

Lean Initiatives Improve Medical Manufacturing Quality

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A lean initiatives program, undertaken over a period of years to improve quality and on-time delivery, has been a boon to the company's ability to meet medical device makers' needs.

About three years ago, the company refocused its ongoing lean manufacturing initiatives to take aim at improving the company's bottom line by eliminating waste while improving quality and delivery. The program resulted in the establishment of "self-directed work teams," composed of employees who implement suggestions on improving manufacturing efficiency and streamlining the manufacturing process.

The management team establishes the overall goal of 100 percent quality with 100 percent on-time delivery, and the self-directed work team determines what sub-goals are needed to meet these goals. The teams determine what they need to deliver perfect quality on time, and have decision-making power for ensuring that orders are being manufactured with the quality required and delivered to the customer in a timely manner. The management team is responsible for training and supplying all resources the teams need to be successful.

The individual self-directed work teams are led by a steering committee of 12 rotating employees, which works to solicit and implement suggestions. More than 65 employees have served on the committee thus far.

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The success of the lean directive has directly affected the company's ability to serve medical device manufacturers. The new manufacturing process allows the company to partner with medical firms early in a rapid prototyping team effort, working closely with the medical device firm's designers, and CSS's internal engineers and material specialists. Quick communications and production of sample prototypes enables medical device companies to conduct limited testing and trials as they develop the device into a more refined product.

The key change resulting from the lean initiatives has been the broader adoption of continuous processing and the elimination of batch processing. Continuous flow, also called one-piece flow, minimizes scrap and alerts the production line quickly to any quality issues, so corrections can be made quickly. Any time parts are made and are left waiting for the next process is a time when possible quality issues can go unnoticed. For example, look at a complicated part that has 15 components to it. Producing each one in a batch of 1,000 pieces means there are as many as 15,000 parts sitting idly on the floor, waiting to be assembled. With one-piece flow, operators take a part from start to finish and know that it is complete and made in accordance with all quality specifications.

The medical industry is one of a few industries with a quality imperative on their products that has adopted the one-piece method for its quality benefits. Especially in orthoscopic surgery where the working field is small, instruments must be extremely precise.



Using lean initiatives in manufacturing to create a product and conduct benchmark testing enables the manufacturing line to produce a better product and hold tolerances device developers are seeking. The self-directed work teams for medical device parts include engineers working closely with shop floor operators who, together, have enabled manufacturing tolerances to shrink sharply. At [CSS](#) [1], we can now hold tighter tolerances than we used to build five years ago, due to the feedback from the members of the lean self-directed work team.

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Each member gives feedback, right down to the person packaging the parts. For example, for one medical part we produce, packaging damage was reported and the team went back and examined exactly how individual parts were sorted and packaged, and came up with a solution. Rejections stopped and parts got to the customer in better shape. With such good quality, there are fewer rejects and time is not wasted on remanufacturing parts.

An even bigger leap is making sure the lean initiatives flow all the way from engineering through the toolmakers and, ultimately, to the assemblers. Here, the people designing the tools are working in a development fashion, giving feedback to the group, including engineers at the medical device firm, engineers at CSS, hands on toolmakers, and assembly people. The wide-ranging discussion includes feedback on what works and what doesn't, which allows toolmakers to go back and redesign the tool rather than waiting to go to trials on the device. The discussion includes representatives of all the first tier assembly people on such items as ergonomics, how the parts are given to the assembly line, whether the parts are put in trays or in an open container, how to pack the parts, and how to get them out easier. In actuality, it's a hands-on motion and time study right on the floor.

One example is a stamped and machined channel application for a stapling device, on which CSS is working for a leading global healthcare products company. To meet market needs, the project required rapid design and the lean self-directed work team worked intensively to determine how parts would flow to the shop floor. Several rounds of discussions and trials led to refinements in target dimensions, changes in fixtures for CNC operations, and adjustments in how the parts would be brought from one station to the next. Leaning out how the part would be manufactured resulted in a better quality part and a higher production rate. The team went from manufacturing 2,000 parts per week to about 6,000 parts per week.

The lean initiatives are a work in progress and we are learning as a group every day. Management's role has changed to being more of a facilitator. It's a lot less about telling shop floor workers what to do and more about asking them what they need. Bringing natural organizational skills from home life into the work environment has resulted in enormous productivity gains and a win for the medical device industry. Allowing employees to take ownership of the manufacturing process ensures the shop runs smoothly and deliveries consistently happen on time.

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[1] <http://www.ctspring.com/>