

Medical Device Manufacturing: Robots Solve

Labor Shortages, Reduce Costs, And Improve Production Quality



How automating with Robotics as a service (RaaS) gives medical device manufacturers a competitive advantage

Medical device manufacturing is a diverse industry, one that makes everything from bandages and test kits to pacemakers and MRI machines. It is projected to grow from <u>\$495 billion today to \$718 billion by 2029</u>, exhibiting a CAGR of 5.5%.

The industry is still recovering from the effects of the pandemic, which shrank the market 1.4% in 2020. While certain Covid-related markets experienced rapid growth, those associated with elective procedures saw a steep decline in demand. Overall, however, industry drivers remain in place, namely an aging population, a growing prevalence of chronic diseases, and an increased emphasis on early diagnosis and proactive treatment.

While the industry is dominated by a small number of international brands like Medtronic, Johnson & Johnson, Abbott, and Stryker, much of the industry's growth will depend on contract manufacturing organizations, which provide a broad range of services from design and development to manufacturing and logistics. The contract manufacturing market is currently valued at \$53.6 billion with a predicted five-year CAGR of 5%. It is a fragmented market with a handful of big players, such as Jabil, Flex Corp, and Integer Corp., as well as more than 300 small and mid-size organizations. The largest segments include orthopedics, minimally invasive surgery, cardiovascular devices, and surgical instruments.

Many contract manufacturers are high-mix, low-volume environments that frequently shift production among a variety of process steps, including a wide range of simple, repeatable tasks. Think of vial filling, centrifuge tending, 3D printing, pad printing, and injection mold part finishing. And unlike other manufacturers, makers of medical devices operate within a stricter set of regulations.

All of which makes contract manufacturers ideal for robotic automation, specifically with Robotics as a Service (RaaS). This white paper will show how swift, incremental automation with RaaS is not just possible for medical device manufacturers—it can help solve three critical challenges and deliver a game-changing competitive advantage.



CHALLENGE 1: Searching for the second shift



Major manufacturers and contract shops are dealing with a chronic labor shortage, one that may be <u>deeper and more</u> <u>persistent</u> than many presume. First, there is the long-standing scarcity of skilled technicians, like master machinists, floor leads, and manufacturing engineers. At the same time, manufacturers are struggling to fill both semi-skilled and unskilled positions on the production floor. These jobs are critical to the tasks that medical devices and components involve.

There is a third layer at work here too. <u>Hospital labor</u> <u>shortages</u> are disrupting procedure volumes and making it even more difficult for manufacturers to predict demand for products that are consumed during these procedures. Ideally, manufacturers need to plan for a certain level of demand but stay flexible enough to adapt when demand ebbs or surges unpredictably—all while keeping operating expenses in check.

CHALLENGE 2: Keeping quality consistently high

Medical device manufacturers need to meet a higher bar for product quality because the industry is so heavily regulated, which makes ensuring high product quality a constant challenge.

The FDA, for example, requires manufacturers to establish a framework of processes to document and investigate any "nonconforming" product, or one that does not meet its FDAspecified requirements. In other words, when a product fails to conform, it will delay production as the issue is resolved. Other components may also be put on hold as well if they are part of the same device. Even worse, the process that catches these errors could break down, resulting in "quality escape," or a non-conforming product reaching the end user. This can result in recalls, fines, and other corrective actions, all of which hurt the reputation of the brand and put manufacturers at risk of losing work or missing targets.





CHALLENGE 3: Minimizing human contact



Many medical devices are made in cleanroom environments, which are designed to prevent contamination by bacteria, viruses, and other airborne particles. Cleanrooms typically feature tightly controlled temperature, humidity, and airflow that conform to ISO standards.

These standards also extend to human workers, who pose a significant threat to cleanroom conditions. Workers must wear personal protective equipment (PPE), such as shoe covers, coveralls, and gloves, as well as follow gowning procedures to reduce the risk of contamination.

Ensuring these procedures are followed consistently requires a significant investment of time under regular circumstances. It can be even more demanding to achieve when production volumes spike and every team is under pressure to maximize throughput.



Filling open roles with robotic automation



Robotic automation gives the medical device industry a way to address all three of these challenges. First, and most important, is the labor shortage.

Robots are extremely well suited to the work performed in the medical device industry. They excel at simple, repeatable tasks, including 3D print tending, multi-step pad printing, and injection molded part finishing—exactly the kinds of processes handled by the unskilled and low-skilled positions that have become so difficult for manufacturers to fill. A single robot can often fill 3 or more machine operator roles, easing labor shortages, and giving manufacturers more flexibility with where they deploy their human resources.

Even more significant is the fact that while traditional robots are specialized to a single task, Rapid Robotics supplies robots that can be pre-trained on multiple tasks and easily moved between them as necessary without any programming or robotics expertise. Alternatively, if your shop takes on a new process or workflow, the Rapid Machine Operator (RMO) can learn a new task and be redeployed in very little time, and with minimal cost.



Increasing accuracy step by step



Maintaining high product quality is another area where robotic automation can help medical device manufacturers keep up. Robots deliver levels of consistency and precision that are impossible for human workers to replicate—let alone replicate 24 hours a day, seven days a week. Robots do not get tired, injured, or distracted, and paired with a high quality vision system they can perform both manufacturing and inspection operations with extraordinary precision. The RMO, for example, regularly achieves a 99.9% quality approved rate on all parts it produces, which is up to 15% higher than a human. This margin, combined with a robot's uptime, can deliver a serious and sustainable boost in quality.

Plus, the robot's process steps are easier to document, which streamlines auditing and compliance.



Automating the clean room



Finally, robotic automation significantly reduces the risk of human contamination in the cleanroom, while simultaneously reducing time spent on gowning procedures for the cleanroom team.

Most injection molded medical devices, for example, are produced in ISO Class 8 cleanrooms. Robots excel at gate clipping, removing runners, and other post-processing tasks for injection molded parts. That means one or more cleanroom workers can be reassigned to a different job.

Reducing human contact can be helpful in non-cleanroom environments too. At the height of the pandemic, manufacturers that relied on connected work cells had to incorporate social distancing and plastic dividers.



Unfortunately, more space between workers meant fewer workers on the floor and lower production capacity.

Even as the pandemic winds down, a temporary resurgence could require a return to these virus mitigation measures. But installing robots in empty work cells stabilizes capacity—and potentially increases it—even as the number of people on the floor stays acceptably low.



Finding a better way to automate with RaaS



Robotic automation can help medical device manufacturers alleviate labor shortages, increase part quality, and minimize human contamination in cleanrooms.

So why aren't more manufacturers choosing this solution? Primarily because of the challenges that have plagued traditional robot deployments, including high costs, long wait times, and difficulties with on-site integration and programming. Traditional robots also tended to be singlepurpose units, which meant manufacturers could be saddled with an obsolete device after a process changed or a production run ended.

Fortunately, not all robots are created equal. Today, Rapid Robotics is rewriting the robotics rulebook with a Robotics as a Service solution that combines four key innovations.

- 1 **Subscription model.** RaaS uses an all-inclusive subscription model that covers the robotic hardware as well as 100% of the service, support, software, and even remote performance monitoring. In other words, Rapid becomes your single point of contact for any issue, and there is no need to coordinate among the robot provider and a system integrator.
- 2 Cost efficiency. RaaS does not require an up-front investment. Combined with a low monthly subscription fee, this helps manufacturers account for robotics as a predictable operating expense. With an RMO from Rapid Robotics, that expense can be as little as \$6-\$12/hour, which reduces overall labor costs while positioning your shop to take on more new business.
- 3 **Fast deployment.** Traditional robots may take five months or more to deploy, and there can be further delays if there are issues after installation. Rapid Robotics takes advantage of 3D printing, digital simulation, and pre-trained AI to deploy robots in just a few weeks.
- Flexibility. Traditional robots are built to do one thing. If that job changes, updating the robot will cost more. The Rapid Machine Operator, on the other hand, uses software that can be pre-trained on multiple tasks and then <u>move between jobs</u> without any additional costs—or even any reprogramming. In fact, it only takes about a minute to complete the changeover, which is helpful in high-mix environments.



Three popular use cases



1. Pad printing:

Pad printing is easy to automate and can be performed much more efficiently and consistently by a robot. Robots can quickly move parts through a multi-stage printing operation, with minimal variation in quality from piece to piece.

Contract manufacturer Westec uses an RMO from Rapid Robotics to complete a pad printing job for Berkeley Lights, a company that makes biological research tools. The product is a diagnostics kit with a disposable plastic chip that requires twocolor printing on one side and a single-color hit on the back.

Berkeley Lights reached out to Westec because it was having trouble keeping up with demand for the kits, running three shifts a day to meet its fulfillment goals. But with the RMO, Westec can run three shifts a day without the need for a dedicated machine operator.

Westec uses a similar setup to support pad printing on an illuminated surgical retractor system made by Invuity (now owned by Stryker). Before the RMO, a single worker would arrange 75 to 100 parts on a cardboard tray to move in and out of the pad printer for three shifts a day. Accuracy was a big challenge because the printing on the tip of the handle is used by surgeons to determine proper insertion depth. Today, the RMO runs this process without an attending operator, delivering highly accurate results 24 hours a day at times of peak demand.

2. Gate clipping

When the pandemic arrived, makers of PCR chips used in Covid tests experienced unprecedented demand—up to 500% higher than normal. At the same time, they were dealing with the same realities as every other manufacturer, struggling to keep production levels up while maintaining social distancing.

One of these manufacturers responded by using an RMO from Rapid Robotics to perform gate clipping. Specifically, an RMO was trained to grab the injection molded chips from a four-cavity injection molding fixture, move them into a gate clipper where extraneous material was removed, then place the clipped chips on a conveyor belt for bagging. Due to the sudden surge in demand, this RMO was deployed in just one week. And, because the manufacturer chose to work with Rapid, they were able to easily redeploy that RMO to another task when demand declined.

3. Vial filling

Filling and labeling pill bottles is not strictly a medical device manufacturing task, but the similarities are clear. In this case, Hayward, California's Truepill needed to scale up significantly. The only problem? The job could only be performed by a licensed pharmacist earning \$40 an hour.

With help from two RMOs working together, the company meets demand in a reliable—and less costly—way. The first RMO picks up the empty vial and applies the prescription label, then passes it to an output tray. From here, a second RMO picks up the bottle and places it in a machine that fills it with the correct number of pills, then places it on another output tray. The operation runs three shifts daily at a fraction of what it would cost if done by pharmacists.

Extensive manufacturing applications



The RMO from Rapid Robotics is a turnkey robotics system that includes a 6-axis robotic arm, custom-designed end-ofarm tooling, advanced vision system, work cell, and a simple user interface—all of which can be pre-trained on a wide range of tasks and integrated with almost any additional hardware, from inspection systems to box builders. Additional applications in the medical device manufacturing and laboratory work fields include:

3D print tending

Install an RMO to move the build plate in and out of 3D printers used to make hearing aids, dental accessories like retainers and night guards, or other components.



PCB assembly

Let an RMO load boards onto a laminator belt from a feeder fixture, then move the laminated boards into a stack for collection.

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Catheter tipping

Equipped with the right gripper, an RMO can do end forming of plastic catheter tubes.



Perform the same amount of work with a smaller team and minimize the risk of contamination for pick-and-place, pad printing, gate clipping, part inspection, and more.

Sample handling

An RMO can be used to handle laboratory samples, label vials, or move samples in and out of freezers.



Set up an RMO to perform the precise plate handling required to tend automated pipetting machines.



Get started right now



Medical device manufacturers are dealing with chronic labor shortages, volatile rates of demand, quality challenges, and the lingering uncertainties of a pandemic. With all of the issues you're worried about, robotic automation shouldn't be one of them. Let Rapid Robotics take on the challenge of managing your RaaS implementation with a fast, turnkey solution that gets to work in weeks, adapts to the changing needs of your business, and positions you to take advantage of your industry's robust projected growth.

Automate your medical device manufacturing shop right now for zero CapEx and see immediate ROI. An RMO from Rapid Robotics can help alleviate labor shortages for as little as \$6-\$12/hour.

Learn how in 30 minutes:

Schedule a free automation consultation at rapidrobotics.com/contact-us

"I've seen a lot of robotics vendors make big promises they can't deliver. Rapid is different. The flexibility, intelligence and subscription pricing of the RMO are unlike anything we've seen from other robotics vendors. We're saving money and winning business that we probably wouldn't have if it hadn't been for Rapid."

Tammy Barras, President, Westec Plastics Corporation









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