Industry 4.0 in a Highly-Regulated Medical Device Factory

By Srivats Ramaswami,

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A recent study by Automation Alley found that 85 percent of national manufacturing executives said their company plans to increase budgets for Industry 4.0 technological advancements, including investments in cloud technology, Industrial Internet of Things (IIoT) and factory robotics. An even larger group (88 percent) believe technological advancements like these can help competitiveness. Increasingly, manufacturers are looking to Industry 4.0 for providing the framework for these investments; more than half of those surveyed reported that their company has a dedicated budget for Industry 4.0 technologies.

This rapid adoption has been driven by the alignment of Industry 4.0's principles with the business goals of these manufacturers: reduced time-to-market, global supply chain visibility, demand management and flexibility, total landed cost, and compliance/traceability.

Of these goals, the focus on compliance and traceability using advanced automation has the greatest impact for manufacturers of medical devices—especially those producing Class III medical devices. Class III devices are generally the highest risk devices, and are therefore subject to the highest level of regulatory control. They usually sustain or support life. Examples of Class III devices include implantable electronics such as pacemakers and defibrillators, and implantable nerve or cerebral stimulators.

Medical device manufacturers were among the leaders in Industry 3.0—the rise of automation among manufacturers and are leading the way towards Industry 4.0 as well because of the benefits provided by these best practices, including automated documentation of production (electronic DHR's) and recording of component data for traceability.

In some cases though, the tenets of Industry 4.0 may conflict with current medical regulatory criteria. For example, Industry 4.0 strongly encourages closed-loop feedback systems, where smart machines make decisions on the fly during the manufacturing process, adjusting alignment of machines, changing speeds, even allowing component substitutions (if they are so programmed). This can clash with the current medical industry practice of validation and verification of processes and controls. Following medical device industry norms, virtually any substantive changes in a manufacturing process or operation must be extensively tested, verified, and documented before releasing to production. Clearly, validation as a current best practice precludes medical device manufactures from moving to a fully closed-loop, smart-machine based system.

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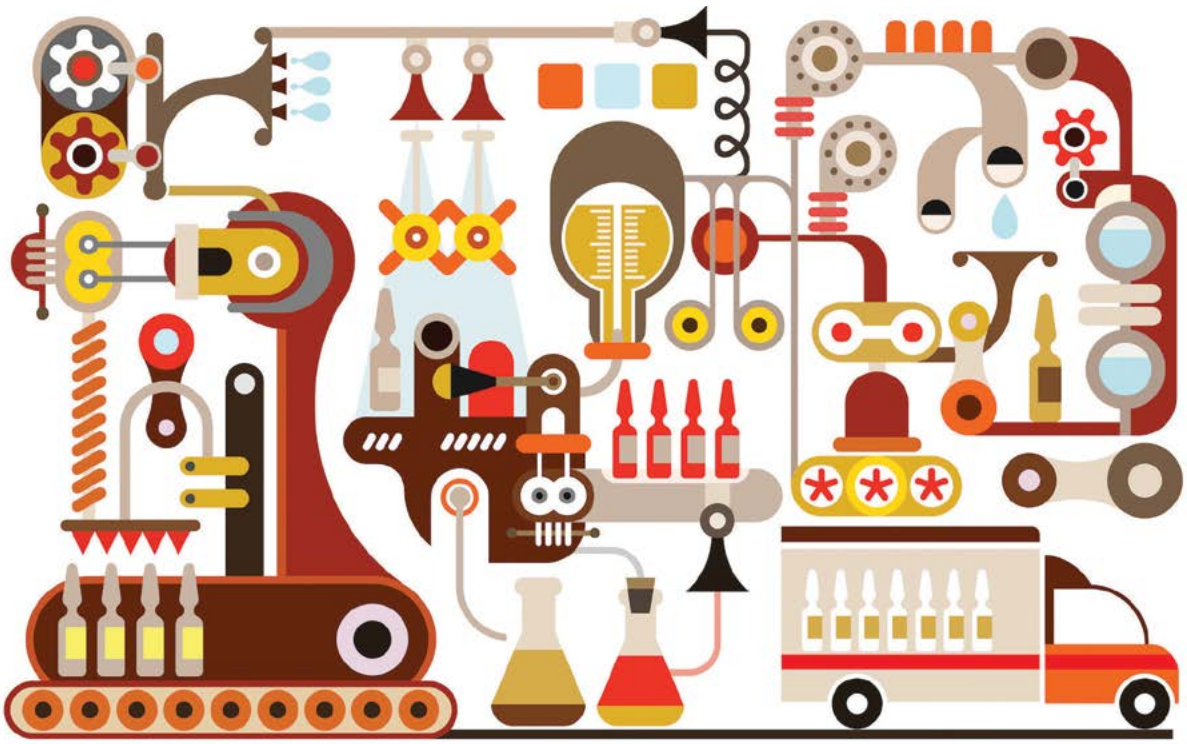
Srivats Ramaswami

Nevertheless, some medical device manufacturers are moving ahead to embrace Industry 4.0 best practices where they can—and they are seeing multiple benefits, including a strong ROI, from their efforts. For example,



one customer of 42Q is a global contract electronics manufacturer with customers in the medical device industry. Their embrace of Industry 4.0, and their use of the 42Q manufacturing execution system, serves as a great illustration of the benefits that can be achieved—even in the most highly regulated manufacturing environments.

One manufacturing line that this company designed around Industry 4.0 principles produces high volume Class III medical devices. A highly-sophisticated level of automation was required in this case for a number of reasons:

- Volumes of 10 million devices per year were planned, which require high-speed lines running 24 hours a day.
- The product includes some components having placement and registration tolerances of less than 10 microns. This level of precision in a high-speed line was not possible without highly specialized robotic equipment.
- The stringent requirements of ISO 13485 and FDA regulations required the repeatability that automation could offer.
- This device must be manufactured in a clean-room environment, and automation reduces the number of people needed in the room.

Production staff load components into feeders, where inspection systems detect component orientation before the components are fed into the line. There are more than 50 steps involved with producing the device, and each station includes a pass/fail inspection. Stations might also include optical inspection to double-check placement of materials (again, at a level where the human eye cannot see the components), and to check the bonds between electronics and plastic or metal. Machine vision systems continuously look at barcodes of components for verification. In line robots pick up only those components or devices that have passed earlier functional tests, with failed components being routed out of line.

As part of their Industry 4.0 initiative, the manufacturer implemented systems (42Q) and analytics to monitor throughput and yield in real time. For example, if the yield falls below certain thresholds (e.g., if 6-8 non-compliant devices are detected in a short period of time), machine to machine (M2M) communications ensure that alerts are sent in real time to manufacturing technicians to investigate the problem. All activity is recorded and fed into the manufacturing execution system (MES) via 42Q and 42Q uploads some of this data into the DHR's.

The throughput of this line is far beyond industry benchmarks, while complete traceability is guaranteed for each component. This state-of-the-art-production line operates with little or no human intervention beyond the loading of component feeders and scheduled maintenance. It truly is a world-class manufacturing facility, demonstrating a real world implementation of Industry 4.0 principles. MT