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REPORT

ERP systems for medical device manufacturers

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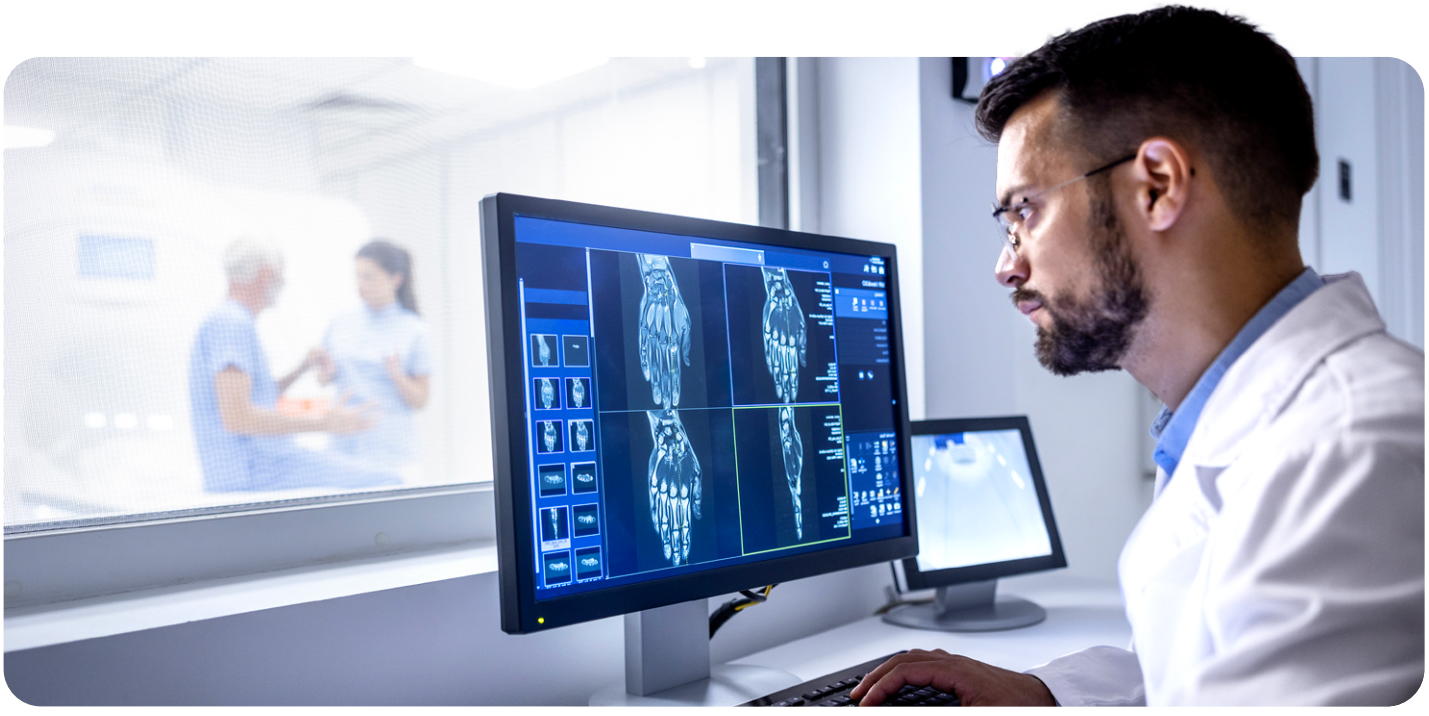
All manufacturers must grapple with issues such as compliance, inventory management, traceability, cost control, and collaboration. But if you're a medical device manufacturer, your challenges are on a different level. People's lives depend on your product, and your product depends on your safe handling of it from the design and prototype phase all the way to customer service. That's why your ERP system is so connected to the vitality of your company; like a pacemaker, it keeps your company pumping at an optimal rate. Don't have an ERP? Have one, but desperately in need of an upgrade? Then read on to find out why cloud-based ERP systems are revitalizing medical device manufacturing companies that were once suffocating under the pressures and regulations of producing and delivering high-quality devices.

In this report, we will dig into the biggest challenges facing medical device manufacturers and how ERP systems can face and easily overcome them.

First up: Regulatory compliance. The one constant in regulatory compliance is that it's always changing. Adhering to these changing regulations from the FDA and the EMA can be challenging: Just as you comply with one standard, new ones can emerge. A cloud-based ERP system with integrated validation protocols can streamline your manufacturing and reporting processes, reducing the complexity of maintaining compliance. Below are several key standards and regulations in the medical device manufacturing industry that ERP systems are designed to manage effectively.



Quality control tracking of your product

(Meeting regulations ISO 13485, 21 CFR 11 and 21 CFR 820): A robust quality control system ensures your product not only exceeds the FDA's regulatory demands but also exceeds the demands the healthcare industry requires to bring safe and effective treatment to their patients. Some ERP systems ensure devices are consistently designed and produced to meet predetermined specifications. And that's great for the now, but what about the future? Your ERP system should also generate data that allows you to identify areas in your design, materials, and processes to enhance the quality and performance of your devices over time. Your commitment to the quality of your products not only facilitates compliance but also enhances your customers' trust. A modern ERP system will assist you in maintaining the verification and validation to meet Good Manufacturing Practice (GMP).

Quality control tracking of your employees

(Meeting sub-regulations 21 CRF 820.25, 820.25(b) and 820.26): Your product isn't the only item requiring oversight by the FDA; your employees are monitored as well. The FDA demands that your personnel correctly perform all activities involved in the manufacturing process. This regulation ensures that personnel have sufficient education, training, and experience to adequately perform their assigned duties, and that you have it all meticulously documented, all of which adds yet another layer of record-keeping and tracking to your job and validation efforts. ERP systems, within their human resource (HR) modules, help manufacturers remain in compliance by tracking the skills and training of staff, thus reducing human input error in a strictly controlled environment.

Risk management processes

The FDA requires medical manufacturers to address potential risks throughout the device's lifecycle, from concept and design to post-market surveillance and maintenance. ERP systems provide risk management processes and protocols that help manufacturers identify, access, and solve malfunctions and defects associated with their products before they reach the market. These quality and risk processes help analyze and evaluate defects and provide the controls you require to resolve them. Your systems should also be able to generate and update a benefit-risk analysis, a risk management plan, and a post-market surveillance process. In addition to these requirements, manufacturers must keep strict documentation of all processes and activities and have them readily available for regulatory authorities and auditors to validate them.

Overall, regulatory compliance eats into a hefty percentage of your daily workload. By updating your current ERP system or upgrading to a cloud-based one, you will have at your fingertips an indispensable tool to considerably reduce that percentage. Because, ultimately, manufacturers agree these regulations are a necessary part of producing the best quality product in an industry that not only improves the quality of people's lives but in many cases, saves them.

Navigating the world's new norm

Over the past three years, manufacturers have endured abnormal worldwide conditions affecting their inventory control, from the pandemic to trade restrictions to geopolitical conflicts. And due to the strict compliance and regulatory measures, medical device manufacturers (MDMs) have quite possibly endured the most. How can the medical device manufacturing industry maintain a successful output of lifesaving goods during this new norm of disruption?

Every manufacturing industry can overcome many of these new challenges by upgrading or investing in a cloud-based ERP system as the first step to normalizing an abnormal situation.

Challenge #1: Stockpiling and stockouts

When the pandemic hit, just-in-time (JIT) inventory management became obsolete, forcing many medical device manufacturers to stockpile inventory and to scramble for alternative solutions during stockouts and supply interruptions. Unfortunately, supply shortages and bottlenecks from China and from other countries currently suffering under geopolitical conflicts have continued to disrupt supply chains worldwide.

So how can manufacturers optimize inventory when nothing is behaving normally? Simply stated, they must automate and take advantage of every technological advancement available to them, from business collaboration and artificial intelligence to data-driven decision making. Having a modern ERP system to manage their inventory is the first step to minimizing the need to stockpile inventory. An ERP's sophisticated algorithms and predictive analytics improve demand forecasting and planning capabilities, helping MDMs to better plan lead times, establish reorder points, and manage safety stock levels. Because an ERP system automates the reordering process and enables supplier collaboration, it sends alerts when inventory levels reach specific points, prompting manufacturers to re-stock or to adjust production schedules to avoid stockouts.

Challenge #2: Supply chain disruptions

Because supply chains worldwide now are highly unpredictable, MDMs need ERP systems to help them build more resilient supply chains. Changes in tariffs, transportation, trade agreements, and compliance standards have required MDMs to diversify suppliers, to implement reshoring or nearshoring strategies, and to localize manufacturing, and ERP systems facilitate these processes. Modern systems provide better communications tools, such as portals, to help you manage relationships with your suppliers and customers, thus streamlining the procurement process and ensuring timely delivery of inventory items.

Challenge #3: Communication failures across your supply chain

Today, the number one office supply is still paper, and fun fact: Over $1.2 billion US worth of sticky notes are sold every year. The number one form of business communication is email, and the number one reporting tool is a spreadsheet.

Why mention those statistics? If you're using outdated processes to track order change communication, whether they are Purchase Orders to suppliers or Sales Orders from your customers, chances are, you are drowning in sticky notes, paper copies of spreadsheets, and printed emails. It's time to give up old-school tracking and communication, especially when research shows that 52% of orders will change at least once, many of them multiple times, and switch to more modern and innovative solutions, such as a PO collaboration solution that automates and manages purchase orders with your suppliers, or Infor CloudSuite Industrial Customer Portal that allows your customers paperless management and real-time visibility into your supply chain. Modern solutions like these free you up from chasing ever-changing customer/supplier demands, enabling you to better collaborate with everyone involved in your floor-to-door manufacturing process.

Overall, these three challenges often leave medical device manufacturing companies caught in the middle of their suppliers/vendors and their customers, and who wants to be in no man's land? The best preemptive measure to avoid that undesirable landscape is to invest in a modern ERP solution, one that can house multiple solutions to your inventory management issues. They offer the necessary visibility, control, and data-driven insights to help manufacturers optimize inventory levels, ensure compliance, and respond effectively to market demands and challenges. And ultimately, they can help you to adjust to the new normal of doing business in an abnormal landscape.

Incorporating cost control with value-added processes

Cost management in the medical device manufacturing (MDM) industry, although necessary, is often not openly talked about—who wants to be the one to say, “We need to make a life-saving device cheaper”? And more often than not, it’s not even possible. But cutting expenses isn’t the same as cutting corners, and oftentimes MDMs must think out-of-the-box when it comes to cost management, and that means going hybrid: If it isn’t always possible to trim the costs of producing a quality medical device that rarely yields a high profit margin, then it is possible to change everything else around the product to optimize the value of the company and its product to deliver high-value patient outcomes.

Managing costs is one way to optimize the value of your product, so we will discuss ways to do that; however, we’ll also discuss evolving ideas to create value in a landscape that is changing more quickly every year.

Managing your production line

Which is the best supplier to use? What’s the ideal expenditure for labor, equipment, and materials that will still yield the highest profit margin without sacrificing quality? How do I robustly manage the quality of each device that leaves our facility? These questions can become paralyzing, especially when the end users’ health and well-being depend on your decisions. You may not be able to use cheaper materials, but you may be able to partner with new-to-market suppliers who are hungry to compete in an ever-growing market. If you aren’t strategically using your ERP system to negotiate favorable terms, select dependable suppliers, and reduce procurement, then it’s time to start. Your system will provide you with valuable supplier performance, pricing, and delivery schedules so you can do more valuable research into ensuring quality and GMP.

With a modern ERP system, your production line becomes much more predictable: It optimizes resources, minimizes downtime, and delivers quality devices. An integrated set of quality control processes into your ERP ensures that defective products are identified and addressed early in the production cycle, preventing costly rework or recall.

Managing how, when, and where your employees work

Gone are the 9-5 work hours and the Monday-Friday workdays. Companies today are not only retaining the work-from-home philosophy that became a necessity during the pandemic but are also adopting innovative hybrid workstyles that custom fit their corporate productivity needs. Hybrid workstyles like hiring employees with transferrable skills who can adapt to a constantly changing work environment, adopting a 4-day work week or a flexible schedule work week, working under a self-management or "distributed authority" structure, just to name a few. So how can you select which work style(s) will reduce labor costs? That's a job for your ERP system which can manage your labor costs by optimizing workforce skills and productivity, tracking hours worked, and identifying areas for efficiency improvements. Medical device manufacturers should take a closer look at their existing organizations and reinvent their traditional business and operating models to adapt to the future.

Configuring the costs of implementing value-added services to your existing and future products

Even if profit margins are high, to stay competitive more companies are integrating a range of services that supplement their core products—it's either that or risk losing market share to those companies that do. Whether manufacturers are partnering with other companies, setting up services as separate entities, or ultimately folding them into their own company, they are now managing both business-to-business (B2B) as well as adding in more business-to-consumer (B2C) needs to better ensure patient outcomes for the end users of their devices.

An ERP system that provides cost visibility and analysis as well as data analytics into current and future trends is vital to helping manufacturers manage these new value-added services from inception to implementation. Innovative technologies such as enterprise automation and decision intelligence tools such as AI/ML help companies better manage and evaluate costs for the care journey of each device area and, in each market they operate in, to determine what their future business should look like. And these technologies keep abreast of the competitive landscape, instituting a robust process to monitor disruptive trends and identify strategic partners.

A moment to discuss data (costs) transparency

To remain relative in the medical device industry you need the capabilities enabled by the latest ERP technologies that provide real-time financial and operational data to track the costs of each stage in the production of your medical device(s). This data is vital in understanding your cost breakdown and identifying areas for improvement. You can shave hours or even weeks by allocating or re-allocating costs to specific products or projects. Also, your ERP system can mine through terabytes of historical data to analyze trends in your processes in a matter of seconds, allowing you the opportunity to improve on your processes immediately.

Overall, medical device manufacturers may not have the luxury, like other industries, to simply look at cost control—not with the products they produce or the regulatory compliances they must obey to produce them. The better approach is a hybrid one: One that incorporates value-added services, innovative partnerships, and cost processes. Honestly, there's no way a single individual, or even a committee of individuals, can do this hybrid approach without the help of a modern ERP system. But manufacturers that do will chart a more successful course in the medical device industry, establishing a higher standard for others to follow.

Improving your collaboration capabilities from pre- to post-market

Synergy can be achieved only through better collaboration, but how can the medical device manufacturing industry utilize this idea? Improving collaboration within medical device manufacturing involves a combination of organizational practices, communication strategies, and technology solutions, and employing a cloud-based ERP system is an integral part of achieving this combination.

From pre- to post-market collaboration, the medical device industry is adopting more of a partnership approach to innovation rather than an in-house one, and manufacturers agree that adopting more collaborative business models with suppliers and customers is the key to their future vitality in the market.

Pre-market/manufacturing collaboration

Medical Device Manufacturers (MDMs) list lack of efficiency in product development/R&D as one of the main reasons adding to the time horizon for new product introduction and innovation, which is why many have begun to look outside the standard in-house business model. In fact, MDMs see entering new partnerships to drive innovation as the top growth driver (second only to increasing R&D spending), and the majority are already adopting more collaborative business models. Collaboration accelerates innovation by fostering the exchange of knowledge and insights. When professionals from diverse backgrounds and across the supply chain collaborate, they bring diverse perspectives to the table, and as a result, this diversity fuels creativity and problem-solving, leading to the development of novel solutions that may not have been possible through isolated efforts.

One advantage of an ERP system is its ability to bring together larger manufacturers with smaller, more agile companies that have developed more streamlined R&D processes, a marriage that helps MDMs bring new and more innovative products to market more quickly. By offering integrated communication tools, such as discussion forums, messaging systems, product lifecycle management solutions, and collaboration spaces, an ERP system provides the backbone for realtime information visibility across teams (engineering, production, quality, etc.) from different companies so they can simultaneously share ideas, updates, and feedback.

In addition to the challenges of product development, MDMs face stringent regulatory oversight to ensure the safety and efficacy of products during (and after) the manufacturing process. Collaboration with regulatory authorities is essential to navigate these challenges. Staying updated with evolving regulations and adopting a proactive approach to compliance are crucial for long-term success. ERP systems can assist in managing and ensuring compliance with various regulations, reducing the risk of errors and delays not only in collaborative R&D projects but also during product manufacturing, delivery, and long-time support and warranty.

Post-market collaboration

Collaboration extends beyond the parameters of pre-market research, design, and development, especially now that MDMs have shifted to a more patient-centric approach, something we've discussed in prior articles in this series. Patient-centric collaboration with healthcare providers and with patients themselves ensures MDMs are receiving invaluable information that helps them finetune devices and address any issues that have arisen in a more timely and effective manner. ERP systems provide real-time, integrated data, giving MDMs a holistic view of the entire product lifecycle and ensuring continuous improvement in the quality of their devices and in the quality of patient well-being. In a field where precision and safety are paramount, "collaboration is not just a strategy; it's the heartbeat of progress, ensuring that every medical device that reaches the hands of a healthcare provider is a testament to the power of working together."

Medical device manufacturing is a complex landscape that requires the harmonious collaboration of various disciplines. Engineering operators, device designers, project managers, R&D Experts, Regulatory Experts, supply chain professionals, healthcare providers, as well as the end users all come together, each contributing their unique expertise. The synergy of expertise from these diverse disciplines paves the way for industry breakthroughs that revolutionize healthcare practices. By incorporating an ERP system, MDMs can ensure that the wealth and breadth of knowledge gained through these collaborative efforts is utilized to the best of its ability, ensuring that the products brought to market are not only groundbreaking but also highly trusted in the medical community.

Keeping track of your progress with traceability

Last up in the challenges facing the medical device manufacturing industry and how ERP systems can meet those challenges, traceability. Simply stated: In a highly regulated industry, such as medical device manufacturing, traceability is crucial. Knowing the entire history of your product or products from design to production to implementation will ultimately save you from minor tension headaches to major migraines. By upgrading to, or implementing, a modern ERP system to manage your critical processes, you can easily overcome four major traceability challenges.

Traceability challenge #1: Lot and serial number tracking

With serial number tracking, every product becomes unique, and every journey becomes traceable from raw materials to the finished product. Nothing can be more headache-inducing than tracking down lost materials or components or maintaining a detailed Bill of Materials (BOMs) for each medical device. A cloud-based ERP system automates both serial number tracking and BOMs, keeping you abreast of every step of the production process: What materials and components you need for each device; where they are at any given time; how to assemble them consistently and correctly; and where they are going once they leave your assembly line. Through automated processes such as tracking and BOM management, you can better comply with the FDA's Unique Device Identification (UDI) requirements.

Traceability challenge #2: Process

Well-documented processes are the backbone of a successful business. And documentation is not just about compliance, it's also about efficiency and effectiveness. ERP systems document each step of the manufacturing process, including production, assembly, testing, and packaging, ensuring that every stage is properly recorded and can be traced back if needed to identify any deviations or defects. And when it is about compliance, your ERP system should include proper validation and test scripts specifically designed to help medical device manufacturers comply with regulatory requirements such as FDA's Quality System Regulation (QSR), ISO 13485, and other industry standards. These processes help ensure that traceability records meet regulatory standards and facilitate audits and inspections.

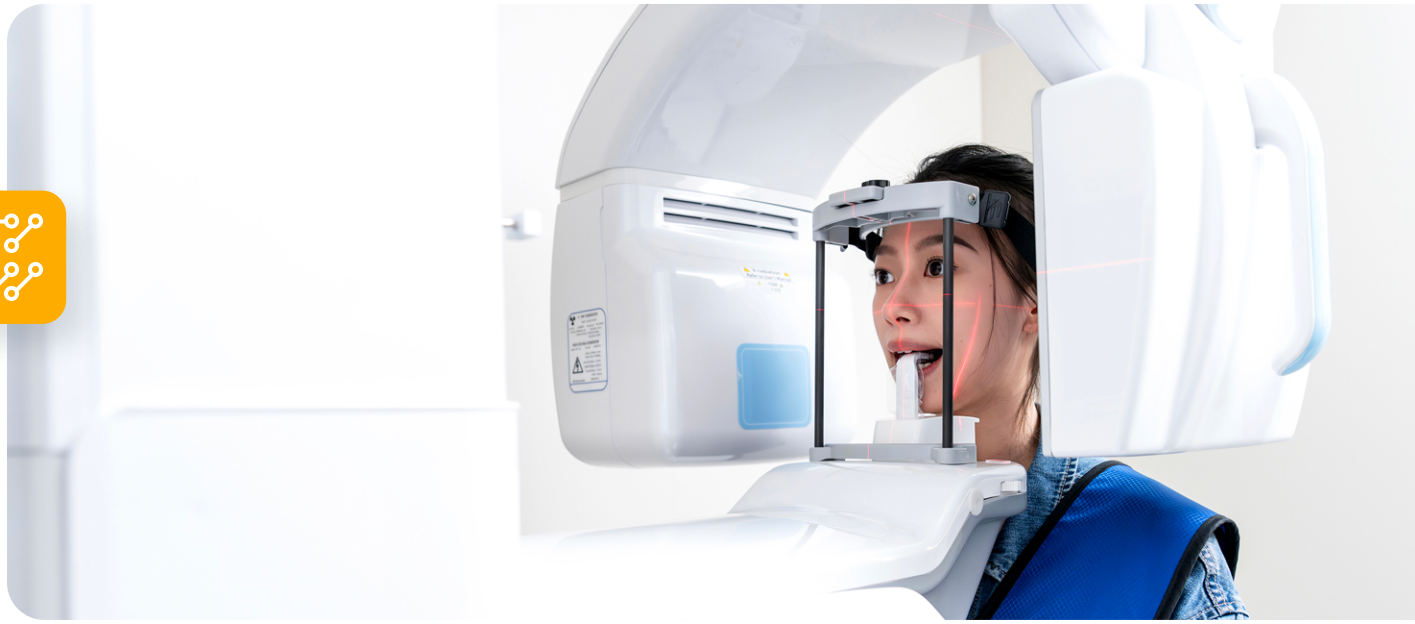
Traceability challenge #3: Material origin and rapid ID

In the unfortunate case of a device recall or quality issue, ERP systems provide visibility into the sources of raw materials and components used in manufacturing. By recording supplier information, lot numbers, and other relevant data, manufacturers can quickly trace materials to their origins in case of quality issues or recalls. Your system will also enable rapid identification of affected lots or serial numbers to minimize the scope and impact of recalls, ensuring that affected products can be quickly removed from the market. And as a result, MDMs can maintain compliance with regulatory requirements, but more importantly, can quickly minimize the impact on patients.

Traceability challenge #4: Integration with quality management systems (QMS)

The backbone of any robust system is its compatibility with diverse environments. Whether in relationships, technology, or other fields, it is a key factor for harmony and effective functioning. Medical device manufacturers require an ERP system with a quality module that supports activities from receiving, production, shipping, and returns. Infor SyteLine ERP and CloudSuite Industrial for example have an embedded quality module providing quality records to auditors or customers covering your entire enterprise, not just the manufacturing process.

No matter the specific challenges you face, ERP systems provide a comprehensive platform for managing traceability in medical device manufacturing. From helping manufacturers ensure compliance, maintain product quality, to responding effectively to any quality issues or recalls, these capabilities will not only reduce your day-today headaches but also give you and your customers peace of mind.



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