

# Lean Manufacturing for Medical Devices

*Employee engagement and empowerment are key to continuous improvements*

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Although there is an abundance of literature about the topic of lean manufacturing, there still is confusion about the principles and how they are applied. What exactly is lean? Is it a form of automation? Does it lead to component shortages? It is hard to argue, however, that many profess that lean manufacturing does have its advantages. In fact, more than half of American companies are currently employing lean strategies and many others getting onboard the lean train. If lean is here to stay, employee buy-in and engagement are vital. That sentiment is especially true for medical device and medical instrumentation manufacturers.

In the medical manufacturing industry regulatory oversight dictates the need for maintaining product quality processes that document and control product configuration and methods. Continuous Improvement goes one step further in adding the challenge to improve efficiency and reduce cost without compromising the quality of the end product. Over the last 15 years, “lean” has gained tremendous traction as a method to address traditional manufacturing practices and reduce waste throughout. While lean strategies are certainly effective, medical companies must approach lean as a collaboration of partners working toward the same goal: to deliver products that result in reliable and cost-effective patient care.

## Employees: A Company’s Leanest Asset

Employees create, add and deliver value to customers. The people on the manufacturing floor play a large role in ensuring the quality of the instruments produced and how quickly they are delivered to market.

Employees desire to make valuable contributions to the business, but to do so they must understand value, be empowered and be included in the decision-making process. Implementing lean tools, such as 5S and Kaizen, enable companies to engage their employees in the battle against *muda*, or waste.

Often, making sweeping changes on a manufacturing floor without the employees’ input can be difficult, frustrating, and counterproductive. Not tapping into these vital resources leads to roadblocks in the implementation of lean tools. That’s why it’s important to have a basic starting point. Training employees on lean principles coupled with support in the power of improvement first will help them begin to think about their roles in a new way. 5S has become a recognized standard as part of lean manufacturing programs throughout



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the U.S., and it provides an excellent starting point for organizations looking for ways to further engage employees.

### 5S: A Value-Add for Medical Manufacturers

5S is a five-step process which stands for: (1) sorting, (2) setting in order, (3) shining, (4) standardizing and (5) sustaining. Sorting is simply getting rid of items in the workspace that are not needed for that particular process, eliminating clutter and allowing employees to follow the next step, set in order, the tools and parts that are needed. The third step is to shine, or clean and tidy the area, which is particularly important in medical device and instrument manufacturing because it allows employees to identify issues that could be problematic down the line and helps make those problems immediately visible so they can be addressed.

Once the initial three steps are completed, it's important to standardize best practices for maintaining the new environment. Supervisors and employees must then work together to protect those improvements in order to sustain the 5S process. To accomplish this at KMC Systems, employees established an audit team that fills out 5S scorecards for each manufacturing cell. The peer-to-peer feedback is reviewed and then the manufacturing teams are able to correct any outstanding issues, encouraging ongoing improvements. Each month, the team with the highest score receives the "Golden Broom" award and is recognized within the organization.

### Kaizen: The Human Element of a Manufacturing Floor

After implementing an organizational change like 5S, medical manufacturers can go a step further by empowering employees to suggest their own improvements through a kaizen program. Kaizen, at its core, is the process of making small changes for the better.

As the proverbial first line of defense on the shop floor, employees are well equipped to assess their own processes for the identification of waste. Developing a process that makes it simple for employees to suggest changes is instrumental to the success of a kaizen program. It also needs to address the problem and have immediate action taken. Integrating the kaizen process into a manufacturing execution system (MES) also sets the program up for greater success.

KMC Systems implemented a program called "Kwick Kaizen" that requires employees to submit a certain number of suggestions per quarter and a drawing is conducted at periodic company meetings to monetarily reward employees for their participation. The company's Kwick Kaizen program is integrated into a Manufacturing Execution System (MES), which is comprised of advanced, proprietary software developed specifically to manage and control a medical instrument manufacturing/quality assurance environment. The system enables supervisor approval for any change or improvement to the manufacturing process with



electronic sign off after appropriate validation and review. This integrated system also manages documentation for traceability and regulatory compliance, ensuring all changes to the manufacturing process are kept on record.

To further educate and engage employees, a monthly newsletter is written and distributed by a member of the manufacturing team, highlighting the latest improvements, celebrating individual successes and using humor to further engage the readers.

### The Benefits of Working with a Lean Contract Partner

The trend toward outsourcing manufacturing from North America to Asia has gained momentum in light of the global economic downturn as medical companies look to reduce production costs; however, choosing a local contract partner that operates under lean principles can be equally advantageous and challenges that trend. Manufacturing facilities that use lean principles to reduce waste ensure that customers are only paying for what is being produced at a given time.

Increasingly, the medical industry is moving toward a zero defect policy when it comes to manufacturing. Lean manufacturing principles contribute to better quality products because tools like 5S and Kaizen seek to ensure components are manufactured in the most efficient and effective way. Working with an experienced medical device contract manufacturing partner familiar with medical product regulatory compliance requirements and one who embraces the lean philosophy are key elements to the attainment of such ambitious quality standards.

### Conclusion

Implementing lean tools like 5S, and engaging and empowering employees through programs like Kwick Kaizen enables medical contract manufacturers to reduce process time, and product cost, while maintaining/improving product quality.

At KMC Systems, we embrace “lean” for our customers, the medical device and instrument companies, in their continuing pursuit of resource optimization so that they can provide the healthcare market with cost effective products focused on better patient outcomes.



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