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How smart factories are changing the future of medical device manufacturing

By Raghu Vadlamudi, Chief Research and Technology Director

Thanks to advances in manufacturing automation technologies, medical device manufacturers can get closer than ever before to achieving zero defects. By working and communicating with machines, new and next-gen technologies increasingly are minimizing raw materials, process and assembly variabilities, among others, that, when left unchecked or done manually, more often lead to errors. They also are enabling manufacturers to address menial, repetitive tasks, and reserve skilled personnel for higher-level roles that require cognitive agility and decision-making.

In addition, rapidly evolving manufacturing technologies like micro-manufacturing and 3D printing, are paving the way for game-changing innovations. All of that translates to improved patient safety, cost savings and faster turnaround. Let's take a look at how each of these smart factory technologies is advancing manufacturing automation along with key considerations for deploying them.

ONE: Machine learning/AI

Just as machine learning/AI technologies are revolutionizing other industries, they are quickly changing the cost-effective game for manufacturing automation. Although it requires an upfront investment in teaching machines "the rules," once it is programmed to "understand" the parameters and requirements, AI simulates human logic and gives direction to the automation system. After an automation system is taught, it makes the right decision every time – and keeps learning and improving. Over time, AI benefits accrue by knowing what happened, being able to predict what is going to happen, and ultimately deciding what needs to happen. Depending on the specific function, this can add up to fewer defects and scrap, and faster production. It also leads to improved patient safety, avoided recalls and minimized skilled labor shortages.

AI has advanced the capabilities of robots by enabling vision systems, too. Not so long ago, parts had to be in a predictable arrangement, and a robot had to be programmed to know where the next part would be and how to orient itself to handle it. With AI, robots can "see" and choose a part, and pick it up from a random pile or display.

This AI-enhanced vision system capability also enables collaborative robots to work safely alongside humans – including sensing their presence, slowing down or stopping and interacting – without the need for protective safety barriers, such as guard lock switches and light curtains, or the systems that control them.

TWO: Vision inspection systems

Advanced vision systems also have improved product inspection processes. As smart and skilled as humans can be, they bring variations in perspective, eyesight, alertness and endurance, among other characteristics, that can lead to inspection variabilities and errors. Advanced automated vision inspection systems, however, apply the same criteria across all inspections, and, as long as they're programmed and maintained properly, consistently and quickly determine the integrity of device parts. For example, a vision system can be implemented into robotics to pick parts from a molding press, inspect the parts and view specific areas of parts for defects. If a void exists, the system will find it and the robot will automatically reject it. Similarly, labeling and packaging can also be automated at high speeds, thus improving delivery timing.

THREE: Micro-manufacturing

Medical devices and their components continue to become smaller – into the micron sizes. These tiny innovations mark breakthroughs in medical device innovation.

However, more innovation is needed before this technology is fully realized. Until then, several manufacturing challenges persist that require creative solutions, particularly with regard to handling, consistency and repeatability. As such, micromanufacturers need to understand the intricacies and limitations of several evolving factors, including:

- Potential variations in raw materials that can impact the design and development of micro-sized parts;
- How to combine existing technologies for the time being to for automated handling and inspection processes, quality checks and output consistency; and
- How to effectively deploy a process integration model within one system to address all the above.

All that said, rest assured, innovative equipment and technology is emerging and developing to meet the needs of micro-manufacturing, including additive manufacturing (3D printing).

FOUR: 3D printing

With the rapid evolution of additive manufacturing, it is now possible to print microparts with microfeatures – including smaller than the width of an average human hair. That opens a lot of innovative potential for medical device designers, because it could bring such benefits as even faster rapid prototyping, print on demand, improved access, waste reduction, among others. But, that said, the technology remains in the early stages. Before it becomes widely adopted and cost-effective, more comprehensive evidence proving its design for manufacturability, safety and efficacy is required.

Challenges to overcome

Finding skilled manufacturing personnel who can teach machines what to do is a significant challenge, as a gap persists between the skills needed and available talent in the industry. The medical device industry is extremely complex. Seamless labor crossover from other manufacturing sectors into medical device is rare, and requires a significant learning curve, including with regard to following stringent regulations.

A related challenge is staying up-to-date on the rapid pace of technological change. This often requires extra resources in terms of time and commitment. One effective way to stay abreast of evolving technologies is to participate in professional and government standards organizations for manufacturing automation, medical device and other relevantly related sectors. By doing so, manufacturers will know better where the industry and specific technologies are heading, and also be able to influence future development.

About the author

Raghu Vadlamudi is our Chief Research and Technology Director. He has more than 25 years of experience in the medical device manufacturing industry managing process development groups, directing and coordinating process validation activities utilizing knowledge-based manufacturing practices. Raghu is an ASQ certified Medical Device Auditor, Certified Metal Cutting Professional, Certified Medical Device Compliance Professional, and a Certified Process Validation Professional.

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