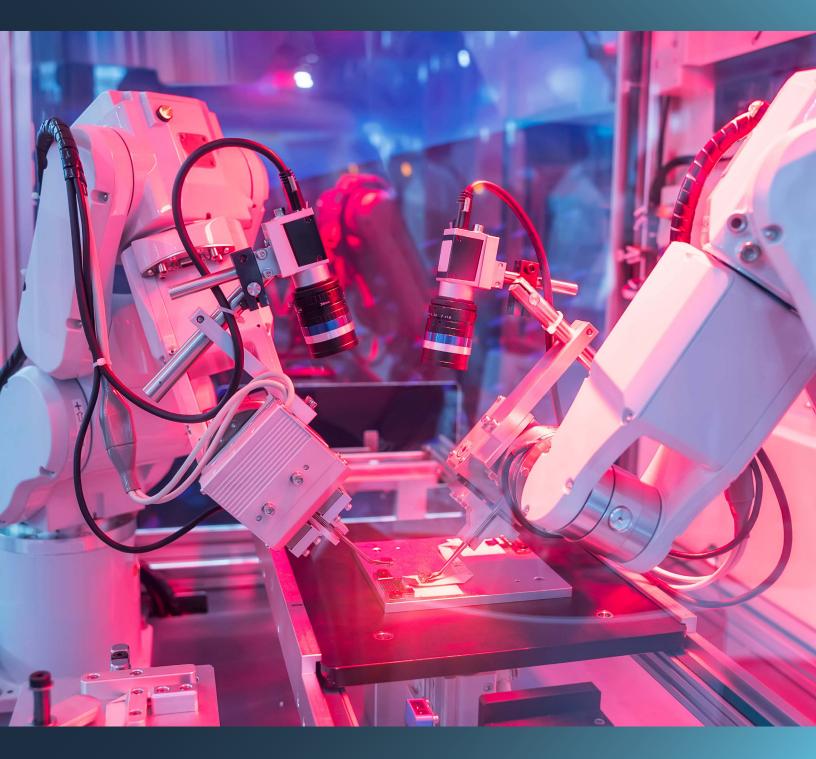
Automating Medical Device Manufacturing





INTRODUCTION

The increased demand for medical devices means that medical device manufacturers need to augment their workforces to increase capacity while maintaining costs. In addition, it is no longer an option to just hire people to meet rising demand for a variety of reasons:

- · Skilled labor, especially regarding industrial automation is not available
- Unskilled labor is not available, unemployment is nearly 0% in many locations, and it is no longer an option to just open a factory in another location to find a new source of labor
- · As capacity grows, quality is impossible to maintain with manual processes

Industrial automation is a solution to labor challenges, but it only magnifies the problem of skilled labor shortages. Since manufacturing automation suppliers have not kept pace with advancements in computing, user interface design and interoperability standards, it is near impossible for a manufacturer to implement, and maintain, automated solutions on their own. Additionally, while the price of robots has fallen 50% since 2005, integration costs have remained the same. Consequently, the cost of integration can now often outweigh the cost of automation hardware.

PROBLEMS

In 1961 a Unimate industrial robot was installed at a factory in Trenton, NJ. While industrial robots have become incredibly strong, precise and resilient (many with MTBF up to 70,000 hours) since then, they are not any easier to use. Ease of use has not stopped their expansion into factories, with over 2.4 million installed in factories arouvnd the world. However, those robots are typically installed in long running assembly lines that justified the high cost of the



implementation given the long payback period of the automated line. Most medical device manufacturers don't run a large, long running automated line. They have a high mixture of parts they produce, and in relatively limited quantities. As such, they cannot justify automation because of the changeover costs of the process.

Implementing a quick to deploy, flexible, and cost effective automation solution that enables low cost changeover is not possible today because:

- Every automation solution requires a custom design
- Automation takes too long to implement
- Inability to pick the right robot, for the right job at the right price
- Robots are difficult to program for new, or even slightly changed, tasks
- · Machine tools lack the interfaces for digital integration
- Designing, and maintaining, automation solutions cannot be done with existing staff because current automation technology is too complex
- · Chavngeover is costly since external services are necessary to reprogram the workcell

Because automation has not been possible, high-mix, low-volume manufacturers have been:

- Unable to scale because of a lack of labor (whether skilled or otherwise)
- Challenged to keep quality high
- Challenged to maintain compliance with the FDA for their manufacturing processes

A PATH FORWARD

What the industry has lacked to solve these problems is a standard way to automate a manufacturing workcell and make it accessible with minimal training to the people already working in the factory. A workcell is typically made up of multiple components:

- Machine Tool common examples are mills, lathes, stamping presses, and wet blasters
- Robot Arm The top four brands for industrial robots are FANUC, Yaskawa Motoman, ABB, and Kuka. For collaborative robots (or "cobots") Universal Robots (UR) is the segment leader. There are also many new upstart players such as Techman and Epson
- Feeders A stand for presenting the part to the robot
- End of arm Tooling (EOAT) Devices attached to the end of the robot arm such as grippers used to pick up the parts
- · Peripherals A wide variety of options such as vision systems, force sensors, and button pressers
- Programmable Logic Controllers (PLCs) Devices from a variety of vendors such as ABB, Allen Bradlee, Rockwell Automation, and Siemens that are able to control some or all of the components that must be orchestrated to implement a complete task



These components are then combined in an endless variety of ways to automate a single worcell. The design task thus becomes very challenging because there are so many options along with the infinite combinations that are possible. This situation of fragmentation and complexity is not unlike the PC market prior to the standardization that occurred when IBM launched the IBM Personal Computer (PC), and later

Microsoft launched Windows. The product that drove the real uptick in PC demand was Microsoft Excel and later the MS Office Suite. Customers demanded there be an easy-to-use, accessible, and interoperable set of productivity applications that would also work with any printer, scanner, mouse or monitor. The standards that developed, such as USB and Plugand-Play device drivers, then resulted in a value proposition for a massive ecosystem of software and hardware providers, all unified by a single operating system. No one wonders if the mouse they just purchased will work with their PC.



SOLUTION

Medical Device Manufacturers, many of whom are private equity owned and require an ROI in 12 months or less, can now implement automation. Automation is now possible since the technology has advanced to a point where a common industrial operating system, with a productivity app accessible to anyone in the factory, can be developed. The components of a platform that has a easy to use human machine interface (HMI), rapid, even agile, implementation times and a cost that enables a ROI 12 months or less are:

- · An enterprise grade industrial operating system
- A hardware controller that enables plug-and-play interfacing of machine tools, feeders, peripherals and EOAT (among other devices)
- Productivity apps, primarily an environment where virtually anyone can program the automation, that requires next to no training
- Vendor independence to enable the right hardware, with an acceptable price point for the application, to be used without any impact to the programs being written
- A drastic reduction, in the fees to design and install and maintain an automation solution

In addition, these components also enable a standardization in the data capture to log, monitor and analyze the entire work process. Medical Device Manufacturers can now store data about each part being manufactured to demonstrate in a provable way how a part was manufactured. This data on the manufacturing process, as well as the data from the systems being used for parts inspection, often done by the same arm, or another robot arm in the work cell, can be used to ensure quality end to end.

CONCLUSION

Automation is necessary for Medical Device Manufacturers to expand their businesses while maintaining their high quality standards. An acceptable ROI, attained in 12 months or less, makes automation a reality, which then unlocks the ability to expand operations through more shifts or higher speed manufacturing operations.

READY ROBOTICS

READY has developed the world's first, robot vendor agnostic, enterprise-grade, industrial operating system, Forge/OS. Forge/OS runs on controllers made by READY such as the Forge/Ctrl that includes pneumatics, 24V I/O and Fieldbus connectors. Task Canvas is the first of many applications to run on Forge/OS that enables virtually anyone, with little to no training, to program not only the robot, but all the other devices, including the machine tool, in the workcell. READY's cloud applications such as READY Industrial IoT and READY Sight allows manufacturers to have access to their data in either raw form, or visualized it in pre-built dashboards. For more information, visit www. ready-robotics.com. For press inquiries contact press@ready-robotics.com.





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