



Benefits of Automating Medical Device Manufacturing

Executive Summary

Robotics and other industrial automation solutions offer many potential benefits to medical device manufacturers. This white paper outlines the benefits, presents important considerations, and serves as a guide to selecting appropriate solutions and partners.

Introduction

Medical devices are specialized and often highly engineered products that must be produced according to tight health and safety regulations while delivering an acceptable return on investment. This is a challenging task that requires medical device OEMs to balance competing priorities. On the one hand, there can be no lapses in product quality, cleanliness, and deliveries because these can have life-threatening consequences. They may also tarnish a manufacturer's reputation and possibly result in regulatory sanctions. On the other hand, there is unrelenting pressure from competitors and customers to reduce costs, which makes it challenging to meet production requirements.

A key strategy that can be used to balance these issues is to automate the production of medical devices. Industrial automation is in widespread use today, having spread to virtually all manufacturing industries because of its proven benefits such as high product quality and repeatability, faster production, manufacturing flexibility, and lower labor costs.

What is Strategic Sourcing?

Today's robotic automation solutions incorporate greater computing and communications capabilities than ever before, enabling them to be more tightly integrated with sophisticated control systems and supervisory factory software. This allows them to better access and make use of production data for improved performance, online diagnostics, and easier recordkeeping to satisfy regulatory requirements.

As new and more complex medical devices continue to be developed, the use of automation to achieve production goals such as speed, precision, repeatability, flexibility, and favorable economics — while ensuring conformance to regulatory requirements — is becoming increasingly important.

Integrated robotic systems bring powerful capabilities to production steps such as assembly, inspection, and packaging. Examples of these systems include:

Automated motion control — Modular, automated transport systems in medical device assembly enable optimized workflows, more flexible production lines, and reduced factory-floor footprints.

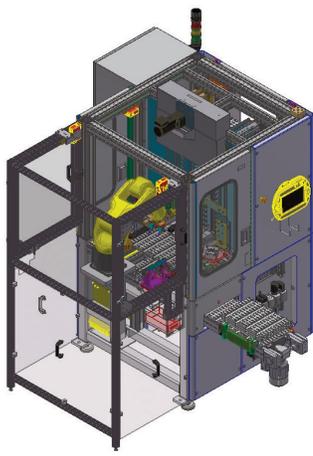
Vision systems — These enable both a greater pick-and-place capability and also add verification/traceability capabilities to robotic material-handling systems, given their ability to scan barcodes.



Force-control sensing — Force-control sensing gives robots a dimension of tactile sensing, and thus the ability to assemble more complex parts with greater sophistication.

Ability to integrate different processes — Automation brings the ability to create a more unified and efficient workflow by combining production steps that previously were separate and distinct; for example, the end of the assembly phase of production can be integrated with the packaging process.

These and other capabilities make possible complex movements that conventional assembly technology can't reproduce; for example, precise cylindrical processing — a common and particularly important process in the production of medical devices. That's because many medical devices and



instruments are fabricated from tubular materials that often have various features integrated along their length.

Endoscopes, for example, are tubular devices that must accommodate cameras, control ports, and irrigation pathways. Endoscope production benefits from automated systems capable of precise angular positioning and motion control of tooling,

which ensures that the device will be built to specification on a consistent, repeatable basis and perform as designed.

But endoscopes are only one example of medical devices that benefit from robot-based automation. Others include needles, stents, catheters, cardiac pacemakers/defibrillators, surgical staples, and contact lenses, to name just a few.

Automation Benefits

One manufacturer of surgical needles and specialty catheters made a major commitment to integrated robotics-driven automation several years ago. The company needed to increase its manufacturing flexibility and lower production costs at a plant that ships high volumes of surgical needles every month in a wide variety of lot sizes — some as small as 500 units.

Robotic automation has improved product quality in many ways. One example is the use of a robot to spray silicone onto needles. Previously, an operator manually sprayed the parts, but that led to inconsistencies in silicone coverage because the spray pattern varied. Now, a robot delivers the exact amount of silicone over the exact path each time, increasing quality and also reducing scrap from poor spray coverage.

The workforce has been relieved of many labor-intensive, redundant tasks where the risk of injury is always present, and now can focus on higher-level, more value-added assignments; for example, the plant has many cleanrooms that required assemblers to wear gowns, hair nets, and safety goggles. Now, a robotic material-handling system routinely carries hundreds of pounds of material that employees previously had to carry in and out of these rooms, donning or removing protective clothing each time.

Thanks to the automation of its production processes, the company has increased its production capacity by nearly 8%, with an additional 40% increase projected over the next several years. Throughput has tripled in many departments, while scrap rates have been reduced significantly.

The cost of direct labor also has been reduced by about 30%, helping the company to remain price-competitive while maintaining superior quality. At the same time, the company says it anticipates being able to continue its trend of reducing manufacturing costs on an ongoing basis. For this plant, which manufactures a great number of similar but different

products in different volumes, the ability of robotic solutions to be reconfigured is a key advantage. It means their capital cost can be amortized over every single product the plant produces, now and in the future as those products change.

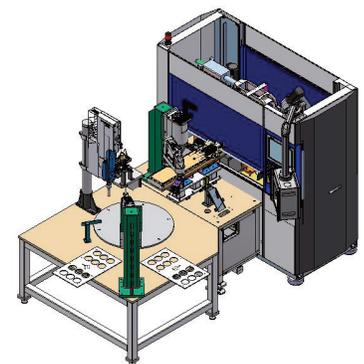
Adopting Medical Device Automation

Implementing automation in medical device manufacturing requires careful planning. Manufacturers must carefully consider issues such as the need to design products for manufacturability from the outset, packaging as an attractive starting point, cleanroom opportunities, and selection of the right automation partner.

Manufacturers will benefit from taking a holistic view of product design and manufacturing. Device designers typically focus on the functions and performance of their designs, but those designs can't be divorced from manufacturing considerations. Ease of product assembly is critical to the accurate, timely, and profitable fabrication of medical devices that must be produced by the millions, such as single-use devices. Product designers also must take the manufacturing process into account because of regulatory issues. Once governmental approval is secured for the production of a medical device, it can be difficult to make even minor modifications to the design and/or to the manufacturing process subsequently.

Packaging is often the first process medical device OEMs decide to automate with robotics, because it is usually less complicated than device assembly, which requires a clean environment. Workers must undergo an intensive cleaning process every time they enter an aseptic environment, but robots can remain in place there, avoiding the risk of transporting contaminants in and out. That makes implementing robotics in cleanrooms very appealing, not only for infection control but also for cost reduction because sterilized products can be produced in an aseptic environment without the need for secondary sterilization. Keep in mind the needs for upfront investment and ongoing maintenance of dust/debris-proof enclosures, though.

Another important consideration is selection of the automation systems supplier. In many ways, this is the most important decision of all, because the success or failure of the automation application largely rests on the supplier's capabilities and attitudes. Device OEMs should expect a supplier to analyze automation system needs, provide a plan for robotic system integration, support equipment validation and qualification, and then facilitate launching and servicing the automation system. For their part, the OEMs must take the time to think through and clearly communicate their needs and requirements so that the supplier can do its job effectively.



Selecting an Automation Solution

Large medical device OEMs with extensive automation experience and substantial in-house engineering resources sometimes consider going it alone on automation projects because they understand the complexities of device manufacturing, unlike smaller manufacturers without those resources or experience. The fact is that industrial automation is a constantly evolving field, and new equipment and new ways of doing things are being applied on an ongoing basis. A solution that was optimum just a few years ago may have been superseded by something better now.



Thus, even for large device OEMs, the real opportunity to benefit from robotic automation solutions comes from outsourcing those projects to specialists who offer three important qualities: extensive, wide-ranging, and current automation experience; a history of serving medical device manufacturers, thus having acquired a firsthand knowledge of the complexities and unique nature of the industry; and a demonstrated attitude that they are true partners in the endeavor, not just vendors.

Cost is always a key consideration in choosing an automation solutions provider, of course, but it is just one thing to keep in mind. More important for the success of the project is finding a supplier willing to work with the OEM to understand and achieve its overall production goals. Therefore, in selecting a supplier, medical device OEMs must assess the following factors:

Quality — Product quality is critical, and the value of a supplier with a robust internal quality system and relevant accreditations (e.g., ISO 13485 and FDA assembly compliance), plus risk-mitigation capabilities, can hardly be overstated.

Responsiveness — The responsiveness of an automation solutions provider is indicative of how that business operates on a day-to-day basis. Be sure to tour candidates' facilities and discuss

specific questions with the engineering and quality teams. Their knowledge, methods of communication, project “ownership” attitude, and responsiveness to inquiries are important clues as to how the relationship will unfold throughout the project.

Understanding the OEM's goals — The goals of automation projects vary widely, from cost reduction, to increased output, to more flexibility. Therefore, it is critical to determine whether a prospective automation solutions provider has a clear understanding of the OEM's motivations and goals. Otherwise, the solutions it offers may fall short.

Size and location — Large automation solutions providers tend to have bureaucratic structures and high overhead, but also access to financing for the newest technology and equipment, making them good candidates for large-scale, geographically dispersed projects. Small providers, on the other hand, may be more suited to small-volume projects in nearby locations. They may not have the ability to significantly ramp product volumes, generate the needed cost reductions, or offer the quality systems required. Mid-sized suppliers are often a good choice because they are small enough to be agile and responsive, yet large enough to have robust quality systems, a large enough client base to spread any financial risk, and a presence in at least one of the world's low-cost manufacturing regions.

Vertical integration vs. specialization — Vertically integrated suppliers offer significant engineering and process teams, supply-chain management expertise, and the ability to reduce costs and pass the savings on to the OEM. Suppliers with a special focus are most valuable for niche processes.

Location — The supplier's location and the country where the medical devices are manufactured will significantly impact unit pricing; however, also make sure to consider factors such as access and distribution channels.

Conclusion

Integrated robotic automation solutions offer medical device OEMs the ability to achieve high product quality, consistency, a faster pace of production, increased manufacturing flexibility, and lower labor costs, all while conforming to government regulations. But because they aren't always easy to design and implement, the choice of an automation solutions provider is critical. When OEMs and suppliers have the common goal to improve production and reduce costs, a successful partnership is established.

About Tessy Automation

Tessy Automation is a contract manufacturer that specializes in industrial automation solutions for OEMs wanting to grow within their industry segment with the help of a collaborative, transparent, and reliable partner.

