Technical

Article

How Industry 4.0 Benefits Medical Device and Equipment Manufacturers

Key Insights & Considerations

- Medical device and equipment manufacturers are demanding more automation of the complete manufacturing and handling value chain.

- Automation applies not only to manufacturing processes, but also to data collection and manipulation.

- The key to achieving error-free, high-throughput manufacturing lies with the core principle of Industry 4.0, which is to combine automation and IT.

- Industry 4.0 enables the collection and use of manufacturing data to improve quality, reduce turnaround times, and meet regulatory requirements.

- To fully capitalize on the benefits of Industry 4.0, choose vendors who have designed products and systems with the integration of automation and IT as a core principle.

The definition of Industry 4.0 was first introduced in 2011. Although there are varying explanations of what exactly Industry 4.0 entails, Germany Trade and Invest (GTIA) – the economic development agency of the Federal Republic of Germany – defines Industry 4.0[1] as:

> " A paradigm shift... made possible by technological advances which constitute a reversal of conventional production process logic. Simply put, this means that industrial production machinery no longer simply "processes" the product, but that the product communicates with the machinery to tell it exactly what to do. "

The consulting group McKinsey & Company defines Industry 4.0[2] in more specific terms, as:

> " The next phase in the digitization of the manufacturing sector, driven by four disruptions: the astonishing rise in data volumes, computational power, and connectivity, especially new low-power wide-area networks; the emergence of analytics and business-intelligence capabilities; new forms of human-machine interaction such as touch interfaces and augmented-reality systems; and improvements in transferring digital instructions to the physical world, such as advanced robotics and 3-D printing. "

Introduction

Manufacturers in the medical industry face unique challenges in terms of product mix, throughput requirements, quality standards, and regulatory guidelines. Whether a company is producing diagnostic equipment for cancer screening, disposable devices such as syringes, or implantable devices such as stents for cardiac procedures, the manufacturing process must be absolutely error-free while delivering high throughput. To achieve these seemingly competing goals, companies are investing more and more in factory automation. And with the rise of Industry 4.0 and the Internet of Things (IoT), medical device and equipment manufacturers are finding that implementing automation in their operations not only improves throughput and quality but provides other benefits as well. If you are thinking of redesigning your machine or designing a new machine, this article is a must-read. We will look at motor-integrated automation technology and cabinet-free technology holistically. Additionally, we explain how you can significantly reduce costs and time in all project phases – from machine design to building and testing of equipment, from shipping to installation and throughout the life of the production equipment.

The Future of Medical Manufacturing: Integrating Automation and Information Technology

Medical device and equipment manufacturers are demanding more automation of not only individual processes, but entire factories to help them meet strict quality requirements mandated by the U.S. FDA (Food and Drug Administration) and other government agencies. This means automation of the complete manufacturing and handling value chain, including product testing, inspection, packaging, and storage and retrieval.

> **The best way to integrate and capitalize on Industry 4.0 capabilities is to choose vendors and products that are designed with the automation-IT connection in mind.**

Just mentioning automation typically triggers visions of manufacturing plant floors filled with robots and machinery. However, the future of automation also applies to the "behind the scenes" functions of data collection and manipulation. For example, when the FDA requires documentation of machine parameters and deviations on a part-by-part basis, automated data collection allows the manufacturing parameters to not only be collected and stored automatically, but they can also be written to files tied to individual serial numbers, providing the required part-by-part verification.

The key to achieving these goals, however, is not simply a matter of adopting more automation. It lies with the core principle of Industry 4.0, which is to combine automation and IT (information technology). The best way to integrate and capitalize on Industry 4.0 capabilities is to choose vendors and products that are designed with the automation-IT connection in mind.

Industry 4.0 Initiatives Drive Openness and Ease of Use

To make this connection between automation and IT, Bosch Rexroth has developed the Open Core Engineering platform, which combines software tools, functional toolkits, open standards, and Open Core Interface technology. Specifically, the Open Core Interface allows programmers and operators to use a familiar software platform – such as National Instruments' LabVIEW, Java, or CATIA – to control the machine, eliminating the need to learn ladder logic or a Bosch Rexroth programming language. The Open Core Interface includes

Software Development Kits (SDKs) that can be used, for example, in Excel's VBA to create a user interface for controlling a motion axis. Then the axis can be run directly from Excel, or the program can be pushed from Excel to a PLC, handshaking with Bosch Rexroth programming software.

In smaller medical laboratories, where technicians work directly with the automation systems, it's often necessary for technicians to make changes to programs, test points, and other machine parameters specific to the sample being tested. Bosch Rexroth's Open Core Interface allows the machine builder or end user to create an interface that provides the technicians with access to certain levels of machine control to customize or change the operation. Once the interface is created, a simple handheld tablet with Excel can be used to transfer the interface to a PLC. This is a simpler – and less expensive – option than using a full-blown, machine-grade HMI, and portability, wi-fi connectivity, and Bluetooth are already built-in.

Machine interfaces are also the root of data collection, but the true benefit of Industry 4.0 is found in how that data is used – for part tracking, error reduction, or process stability – all of which play a critical role in the manufacture of medical devices and equipment. The controller, or IoT gateway, is at the heart of Bosch Rexroth's technology solutions for Industry 4.0, allowing a user to capture data and broadcast or use that data in a manner that helps them improve quality, reduce turnaround times, and meet regulatory requirements. Software such as ActiveCockpit serves as an interactive communication platform that processes and visualizes production data in

real time, easily connecting with back-end MES or ERP systems, allowing rapid diagnosis and optimization of machines and processes.

For example, Open Core Engineering principles are applied to Bosch Rexroth's EFC variable frequency drive, which incorporates networking capabilities that allow for remote control and monitoring. When used with the VarioFlow *plus* conveyor system, the user has easy access to the machine via wireless or Bluetooth connectivity. This allows the operator to adjust speeds, inspect diagnostic codes, view machine parameters, or take any action deemed acceptable according to their clearance level – without ever opening an electrical enclosure or summoning the engineering department for support. Similarly, maintenance personnel can choose to be alerted to problems via email or text message and receive diagnostic codes without having to travel to the machine and connect to it.

Of course, the security of data gathered, stored, and shared through IoT and Industry 4.0 applications is a significant concern in medical device manufacturing and diagnostic industries. The more data that's available – and the more ways in which it's made available – the more opportunities there are for it to be used inappropriately. It's unavoidable that any time there is an IoT gateway on a machine, there is a risk of leaks or hacks. Security is the biggest hurdle to complete adoption and integration of Industry 4.0 principles, so users and machine builders need to understand the risks and how they can be mitigated or reduced. Currently, Bosch Rexroth's cloud-based apps use certificate authentication, and an external industrial VPN is recommended for secure remote access.

Capitalizing on the Benefits of Industry 4.0

The scale of capital investment required for automation in medical device and diagnostic equipment manufacturing, together with the critical nature of the products and processes, place unparalleled demands on suppliers for robustness, accuracy, and interoperability of
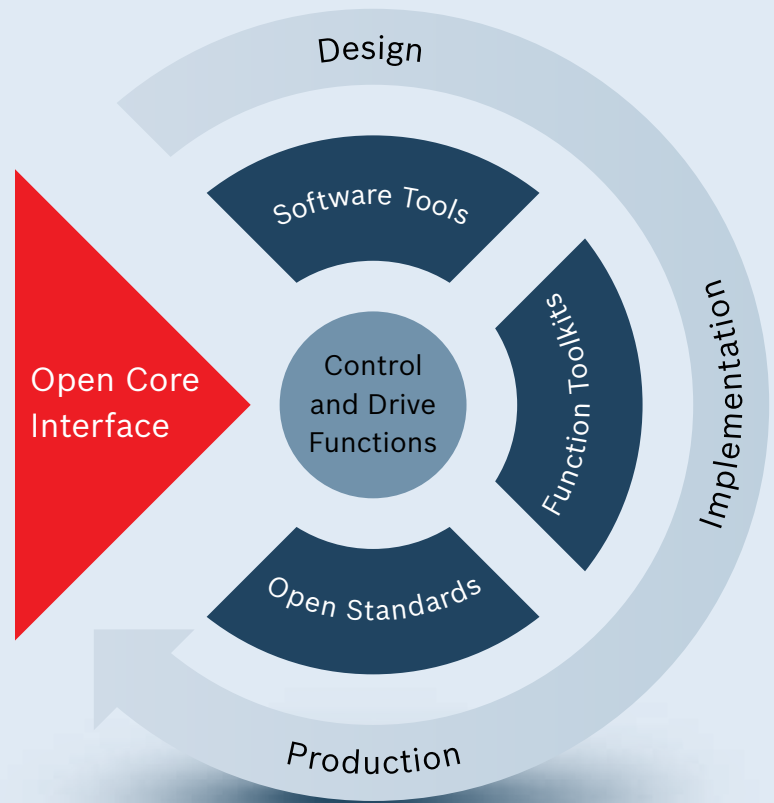
Open Core Engineering is:

▸ **Efficiency**

▸ **Flexibility**

▸ **Individualization**

▸ **Future-proof solutions**

Complete automation solutions for manufacturers of medical devices and diagnostic equipment require ease of use and interoperability.

the parts and systems used in automation and Industry 4.0 initiatives. With an extensive range of automation products and integrated solutions – including linear motion components, Cartesian robots, conveyors, motors, controls, tightening tools, and RFID and sensor technologies – Bosch Rexroth is unique in its ability to meet these requirements.

As Industry 4.0 and IoT projects expand their reach across the manufacturing floor, products that were once seen as commodities – such as linear guides, ball screws, and sensors – will become key enablers of advanced functions, including real-time monitoring, predictive and preventive maintenance, and part tracking. Combining traditional automation with advanced sensing technologies, such as the XDK sensor box, which is a turnkey kit that provides instant IoT connectivity for devices or machines, is just one example of this type of integration.

Manufacturers of medical devices and diagnostic equipment are relying more and more on automation to ensure a fully robust process and meet regulatory requirements. Complete automation solutions require ease of use and interoperability. Fortunately, vendors such as Bosch Rexroth have designed products and systems with the integration of automation and IT as a core principle, allowing customers to fully embrace and capitalize on the benefits that Industry 4.0 can provide.

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Summary

Achieving error-free, high-throughput manufacturing is made possible when the core principle of Industry 4.0 is put into action. The combination of automation and IT inspired Bosch Rexroth's development of its Open Core Engineering platform and various other Industry 4.0 technologies such as ActiveCockpit and IoT Gateway. Industry 4.0 technologies such as these enable the collection and use of manufacturing data to improve quality and meet the rigorous requirements of the medical industry.

References

1. *"Industrie 4.0 – What Is It?," Germany Trade and Invest, https://www.gtai.de/GTAI/Navigation/EN/Invest/Industries/Industrie-4-0/ Industrie-4-0/industrie-4-0-what-is-it.html*

2. *Cornelius Baur and Dominik Wee, "Manufacturing's next act," McKinsey & Company, https://www.mckinsey.com/business-functions/ operations/our-insights/manufacturings-next-act*

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