



Big Data and Automation Trends in the Medical Device Industry

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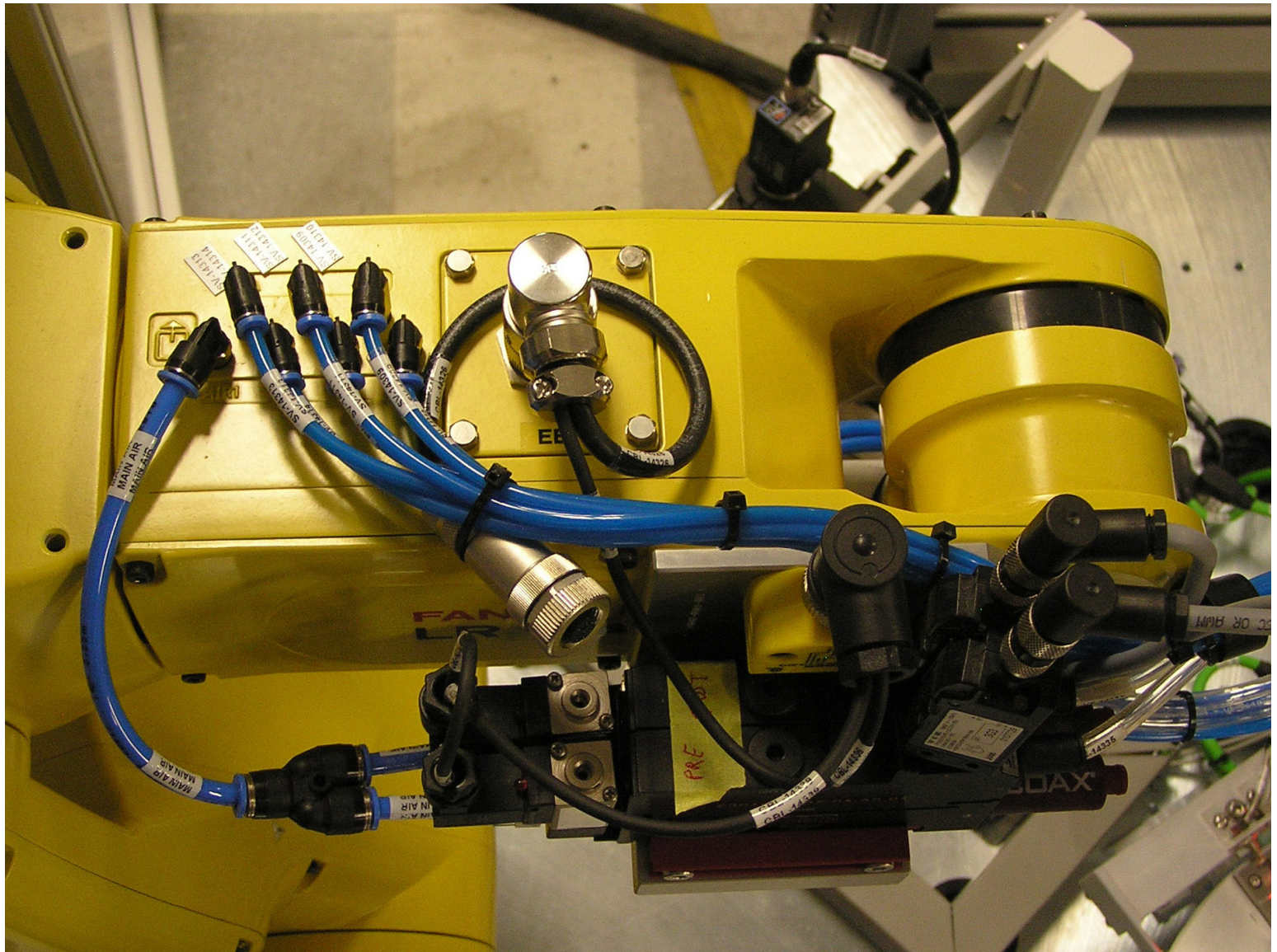
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Intro

Golf fans marveled at the 2019 victory for Tiger Woods in the Augusta Masters Tournament after a series of back surgeries - a victory made possible by the advances in medical technology created in partnership with medical experts and the medical device industry.



The Medical Device Industry Outlook: Rapid Growth

According to the U.S. Department of Commerce, the United States is the largest medical device market in the world with a market size of around \$156 billion (2017). Zacks Industry research in 2018 ups the revenue estimate to \$180 billion, and cites JPMG data that estimates that the global annual sales are forecasted to reach \$800 billion by 2030. The aging global population and advances in science ensure demand that in turn, will fuel sales.

The industry as a whole is waiting for the legislative outcome of the repeal of the Medical Device excise tax that has promise to increase both hiring and investment in medical device manufacturing firms.

On March 7, 2019 U.S. Senators Pat Toomey (R-Pa.) and Amy Klobuchar (D-Minn.) introduced bipartisan legislation to repeal the punitive medical device tax. The 2.3% excise tax, when implemented from 2013 - 2015, resulted in 29,000 jobs lost along with a \$34 million dollar reduction in research and development.

The repeal of this tax is projected to attract further investment along with the global growth fueled by an aging population and medical breakthroughs signal a bright future for the expansion of the medical device industry.

Growth Fueled by Innovation

As the medical device industry prepares for a 5% year over year increase in global sales, the manufacturing side of the business needs to incorporate the best practices of modern techniques to keep pace with scaled production and continuously meet customer demands for rapid prototyping, data acquisition, cyber security, and fast delivery as well as producing optimum quality while controlling cost.

The key to growth is a company's ability to rapidly introduce new product developments in this demanding market. One practical solution is to partner with a supplier that can expedite time to market without sacrificing quality.

According to Joe Raffa, Vice President and General Manager of global contract manufacturing company Tessy Plastics:

"The factors that will impede growth or delay in market expansion is new product development. If there aren't any upcoming techniques being developed in the medical device industry, there will most certainly be a delay in market expansion. An example that would produce growth specifically in the medical industry, would be a technique to perform surgeries through existing orifices rather than creating an incision.

The biggest trend that favors growth is the demand for companies to outsource their technical needs. In other words, companies that need assistance with research, development and engineering in order to develop a new product is the most ideal case for Tessy. We truly like to be involved in the early stages of new product development so that we can work on the project from start to finish. We would rather have a challenge or idea brought to us, so that we can offer a solution, design, or technique that will help the customer be successful."

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Additive Manufacturing

Additive manufacturing is the process of creating an object by building it one layer at a time. Typically, this refers to 3-D printing, a process in wide use, particularly for rapid prototyping and tooling. There are limited opportunities to use 3D printing for final production due to speed and materials, nonetheless, 3D printing has created innovation in terms of cost reduction and efficiency by building accurate models to test designs, create fixtures, jigs, inserts and customized products.

Prototyping enables OEM's and their sourcing partners to take advantage of time and cost benefits for a design for manufacturing (DFM) strategy by reducing unnecessary manufacturing steps and streamlining processes in advance of final production.

Tessy Automation specializes in developing assembly automation solutions for the medical device industry. Bruce Courtney, Tessy Automation Vice President of Sales & Marketing, commented "We value an invitation to review a product or application early in the development stage. A small chamfer or other features can be significant relative to DFM. We use an in-house 3D printer to mock up and test approaches and techniques. Especially in the medical industry, we get involved with phased approaches including low volume pilot lines ramping into full production-worthy automated lines."

A specialty manufacturing company approached Tessy Automation and shared a pain point relative to a new program to develop a process to assemble a detonation device with a live primer that had to be handled safely. Tessy Automation, working with the customer, was able to perform some testing and define a workable scope with safe operating conditions and still integrate the processes needed.



The production machine was delivered and has been running very well. The program Manager shared the following comment:

"I can honestly say that of the five automated machines we built for this project, the one from Tessy Automation went the smoothest and is the most functional and user friendly. I am looking forward to working with you again on future projects."



IoT Opportunities & Challenges

The industrial Internet of Things (IIoT) according to technopedia is “a term for all of the various sets of hardware pieces that work together through Internet of Things connectivity to help enhance manufacturing and industrial processes.” This technology is essential in the medical device industry where quality and compliance issues take precedence in manufacturing process monitoring.

The opportunity for the collection of data in addition to continuous monitoring is the ability to use the information to analyze systems and processes enabling continuous improvement and efficiency measurement. The collection of this data as well as data across all of the equipment in the value ecosystem equips users to predict maintenance, downtime and resource issues. The challenge for all things connected to the Internet is data security, essential for protecting intellectual property and patient privacy.

Help Wanted – Skilled Technical Workers

Manufacturing across the United States is experiencing a shortage of skilled workers in manufacturing. Because most occupations that benefit from automation do not replace workers, the emphasis should be on training

the work force to work with automation technology and encourage workers to be partners in developing new solutions to foster further innovation.



Automation, a Growing Trend

“Robotics, machine learning and artificial intelligence are reshaping automation, allowing companies to improve quality, maximize value, keep costs down or offer new services,” according to Medical Design and Outsourcing. Continued improvements in automation designs have enabled automation architects to develop solutions for each new generation of medical device components and sub-assemblies.

Research reported by the World Economic Forum and McKinsey revealed that currently less than 5% of occupations consist of activities that are 100% automatable, however 62% of occupations have at least 30% of their activities that are automatable. These numbers indicate that there remains a vast potential for future technical automation as companies recognize the benefits in speed, quality and efficiency that automation provides.

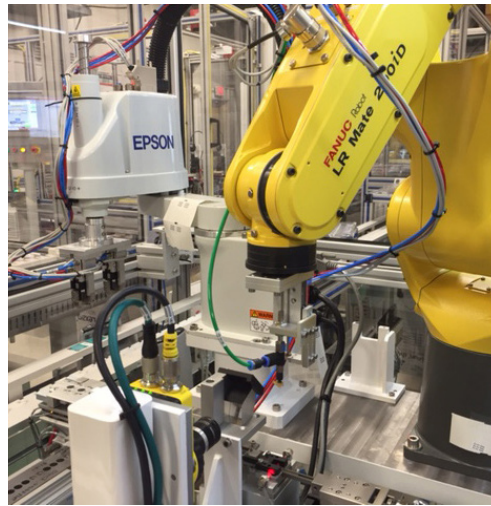
Automation's Growing Role in Medical Device Manufacturing

According to Medical Product Outsourcing, “In particular, automation is a key IoT technology that helps the manufacturing orchestra run smoothly.” Cost reduction is a serious concern considering the shifting global landscape with tariffs and ongoing negotiations with China, the impetus is to produce components and assemblies domestically – OEMs will seek alternatives to re-tooling existing plants, and explore solutions that take advantage of automation.

What types of products are the best fit for automation? When asked this question in a recent interview with Tessy Automation's Bruce Courtney, he responded, “We regularly work with medical devices, consumer products, electronics, etc. Typically, these are components that fit in your hand and often have very unique assembly or performance requirements.”

In the future, automated processes will benefit from emerging technologies in nanotechnology, artificial intelligence (AI) and augmented reality. Currently as science develops new materials for miniaturization, automation technology will advance to handle smaller, more fragile parts with the precision accuracy demanded by the industry.

The manufacturing process data will support the organizational need to meet stringent compliance requirements and ensure the safety of patients.



The Medical Device Industry Outlook is Bright

Medical device manufacturing can meet the increasing demand in the industry by taking advantage of all of the opportunities offered through Industry 4.0 – additive manufacturing, the industrial Internet of Things (IoT) and automation. Automation will not completely replace the work force, it will enhance the workforce through partnerships and training to develop skilled technical employees.

A wide variety of products and components are enhanced using automation for manufacture and assembly. As additive technologies advance, there will be greater opportunities for scaled production, and on the automation side, greater precision for smaller, more sensitive parts.

Beth Ryan is a freelance writer based in Cambridge Springs, PA. Her content marketing work is focused on global manufacturing, and her day job is program coordinator for the Center for Business and Economics at Allegheny College.

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Assembly Automation Solutions

We specialize in designing, building, and integrating assembly automation solutions for OEM's and manufacturers of complex components.

Our unique ability to design, build, and integrate lean turnkey automation systems in-house has given us the advantage of creating shorter lead times, quality production, and top of the line customer service.

Our specialty industries include healthcare, pharmaceuticals, electro-mechanical devices, energy storage systems, consumer electronics, and transportation.



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