



The future of medical device manufacturing

Aging Baby Boomers will require an increasing amount of medical care in the coming years, adding an extra layer of complexity for medical device manufacturers. To remain innovative, medical device manufacturers must adapt to the changing demographics of an aging population, while keeping up with the regulatory requirements that govern how medical device products are developed, manufactured, marketed, and sold. With a next-generation enterprise resource planning (ERP) solution, medical device manufacturers can prepare their businesses for changing Baby Boomer needs, while controlling costs and preparing for the future.

Take advantage of heightened demand

As people get older, history proves they will require more medical care. That has critical implications for the medical device industry, since Baby Boomers (people born between 1946 and 1964) began crossing into the “65 and older” category in 2011. According to US Census Bureau projections, the number of Americans who are 65 and older will double to 83.7 million by 2050.¹ At the same time, medical device manufacturers are also under pressure to navigate changing market dynamics, countering price and cost pressures, and adapt to an evolving regulatory and risk environment, while still promoting innovation.²

Innovation is critical to a medical device manufacturer’s success in this highly competitive—and highly regulated—market. As demographics change and the population ages, medical device manufacturers, suppliers, and service contractors face a complex and changing regulatory environment that has an incredible affect on the research and development, manufacture, inspection, sale, and maintenance of products. That’s because the FDA continues to change regulations governing approval of new products, standards for good manufacturing practices, and standards for maintenance, inspection, and repair of medical equipment.

Plus, medical device manufacturers are faced with a medical device tax, patent and intellectual property issues, product liability, rapid product obsolescence, and competition from alternative products, such as bone, organ, and tissue replacements. In order to maintain a heightened state of readiness and responsiveness, medical device companies such as yours must rely more heavily on IT solutions. With next-generation ERP systems that include the newest analytics and tools for collaboration, you can meet Baby Boomer demand, while controlling costs.



Gain a stronger competitive advantage

Upstart medical device competitors can overtake your company before you realize what happened. But by embracing a couple of key initiatives, you can go a long way toward maintaining a strong competitive position. The initiatives you should embrace include:

Increase agility

Agility in manufacturing means more than increasing the end-to-end throughput that starts with initial program management. Speed is only one factor, although it is certainly an important component. Agility also depends upon access to qualitative insights. The ability to adapt and respond to external requirements is a good litmus test for process modernization. Fortunately, advanced ERP technologies simplify these complex processes.

Automatic monitoring and escalation alerts can help you track key issues and abnormal events, both internally and within your external supply chain. Easy-to-use, real-time reporting and analytic tools help personnel throughout your operations monitor their goals, key performance indicators, and driving factors.

Your next-generation ERP solution should focus on critical challenges, such as:

- **Supply chain management**—Lower costs and reduce lead times by integrating your system with the supply chain management systems of distributors and hospitals that need to deliver supplies the same day.
- **Quality management**—Establish, track, and manage every engineering activity and supply chain expectation. Create critical specifications for products, processes, equipment, and measuring devices, and improve collaboration with vendors, customers, and employees.
- **Manufacturing control**—Make many of your most complex manufacturing processes faster, more reliable, and more profitable with sophisticated manufacturing management capabilities.
- **Sales and operations planning**—Make better plans with relevant, up-to-date information from many sources.
- **After-market service and maintenance**—If you support your customers with installation, warranties, ongoing maintenance, or break-fix repairs, get the specialized functionality you need to manage your service operation.

Improve collaboration

Collaboration tools are another way that ERP technology keeps up with changing demands. Because organizations are operating with ultra-lean workforces, “social enterprise” is more than a buzz phrase—it’s a way to improve production with synergy and collaborative thinking. Manufacturers and suppliers can take advantage of fully integrated solutions that allow real-time collaboration and data sharing, including computer-aided design diagrams and 3D images.

With seamless connectivity throughout the manufacturing supply chain, you can maintain tighter version controls, manage ripple-effect changes, track critical escalations, and capture relevant dialogue in context to the product. You’ll be able to track, report, and validate team decisions—one of the greatest benefits of an integrated collaborative system. Because the ERP system documents data in terms of the shift, machine, and product, you can reference the content for future decisions, plus reporting and process improvements. This historical documentation proves invaluable when legal or compliance issues arise, such as questions about due diligence, intellectual property rights, and change validation or risk mitigation. Nothing is left to memory, guesswork, or chance.

With collaboration tools, you can also speed product introductions and innovation while reducing risk due to poor cross-discipline knowledge. Greater cooperation between design engineers, suppliers, and production teams helps to speed the entire product development cycle, from creative brainstorming all the way through costing, testing, and production. For example, your teams can use collaboration tools to confirm model numbers and ensure that correct versions are used on the assembly line and on scheduled preventive maintenance. They’ll be able to get questions answered immediately, without time-consuming, costly delays.

Thanks to instant communication tools, you’ll be able to accommodate last-minute change orders and shop floor scheduling shifts with minimal disruption to the overall process flow.

As a result, you can bring new concepts to market more quickly, while quickly responding to shifts in market demand and changes in regulatory compliance issues.



Support manufacturing excellence

With Infor® Industrial Manufacturing for Medical Devices, you get the tools you need to meet Baby Boomer demand while controlling costs. With a single system, you can track the movement of materials and parts from receipt to shipping. You can help ensure that products meet or exceed the standards required by customers and regulatory agencies. Also, because Industrial Manufacturing for Medical Devices includes FDA validation scripting, you'll be able to safely use electronic signatures, confident that the system complies with Title 21 CFR (Code of Federal Regulations). You'll be able to safely use electronic signatures, because the system complies with Title 21 CFR (Code of Federal Regulations). You'll also be able to manage the complete lifecycle of your products, from innovation and product design to aftermarket service and preventive maintenance.

With Industrial Manufacturing for Medical Devices, you get the tools you need to:

- Trace lots and serial numbers in the event of recalls.
- Record the history of devices, leading to product improvements
- Track customer complaints and help desk interactions, improving customer service.
- Quickly handle the return material authorization (RMA) process, increasing efficiency.

¹ US Census Bureau, "An aging nation: The older population in the United States," May 2014, p. 1, <http://www.census.gov/prod/2014pubs/p25-1140.pdf>.

² Deloitte, "2016 Global life sciences outlook," 2015, pg. 8, <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2016-life-sciences-outlook.pdf>.

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