

## Lean for Low Volumes

In today's manufacturing and business climates, there is no excuse for orthopedic companies to avoid implementing Lean principles or a similar program.

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Lean principles are all the rage in manufacturing, and for good reason: They can reduce steps and cut costs. But they are best known for their use in industries that produce goods in high volumes and don't have a plethora of regulatory requirements. Can they be translated to orthopedic manufacturing, which usually works in low volumes and is subject to strict regulations? A number of experts say yes.

Even if orthopedic companies cannot follow Lean principles in the same way that IBM and Toyota do, they still can benefit tremendously from the practice. That is because Lean principles are not about following a formula as much as they are about eliminating waste and finding ways specific to your operation to produce products faster and better.

"The benefits of implementing Lean transformational activities are the same, regardless of the product or service," said Tom Pesaturo, principal of Exceeda Consulting, a Cambridge, Mass.-based firm that helps clients implement Lean tools, techniques, and methodologies. "Lean focuses on improving work activities to produce the highest quality product and/or service in the shortest lead time, with a minimum amount of materials, equipment, labor, and space. The key is to eliminate non-value-added activities and increase the value-added work by eliminating waste and reducing variable work."

### The Challenges

Orthopedics is one of the toughest industries in which to implement Lean principles, notes Pesaturo. This, he said, is due to a number of conditions, including compressed design times, small production runs, short product life cycles, precision assemblies, multi-step assemblies, strict cleanliness controls, and strict quality controls.

Unilaterally imposing a transition to a Lean process isn't going to work. A lot of research must be done to determine how such a process can fit into your goals and those of your customers, and how it can be tailored to the essential steps of your existing processes.

"The biggest challenge is to ensure that your Lean efforts are well-aligned with your customer and corporate values and, most importantly, that these activities are fully compliant with all FDA [U.S. Food and Drug Administration] regulations," said Jodie Gilmore of Onyx Medical Corporation, a manufacturer of wires, pins, drills and screws based in Memphis, Tenn. "This is the only way that any effort can be sustained and effective."

Jerry Wright, senior vice president of Lean enterprise for DJO Incorporated, an orthopedics OEM based in San Diego, Calif., notes that perhaps the biggest challenge to implementing Lean ideas is "our own paradigms of how to look at making devices." Because FDA Good Manufacturing Practices regulations are so strict and specific, and because device companies often have been using the same practices for generations, it can be difficult at first to conceive how a manufacturing process could get any better than it already is. But he notes that "once we are aware of a better way to produce and reduce waste, it's easier."

This is why a successful Lean program is never going to be realized without a thorough planning process, said Jon Dobosenski, North America business manager for Tornos, a global manufacturer of Swiss-style lathes with U.S. operations in Brea, Calif., Lombard, Ill., and Bethel, Conn.

"In order to be successful with Lean manufacturing, you need everyone to be able to buy into the concept and then be willing to look at their process and how to combine or reduce steps," he said. "Once everyone is on board, you can then plan out a number of issues within the company. You must plan from the start of the job all the way to the final shipping what steps are necessary and what can be reduced."

Questions that need to be asked, he explained, include what equipment is necessary, whether the tooling used is effective for setups on all platforms (or as many as possible), and whether the layout of the shop is working hand-in-hand with the processes carried out in manufacturing.

The extra documentation that comes with orthopedics manufacturing thanks to FDA requirements can be an obstacle to implementing Lean manufacturing if you let it, but there are ways to incorporate those requirements into your planning process.

"It should be addressed as the implementation is planned and carried out," said Pesaturo.

Some of this has to do with personnel structure, said Tim Pierce, senior Lean Sigma Program manager for Medtronic Spine, Biologics, and Kyphon in Warsaw, Ind. Someone familiar with regulatory requirements needs to be represented in every significant Lean event or project.

"The key to implementing in this environment is to ensure that all projects, events and efforts have a diverse team," he said. "One of the first actions of preparing for any event or project is to define the potential impact and identify all departments that need to be involved. Building a team that has representation from all departments will help us achieve the identified improvements."

### The Benefits



It is well worth it to work through these challenges. The most obvious reason to pursue Lean initiatives is cost.

“One of the biggest benefits of using Lean manufacturing principles is cost. Especially in the orthopedics industry, the material used to produce the end product is fairly expensive. The more efficiently you can handle the material, the more profit you will gain,” said Dobosenski.

The main way Lean processes reduce cost is by eliminating waste. Pesaturo outlined seven categories of waste that Lean principles target: defects, overproduction, transportation, waiting, inventory, motion, and overprocessing. “We define waste as ‘any human activity that absorbs resources but creates no real value,’” he said.

What Lean principles do instead is emphasize value-added activities, Pesaturo continued.

“Those are defined as ‘activities that increase the worth of a product or service for which the customer is willing to pay,’” he added. “We work with our customers to ensure they are achieving the Lean nirvana by orienting the workplace and adjusting the work tasks so that the product or service is always in a state of constant value-adding.”

Wright said that Lean principles have allowed DJO to produce better-quality products with less waste and shorter delivery times. “It also reduces our costs of manufacturing and inventory thanks to less waste, greater employee productivity, and less work-in-progress inventory,” he said.

Pierce said his firm has used Lean principles to focus in five areas: safety, quality, cost, delivery, and organizational development.

“Improvements in these areas in the orthopedic industry typically come from standard work, root cause analysis, lead time reductions, inventory control and reductions through Pull systems, statistical process control and cellular manufacturing,” he said. “We strive to produce the highest quality products with the shortest lead time and the optimal cost.”

Quality improvements often follow from process improvements and efficiencies because a successful Lean process eliminates nonessential manufacturing steps, and streamlines processes. The more steps there are to a process, the greater the chance there is of an error happening or a problem occurring.

“Swiss Turning, for example, has thrived on pushing Lean manufacturing by doing more processes within the envelope of one machine instead of moving the production part from mill to lathe and so on,” said Dobosenski. “By doing more processes within the one machine, you eliminate manual setup time from machine to machine, you eliminate extra support material which would have been required for clamping and reference in multiple setups, and you achieve higher quality and accuracy because the part never leaves the machine and you do not have to worry about tolerances and alignments between different machines.”

## Leveraging Low Volumes

Low-volume runs, often necessary in orthopedic manufacturing, inherently are less efficient than high-volume runs, but that does not mean that they cannot be improved by Lean principles.

“Lean principles can be applied to just about any kind of process,” said Gilmore. “The goal is to identify and eliminate waste and non-value added effort. For low-volume processes, this means making sure that your operation is flexible enough to handle the low volume and—likely—high mix, while still remaining efficient and compliant.”

The key is fully understanding all steps in the process and determining which ones can be streamlined or eliminated.

“It’s all about upfront investment in engineering,” said Kelly Lucenti, president of Millstone Medical Outsourcing LLC, a provider of customized outsourcing solutions based in Fall River, Mass. “You must make that commitment. You have to invest time and engineering resources to clearly lay out how things will flow through for small lot sizes. Validations add expense, but you must do them, so that the process will be without issue.”

There are a number of tools that can help with this, according to Pesaturo.

“In companies where production runs are short or at low volumes, taking the concepts of Lean beyond the manufacturing environment and upstream in the system is key to capturing the benefits of Lean,” he said. “In a small-run manufacturing environment, it is important to choose the tools that will provide the biggest payback. While there are no cookie-cutter solutions, Lean tools such as Six Sigma workplace organization, visual management, setup reduction, and mistake proofing are examples of important elements in short-run manufacturing environments.”

Pierce agrees. “Lean Sigma tools can be applied in any environment, just applied differently,” he said. “In a low-volume, high-mix situation, there are still systems that can be put in place, such as policy deployment, Six Sigma, cellular manufacturing, pull system, standard work, problem solving, and so on. Successfully implementing these tools will turn even a low-volume, high-mix process into a model Lean manufacturing system.”

In addition to eliminating steps from the process, a successful orthopedics Lean manufacturing program will have achieved efficiencies by timing its production runs in a certain way. This is essential for low-volume operations.

“Plan your jobs so that you are producing the same families of parts and also look at common cutting tools,” said Dobosenski. “At this point, it could be as simple as making sure you don’t need to move the same tool to a different position when going to a different part when a simple program change could eliminate moving the tool. Every little step you take to improve the steps in a process, no matter how small, adds to a reduction in wasted time

and an increase in production.”

## Training & Implementation Issues

None of the benefits and efficiencies of an orthopedics Lean manufacturing program will be realized if your personnel haven't been trained properly and don't understand what they are supposed to be doing. All the planning and reconfiguring in the world won't mean anything if the execution is fumbled.

Therefore, a comprehensive training program is an essential part of a transition to a Lean manufacturing system.

It is very important to get employees to think about Lean concepts, particularly as to how they add value for the customer. If those are fresh in their minds, said Gilmore, they better will be able to understand their roles in the new system.

“There are so many formal Lean techniques and buzzwords, it can make your head spin,” she said. “From my perspective, the most important aspect to making sure that any Lean effort can be effective and sustained within an organization is to try and instill a Lean mindset at all levels throughout the company. Challenge every employee to ask themselves, ‘is my activity/my work/ my effort adding value for the customer? Will it efficiently and effectively yield a conforming product each and every time?’”

Indeed, said Dobosenski, “in order for it to work, everyone must understand the goals, believe in the plan, and most of all, be a valued part towards the success.”

Video training is helpful, said Lucenti. “We develop videos, which you can do with free software online, for every step of every operation within our facility. It's a great tool for operators, being able to watch a video on how to do what you're supposed to do. It's a more comprehensive experience that way.”

It also helps if workers can be fully involved during the planning and transition processes, said Dobosenski.

“You can show a power point to explain the concept, but the only way it will work is if the entire company knows the end goal and gets involved with the process,” he said. “The first goals may be small, but they need to be something you can measure. Once you decide what you would like to achieve, like a 5 percent reduction of scrap, then allow the team to evaluate, plan, implement, and then track the progress. Once progress has been made and the team sees the benefit, then start expanding out to other processes.” Hands-on training is extremely important, said Pesaturo.

“Lean manufacturing can't be learned in a classroom environment only,” he said. “While learning can come from the exercises and concepts taught in class, deep understanding will come from actual application in the workplace. We feel the most effective training is spent hands-on applying the Lean tools where the work gets done. Finding training delivered by qualified instructors with years of experience in actual Lean implementations is key. This helps eliminate any doubts that ‘Lean can't be applied here’ and allows you to realize the benefits of Lean without expensive trial and error. Most importantly, you have to keep it simple and non-threatening for the participants.”

It usually works best to start with training on general principles before moving to training for specific operational improvements, noted Pierce.

“Most often we start the general population with a Lean Sigma awareness training so they can gain an understanding of tools and terminology, as well as become valuable resources to support and participate in continuous improvement efforts,” he said. “We provide tool-specific training when applied and always kick off Kaizen events and Lean Sigma projects with training involving content focused on that specific project or event.”

It also is important to continually ensure that employees understand everything they have been shown and told, Millstone Medical's Lucenti added.

“In medical devices, you also have to make sure that they comprehend what you've trained them on,” he said. “You can implement certification programs to test and verify that they understand the training. That ensures you have a ready force of personnel to do small lot sizes.”

Wright agreed that training is a process that is never totally finished. “The best way to train your personnel is to have them use the principles in action, to actually apply what they have learned immediately to really understand the concepts,” he said. “They will need to be used continuously. You are never finished applying Lean; it is a continuous improvement process applied to an ever-changing business and market.”

Continuous improvement also means keeping an eye out for new technologies that can make your processes even more streamlined. It particularly is important to keep a look out for advances in automation and tooling.

“Programming software companies are designing their products to be able to help better determine tool life, allow more tools in the process at the same time, and allow you to program with modules for repetitive processes,” said Dobosenski. “Machine manufacturers generally offer software that help take full advantage of machine-advance functions within their controls and optimize production within the envelope of the machine. Automation and tooling suppliers are developing their products to work with multiple brands of machinery to allow one robot to automatically feed and manage multiple machines.”

## The Bottom Line

There is more than enough evidence to suggest that the orthopedic manufacturing environment benefits from the implementation of Lean principles.

Because Lean is, more than anything else, about leveraging tools and resources specific to your process in order to reduce waste and save costs, arguments against it such as “FDA regulations make it too cumbersome” or “we don’t run volumes high enough to make a difference” don’t hold much water. “Regardless of the business, if we eliminate waste, we improve the workflow, which decreases cost and improves profitability,” said Pesaturo.

In fact, orthopedic OEMs who are not implementing Lean principles or have no plans to may be at a significant competitive disadvantage.

“If you are not currently pursuing Lean principles or a similar continuous improvement strategy in your business, you’d better get started immediately, or be prepared to lose market share in the coming years to those companies that are doing it,” said Wright. “Lean is synonymous with sustainable business development by designing value for the customer; reducing, reusing and recycling to control costs; and designing for end-of-life considerations.”

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