How Taking a Lean Approach to Quality Improves Profitability for Medical Device Manufacturing

Rick Gallisa

As a medical device manufacturer, it is no secret that complex regulations continue to be increasingly challenging to meet. But beyond regulations, product quality is paramount for patient safety and brand protection. The other side of the equation is minimizing costs in R&D, manufacturing, the supply chain, and compliance.

Further, as technology and product innovation lifecycles continue to compress, more complexity is added to the equation. Together, these industry pressures often lead to conflict, which exacerbates management's task of providing impactful value to patients while maintaining the financial community's expectations.

If you face these challenges, then I would propose an effective strategy might be to first look at how your production, inventory, and quality management processes are being managed and continuously improved. An approach that yields the highest flexibility and visibility for improvement might just help you to achieve greater process improvement and regulatory compliance for the lowest possible cost structure.

In other words, why not take a Lean approach to Quality?

For most device makers, manufacturing objectives include improving efficiency, cutting waste, and reducing costs—and doing so while under intense regulatory scrutiny. New processes, products, or demand shifts, however, often require a new approach to doing business. Often times, these changes can result in production delays for a myriad of reasons, such as new process validation, quality planning & testing for production control, or sourcing and vetting of new key component suppliers for new products or expanded geographic markets.

These potential disruptions can be significantly diminished.

Best-in-class medical device manufacturers are now starting to synchronize their production, warehouse, and quality processes with suppliers, effectively establishing collaboration between their internal production processes and those of their suppliers. During times of economic uncertainty, opportunistic windows can

sometimes be opened, helping to negotiate new terms and conditions as a way to ensure future profitability. Now might be an excellent time to consider such a change.

Another consideration: instead of doing an inspection at the receiving dock after goods have already been received from your suppliers, what if the delivery didn't occur until the inspection results had already been performed, having been agreed upon between manufacturers and their suppliers? Not just certificates of acceptance, but data that can be built into electronic Device History Records for more robust genealogy. The results can then be electronically transmitted and verified in a far more efficient manner so that medical device manufacturers can better control their suppliers' flow of approved subcomponents and raw materials, minimizing inherent organizational inventory buffers.

This process improvement could redefine how production processes are executed. Raw materials could be scheduled to arrive as they are used, in exactly the right quantity and with exactly the right quality, resulting in less waste and improved operational throughput.

In fact, delivery schedules could be better synchronized, with increased visibility to your supplier's operations, helping to improve efficiency. By receiving materials not only just in time, but also in sequence, as applicable, production efficiency can be significantly improved. This efficiency, when combined with sufficient flexibility to adjust operations should a supplier disruption occur, can lead to significant process improvement. This practice originated in the automotive industry and its tiered supplier networks—the origins of Lean—many years ago, and is still being refined for optimization as markets shift. This is not unlike the landscape facing medical device manufacturers today.

This intelligence could then form a basis for corrective actions with suppliers, helping manufacturers to further engage suppliers in quality improvement processes where real "ownership" can be established, managed, and maintained.

To keep up with unique industry challenges and move innovation forward, it is more important than ever to take a Lean approach to quality. Implementing real-time visibility and control across operations and your extended manufacturing supply chain network could result in many benefits. Advantages include reduced time for new product introductions and more standardized, consistent business processes to help address both global regulatory requirements and internal corporate manufacturing goals.

Rick Gallisa is a Life Sciences Industry Director at Apriso [1], a manufacturing operations management software provider that offers global solutions for manufacturing excellence.

Source URL (retrieved on *03/11/2014 - 11:18am*):
http://www.mdtmag.com/blogs/2012/01/how-taking-lean-approach-quality-improves-

profitability-medical-device-manufacturing?qt-recent_content=0

Links:
[1] http://www.apriso.com/industries/life_sciences/