



Medical Device Enterprise Resource Planning (ERP) System Checklist: Essential Features For Your Next ERP System

Your product breakthroughs in the medical device industry are made possible by innovative thinking, patented processes, and quality manufacturing. However, there isn't an easy formula for success if your business management software can't satisfy the complex regulatory requirements, control, and customization needed to support your product launch. Whether you're a start-up medical device company looking to commercialize your next innovation or an established manufacturer that wants to increase visibility across its supply chain, the following checklist highlights essential features you should look for when evaluating medical device ERP systems.

Choose a medical device ERP system that...

✓ Integrates all key business functions into a single system

In the US, where 80% of the medical device companies are categorized as small to mid-sized enterprises (SMEs), competition is intense. Beyond product differentiation, medical device manufacturers must look to business technologies for new opportunities to remain competitive. Medical device manufacturers try to meet process needs by using multiple applications - often at the expense of creating a disjointed business. This results in information silos that cause inefficiencies and errors as data is rekeyed to connect one system with the next. Today, medical device manufacturers are choosing ERP systems that integrate all functional areas of the business into a single database. This limits exposure to costly data entry errors and results in greater cost efficiencies for more streamlined operations.

✓ Provides real-time visibility throughout supply chain

The right medical device ERP system will provide you with real-time visibility throughout your business and supply chain. Take for instance the ability to automatically update batch numbers with batch management. Because the ERP system is integrated you have greater visibility; you can manage your inventory both at the product and batch level. When your business picks ingredients needed to manufacture a medical device component, you would now be able to pick from fewer batches which would have otherwise been carried out manually. The result is less time and effort spent to produce the component which equates to greater efficiency.

✓ Meets standards for medical device traceability

Industry regulation requires that medical devices are tracked once they enter the supply chain. Tracking requires that medical device manufacturers use a system that can gather information about their devices quickly to locate them in commercial distribution. In a case where failure of a device could result in serious health consequences, such a system will ensure that your company can remove defective or potentially dangerous medical devices from the market and provide notification to regulatory authorities such as the FDA about a medical device recall. Look for a medical device ERP system that includes features such as serial number traceability to ensure you can track medical devices not only in the warehouse but once it enters the supply chain.



✓ Ensure software compliance with all necessary medical regulations

The medical device industry is one of the most regulated in the world. When evaluating your next medical device ERP software, ensure that it can be validated for FDA compliance and that it supports the ability to keep record of device revisions, malfunctions, and corrections. Depending on your country, you'll need a system with the flexibility to be validated for additional regulatory processes and procedures. For instance, US medical device manufacturers require that their system includes electronic signature and document control to comply with 21 CFR Part 11 which can be handled by a compliant ERP system. However, if you plan on distributing your products to other countries, there will be other regulatory bodies whose requirements you must conform with. Selecting a flexible medical device ERP system now will save you compliance delays when entering new markets later.

✓ Manages medical device quality requirements

From orthopaedics, surgical instruments, to diagnostic apparatuses; whatever the segment, medical device manufacturers must ensure that their chosen medical device ERP system will also provide quality management for their class I, II, III, and IV medical devices. This includes quality standards compliance such as TS13485 and ISO 9001. The right medical device ERP system will possess the ability to configure workflows that ensure quality check procedures are followed at each juncture of the component's production. Once the qualitative or quantitative measurements are defined in the system, you can set up the Acceptable Quality Level (AQL) at each production checkpoint. This will ensure that a medical device or component doesn't proceed to the next step until criteria are met; thereby managing quality of the medical device or component in a cost-effective manner.

✓ Adapts easily to global regulatory requirements of your customers

Medical device manufacturers are often part of a complex global supply chain, which means satisfying the requirements of international customers and regulatory procedures that differ from country to country. When evaluating medical device ERP systems, it's important to consider requirements from multilingual system user interfaces, currency, and measurements. By choosing a system that supports EDI (electronic data exchange), smaller start-up medical device manufacturers become more marketable to larger supply chain partners that use it. EDI facilitates greater customer interaction by sharing business critical data through customer portals. For your supplier, this enables them to check stock on hand, or set up for automatic ordering once inventory of an essential component is depleted.

✓ Supports mass customization of medical devices

For medical device manufacturers in personalized segments such as prosthetics, one size does not fit all. Serving customers on a global scale means producing components that are customized to their specific requirement of length, diameter, and material. With each new customer order comes a workflow from quotation, manufacturing, several iterations of design and configuration, through to production. With so many steps it can become difficult to organize data about the specifications of the components produced and the customer orders. Due to the proliferation of mass customization, medical device manufacturers should choose an ERP system that has an integrated production module to efficiently manage component variances in a single system. Data collected throughout an integrated production module can then be reported upon at a moment's notice without having to reference cumbersome emails, printed forms, or Microsoft Word documents.

How Vision33 Can Help Your Medical Device Company Grow & Increase Profits

Bringing innovative medical devices to market requires innovative business solutions. If your current system does not possess the essential features outlined above or if you'd like help with ERP selection, then contact a Vision33 consultant today. Our certified ERP consultants are standing by to discuss how your business can achieve FDA compliance and bring your products to market faster.

Vision33 offers medical device manufacturers services including:

- ERP system recommendations
- System validation
- Business process consultation
- ERP systems subsidiaries integration
- Software customization



“ Implementing an ERP system has helped us bring together finance, supply chain, logistics, warehouse management under one platform. It really transformed how we do business at Avinger.”

Bill Francis, Director Information Technology, Avinger, Inc.

About Vision33

Vision33 Inc. is a global IT professional services consultancy that solves customer business challenges through the promise of technology and the value it delivers. We partner with growing and large organizations in both the public and private sectors to understand their vision and help them reach it with the right blend of strategy, consulting, and technology. Vision33 global team of results-driven resources provide world-class experience through our office locations in North America and Europe. For more information about Vision33, visit www.vision33.com.

Contact a Vision33 ERP consultant today



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