organizations

Epicor recently briefed Axendia on its Medical Device product offerings. 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 Device 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. Epicor offers a fully integrated ERP solution to high growth Medical Device manufacturers with complete visibility of all processes under one solution,” noted Christine Hansen.

Epicor’s Medical Device ERP platform offers an integrated suite of applications that support innovation:



- Human Capital Management**
 - Core HR
 - Global HR
 - Candidate Self-Service
 - Employee Self-Service
 - Talent Management
 - Training and Development
 - Position Control
 - Timesheets
- Service and Asset Management**
 - Service Management
 - Returned Material Authorization
 - Service Contract and Warranty Management
 - Case Management
 - Maintenance Management
 - Field Service Automation
- Production Management**
 - Job Management
 - Advanced Production
 - Kanban Lean Production
 - Manufacturing Execution System
 - Advanced MES (Epicor Mattec)
 - Quality Management
- Supply Chain Management**
 - Purchase Management
 - Supplier Connect
 - Supplier Relationship Management
 - Inventory Management
 - Advanced Material Management
 - Manifesting and Freight Management
 - Shipping and Receiving
 - Warehouse Management
- Planning and Scheduling**
 - Forecasting
 - Master Production Scheduling
 - Smart Demand Planning
 - Material Requirements Planning
 - Scheduling and Resource Management
 - Advanced Planning and Scheduling
 - Infinite, Finite, and Constraint-Based Scheduling

- Financial Management**
 - Global Engines
 - General Ledger
 - Financial Planning
 - Accounts Receivable
 - Credit and Collections
 - Accounts Payable
 - Rebates
 - Tax Connect
 - Cash Management
 - Asset Management
 - Advanced Financial Reporting
- Customer Relationship Management**
 - Contact Management
 - Customer Connect
 - Marketing Management
 - Lead and Opportunity Management
 - Case Management
 - Mobile CRM
 - Integration to Salesforce.com*
- Sales Management**
 - Estimate and Quote Management
 - Order Management
 - EDI/Demand Management
 - Point of Sale
 - Commerce Connect
 - Customer Connect
- Product Management**
 - Bill of Materials
 - Routings
 - Engineering Change and Revision Control
 - Document Management
 - CAD Integration
 - Product Lifecycle Management
 - Product Costing
 - Product Configuration
- Project Management**
 - Project Planning and Analysis
 - Project Generation
 - Project Billing
 - Resource Management
 - Contract Management
 - Planning Contract
 - Time Management
 - Expense Management

- Business Intelligence and Analytics**
 - Operational Reports/Dashboards
 - Descriptive Analytics (Business and Financial User Reporting/Dashboards)
 - Diagnostic Analytics (Scorecards/KPIs, Financial Planning)
 - Predictive Analytics (Forecasting)
 - Data Warehousing
 - Role-Based Analytics and Business Intelligence
 - Mobile Business Intelligence

- Global Business Management**
 - Multicompany Management
 - Multicurrency Management
 - Global Multisite Management
 - Multilingual Data Management
 - Master Data Management
 - Scalable Deployment
 - Global Engines

- Governance, Risk, and Compliance**
 - Corporate Governance
 - Risk Management
 - Security Management
 - Business Process Management
 - Global Trade Compliance
 - Electronic Compliance Reporting Tool
 - Environmental and Energy Management

- Business Architecture**
 - Cloud Deployment
 - Microsoft® .NET and SQL Server® Optimization
 - Enterprise Experience
 - Web Access, Mobile Framework
 - Enterprise Query and Application Search
 - Business Process Management
 - Social Collaboration Platform
 - Enterprise Content Management
 - Electronic Compliance Platform
 - Security Management
 - Service Architecture, RESTful Services
 - Business Integration and Orchestration Platform

Source: Epicor

Regulatory Compliance Shift

It is a common misconception that FDA requires extensive testing and documentation to demonstrate assurance of modern computer software used in automation, and quality systems.

As a result, “many companies are still printing documents for use as their batch record, then they fill it out, and then they put it back into their doc management. And that is not sustainable, because they are not getting any value out of the data,” said Trevor Steel. The data is lobotomized as soon as is stored as a static document.

The fact is that the FDA is encouraging the use of automation, information technology, and data management solutions to support the development and manufacturing of high quality medical products. The agency recognizes that automated systems can provide significant benefits to drive enhanced product quality and safety thereby reducing patient risk. See: [FDA Debunks Industry Myths on Electronic Batch Records and Review by Exceptions](#)

According to Cisco Vicenty, “The FDA has become geared towards driving a more continuous improvement and a manufacturing and product quality focus within the Medical Device industry.” See: [FDA Shares Insights on Digital Transformation & Manufacturing Modernization](#)

Using technology to gain deep product and process knowledge results in improved product quality. This new perspective provides a risk-based approach to non-product validation activities reducing the time to clearance and driving product quality excellence. See: [FDA Answers Your Questions on the New Approach to CSV](#)

“We are seeing our customers collecting all their product data in the Epicor central repository” commented Trevor Steel. “Because you have all of that data in one validated environment, they don’t have to print out a batch record. And then, when an auditor comes in, they typically ask you, “can you show me the history records for this batch” – they will go to the system of record, which will be Epicor for Manufacturing and show them the data, along with the associated audit history.” he added.

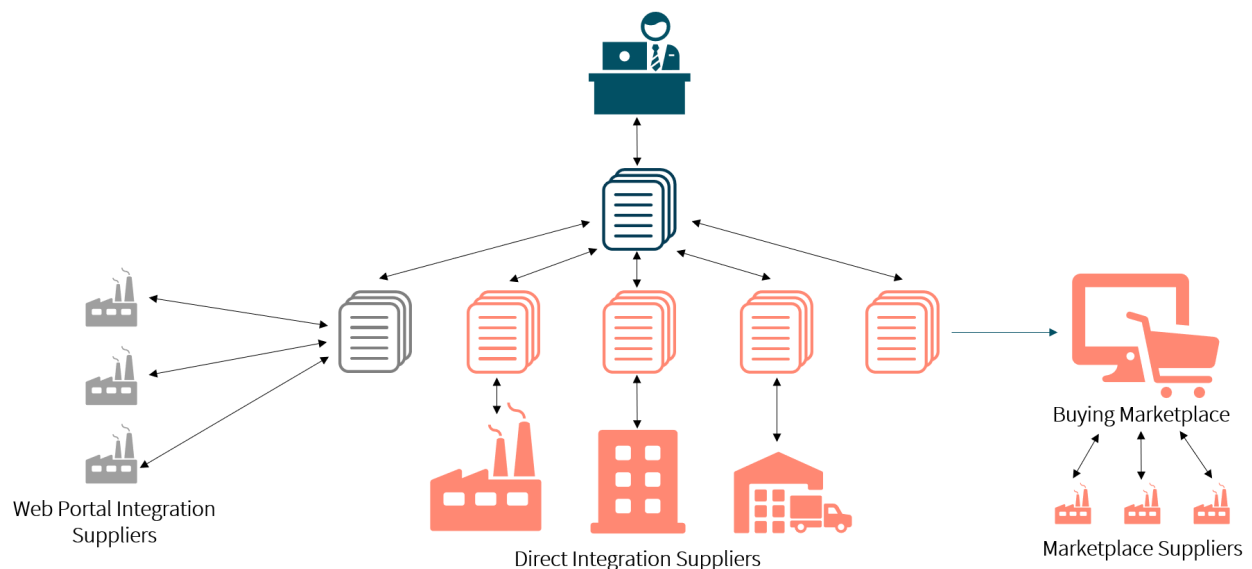
Smart Sourcing to Increase Resilience

While globalization will continue, current disruptions and the potential of future Black Swan events are driving organizations to reassess their outsourcing models. These include build, buy, or partner as well as onshoring, offshoring, and outsourcing decisions. In addition, these companies must shift from rigid supply chains to value networks. These value networks must be integrated and flexible, yet tightly controlled, with transparent data at every layer of the sourcing, manufacturing, and delivery process.

To this end, companies must consider the shift to value networks based on a “smart sourcing” strategy that evaluates the total cost and implications of their decision, not just the initial cost. See: [COVID-19 Black Swan Colliding with Your Supply Chain?](#)

These, along with improved visibility, would support product and process controls based on actual parametric attributes, rather than incoming inspection testing. This approach also drives improvements in operational efficiency and on-time delivery while reducing inventory, operational cost, and the cost of poor quality.

The ability to leverage smart sourced supply networks allows life sciences manufacturers to build resilience proactively, instead of reacting to shortages after they happen. Integrated solutions can predict people, processes, and product constraints, while optimizing against business and regulatory conditions to drive supply network effectiveness and competitiveness.



Source: Epicor – Supplier Digital-Integration Suite.

Trevor Steel noted that “We have capabilities like consolidated purchasing and visibility to the data. If you are in manufacturing, as part of the supply chain where one region would support another region, because it is a lower cost area, intercompany transactions can also be accomplished directly within the application itself. For items deployed across multiple regions and geographical locations there is a full audit trail and visibility to the supply chain.”

Operational Efficiency Through IoT and Metrics

While Epicor includes an advanced MES that offers controls to equipment, Microsoft Azure IoT Hub capabilities are also leveraged to give customers more ad hoc connections. Through the business process management structure these notifications go right into the Epicor Collaborate messaging stream and can trigger activities in other applications.

Integration to non-Azure and non-Epicor applications can be done using a number of different methodologies- with REST API and Epicor Functions as the standard.

Epicor's functionality allows colleagues and partners to collaborate through shared metrics, supporting data driven decisions to improve productivity.

Andy Dancan pointed out that Epicor "can do things like monitor systems and can automate processes for maintenance jobs. If one of the machines needs to be shut down, that information would be sent to the appropriate colleagues via their 'collaborate' module." He continued "you can actually take snapshots to send out and collaborate between other departments to understand and figure out what's going on".

This functionality also enables trading partners across the value network to share metrics in real time with suppliers, CMOs, packaging organizations and distributors to improve visibility control and collaboration.

Trevor Steel pointed out that this ability to "analyze the data and collaborate on the data allows an organization to refine down to where notifications occur, so that notifications are received before an out-of-compliance circumstance arises." This risk mitigation feature supports the shift from the reactive to a more proactive or ultimately predictive operation.

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Managing Products Across Their Life Cycle

Closing the loop on changes is a big challenge for the Medical Device industry. See: [Industry Executives Discuss Change in a Complex Environment](#)

For example, once a field action is triggered, a multitude of resources are deployed in an effort to “identify the root cause.” However, this is only half the battle. Ensuring that effective corrective and preventive actions are implemented can result in process and product changes. Unfortunately, regulators have found that many issues leading to field actions were related to design problems that could have been corrected during the design process.

As a result, FDA is requiring closed loop “Total Product Life Cycle” approach for certain devices. The Total Product Life Cycle (TPLC) approach calls for the integration of premarket and postmarket data about Medical Devices. It includes information pulled from Premarket Approvals (PMA), Premarket Notifications (510[k]), Adverse Events, and Recalls. This requires a closed loop approach that ensures any issue is effectively addressed. See: [Does Having a Closed Loop Process Really Matter to Your Business?](#)

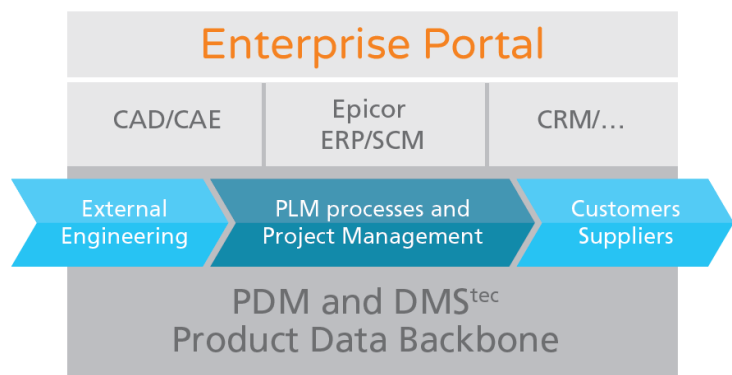
Epicor’s PLM solution has four major components according to Christine Hansen:

- ▶ One is the management of documentation and having a centralized vault.
- ▶ Secondly, the PLM system handles both mechanical and electrical CAD integrations. So, if you are developing a complex component and you have drawings and integrations with CAD systems from both sides, you can bring those together into a single system.
- ▶ Thirdly, it has the robust workflow capabilities that are needed within the industry to efficiently and effectively resolve complex approval processes.
- ▶ Fourth, integration with ERP automates the flow of engineering data to production, ensuring the accuracy and timeliness of production.

The entire design to retire lifecycle process can be managed utilizing the applications included, and fully integrated with, Epicor for Manufacturing. As Christine explained:

“what the designer designs flows right into production, including the drawings and documentation. There are no human hands that must touch it. So, it becomes a very seamless process that reduces the risk of errors.”

Christine elaborated: “From a process perspective, we have not only embedded quality solutions but also integrations into the QMS solution for customer complaints management. Case Management within ERP is also available.”



Source: Epicor. The Product Data Backbone from Epicor PLM integrates CAD, product and document management in a single electronic vault.

Out-of-the-Box Solutions Drive Operational Efficiencies

To accelerate product innovation across the product life cycle, high growth Medical Device companies are looking for industry standard out-of-the-box solutions to drive operation efficiencies. Companies that often use rudimentary systems based on point solutions and spreadsheets are looking to their vendors to say, "I'm willing to change the way I do business, if you give me out-of-the-box use cases" based on industry standards they can implement day one.

According to Christine Hansen, Epicor implements their system using best practices and then layers on top of that, some of the processes that make each customer unique. So generally, it is 80+% best practices out of the box, the rest unique workflow and configuration.

As Trevor Steel pointed out: "Where Epicor really helps is after a device manufacturer has gone through that initial development cycle of a device; when they start to think about how approval is coming in X number of weeks, X number of months. What they are going to face at that point is an explosion of scalability requirements due to their rapid growth. They are not going to be able to sustain what they do based on Excel and paper-based systems. So, particularly in the high innovation cycles of startups, we see they are not worried about finances as much as they should be."

"An ERP solution layers over the informal development and innovation aspects of the startup, a layer of formality that they can then be used to scale the business significantly and be successful. And maintain approvals once they have their product approvals, because the FDA is going to come in on a regular basis and is going to inspect. And if you have been in business for a year and then you end up with a handful of 483s, that is not going to do you any good, right? I mean, you do not want to be on that list," added Andy Dancan.

"From a scalability perspective, Epicor is like adding jet fuel to the mix for them. It really allows them to work, forget about that stuff and focus on production and shipping products that comply. It's a paradigm shift when you go from a startup to a product shipping company. And what we bring is the ability to layer those controls over the top" concluded Trevor Steel.



In Brief

High growth Medical Device companies are looking for cloud native enterprise-wide platforms to accelerate innovation and support improved outcomes across the entire product lifecycle. They are also looking to improve product quality and manage costs to sustain financial growth.

Modern ERP provides a platform to support Digital Transformation and accelerate the Medical Device innovation cycle as well as improve visibility, control and collaboration across the entire value network.

The transition to value-based healthcare models is adding price pressures to the industry. This is especially evident in high growth Medical Device companies, where stakeholders want to focus resources on bringing innovative products to market, not on IT infrastructure and services.

In addition, regulators are incentivizing industry to transition their focus from checking regulatory compliance boxes to improving product quality and patient outcomes.

The use of an integrated cloud ERP platform approach should support accelerated innovation, improved product quality and patient outcomes while managing profitability and value. A cloud platform that supports more agile upgrades ensures that systems are always current to meet the ever-changing business, technology, and regulatory requirements of high growth Medical Device companies.



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