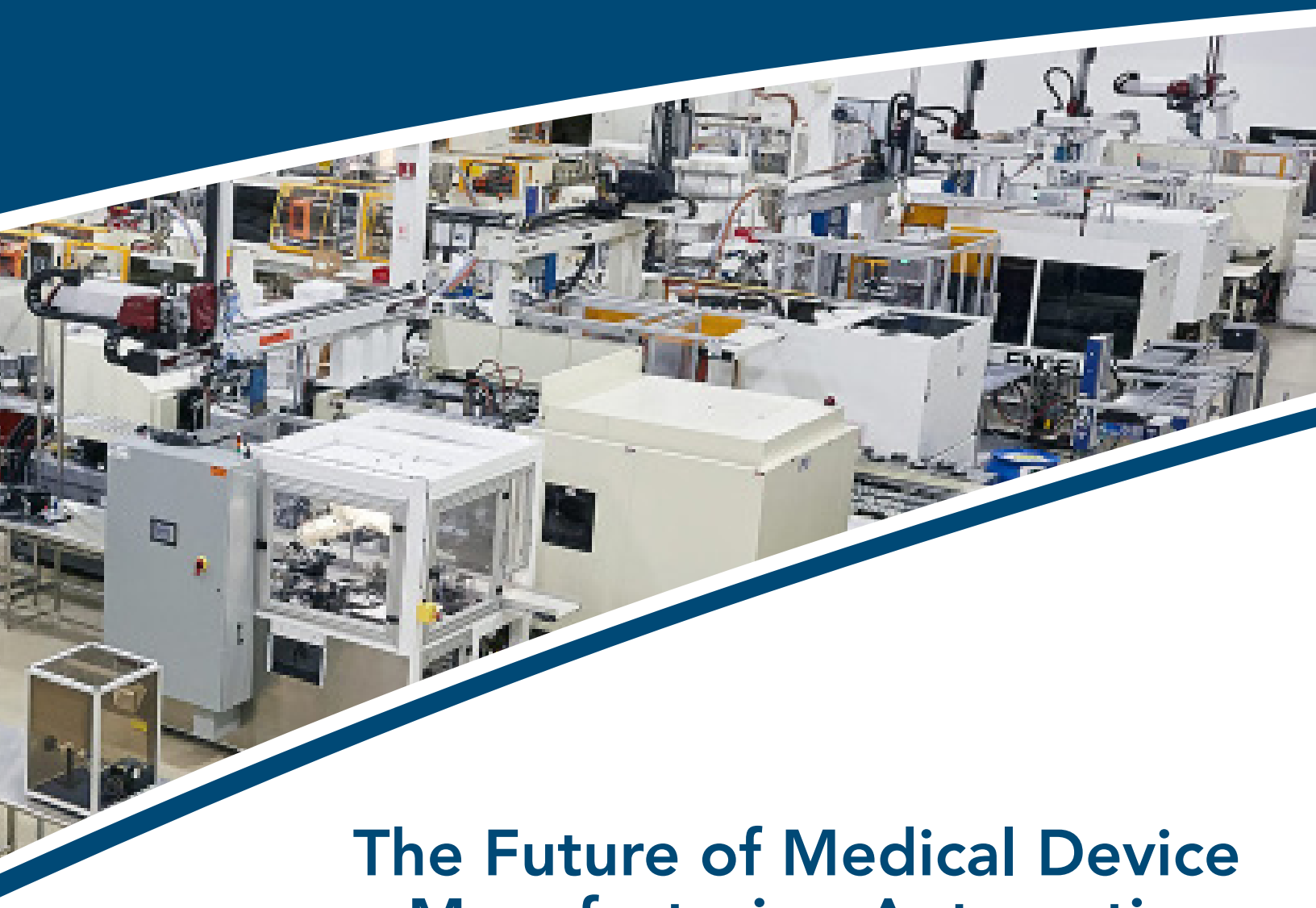

The Future of Medical Device Manufacturing Automation: 3 Trends to Anticipate and Prepare for in 2024

By Raghu Vadlamudi
Chief Research and Technology Director

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1. Re-engineering to survive – and thrive – under pressure

It's no secret most manufacturers are under constant pressure to be more cost effective and faster to market. In this quest, legacy products often get extra financial scrutiny and deprioritized in favor of promising new innovations that demand more attention.

But the industry is changing – and fast. Increasingly, OEMs have many more choices, including to re-engineer products still widely in use to cost less to produce.

Thanks to advances in product development and manufacturing technologies, many products developed even 5 or 10 years ago, can now be updated. For example, many production steps that used to require manual steps, certain materials, or capabilities can now be automated or otherwise tweaked to reinvigorate a popular product's long-term profitability.

While making the transition requires design and development due diligence, the investment of time and resources can be well worth it.

In one recent case, a global OEM with an implantable device transitioned a conventional injection molding process to an automated vertical molding process. This shift made it easier to consistently produce the part at a lower price point with less waste. It also helped address limited staffing resources by automating repetitive tasks with robots, so skilled workers could focus on processes and tasks that require thinking and decision making.

In another recent example, an OEM took advantage of advances in manufacturing technologies to improve the production cost efficiency of its 10-year-old medical device. Product engineers figured out how to consolidate three machined and assembled components into one molded component, without compromising the product quality or extremely tight tolerances. The transformation saves the company nearly 50% in manufacturing costs for the medical device.

2. Rapidly evolving 3D printing gives early adopters future stake

Only a few years ago, additive manufacturing seemed like a thing of the very far future. But the future of 3D printing intricate medical device components and features is here – and already making the once impossible possible.

Micro parts and features too intricate, small or expensive to mold or machine can now be created using additive manufacturing. That's because using 3D printing allows a part to be built layer by layer, rather than formulating and molding plastic or running up against the limitations of precisely machining metals.

With its relatively low cost of entry, additive manufacturing is also set to transform what "speed to market" means. It also makes product development "trial and error" far less expensive and time-consuming than traditional prototyping processes, especially for tight tolerances and complex geometries. Product development teams can easily (and cost-effectively) print a part for review, recalibrate the specs and print it again as necessary until it meets performance goals.

With these technological, design and financial hurdles minimized, expect innovations to progress quickly across all markets, but especially in cardiac and neuro devices and components.

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That is, once a few more hurdles are cleared.

Before 3D printing can realize its full market potential, the use of the technology needs to become mainstream. And before that can happen, more leaders need to take the lead and industry standards need to be set.

The first hurdle is in motion, as more manufacturers are using 3D printing. The second hurdle, however, will likely take a bit more time. While the U.S. Food and Drug Administration has already approved some 3D printed medical devices and drugs, more data is needed before industry approval processes can be established.

In other words, we're *this* close – and by that, we mean very soon.

3. Industry 4.0 making smarter, more competitive medical device manufacturers

As ChatGPT will explain (and most of us in the medical device industry know): "Industry 4.0 aims to create 'smart factories' where machines, systems and humans collaborate more efficiently. It leads to more flexible, adaptive and interconnected manufacturing processes, thereby improving productivity, reducing waste and enabling quicker response to market demands."

And ChatGPT is right.

Sure, the healthcare industry tends to lag behind other industries for many reasons, including the: complexities of regulatory and compliance standards; long product development cycles; value of legacy systems that still work versus the investment to implement new ones; and shortage of skilled workers.

Of course, this all requires resources and know-how to deploy, implement and maintain. And it also all depends on the needs of the organization.

As it is generally unrealistic to adopt every smart technological advance at once or in a short term, "smart" medical device manufacturers are making incremental updates and upgrades, based on their primary business and portfolio needs. Step by step, these "smart" manufacturers are:

- Implementing connected devices and sensors to monitor manufacturing processes, improve quality control, predict maintenance needs and integrate technologies to create efficiencies.
- Deploying robots and collaborative robots to automate repetitive and inspection tasks that require precision, while saving skilled human workers for high-level, decision-making roles and needs.
- Using simulation technologies to predict material variations and product performance.
- Leveraging artificial intelligence and machine learning for data collection and analysis to optimize manufacturing processes, improve quality, increase productivity and create efficiencies.
- And more.

In the near-term, look for more medical device manufacturers to begin catching up – and quickly – to push ahead on Industry 4.0 technologies to gain better control over products and faster timelines.

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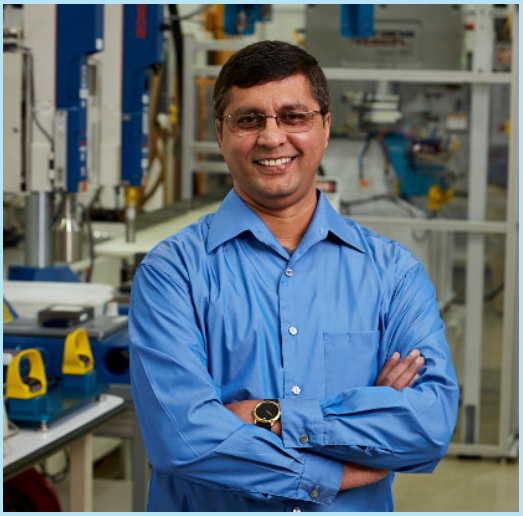

About the author

Raghu Vadlamudi is our Chief Research and Technology Director. He has more than 25 years of experience in the medical device manufacturing industry managing process development groups, directing and coordinating process validation activities utilizing knowledge-based manufacturing practices. Raghu is an ASQ certified Medical Device Auditor, Certified Metal Cutting Professional, Certified Medical Device Compliance Professional, and a Certified Process Validation Professional.

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