



BUILDING A SOUND QUALITY MANAGEMENT SYSTEM

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The potential benefits of developing a sound quality management system far outweigh the risks. Today's manufacturing industry can no longer rely solely on the old wisdom of previous decades; global supplier networks and disparate geographic manufacturing sites make the task of implementing an integrated, enterprise-wide quality management system all the more arduous. Companies around the world are devising creative strategies to leverage IT resources to improve quality and lower the overall cost of quality; a globalized economy demands no less of manufacturers. Far too many manufacturers remain entrenched in a 20th century mentality, which views an enterprise-wide quality management system with a skeptical eye. The reasons for deploying a new quality management solution are easy to outline, but the specifics of how to implement such a system are more difficult, but certainly not impossible, to pinpoint.

REASONS TO DEPLOY A QMS.

A common misconception within the manufacturing

industry essentially boils down to viewing quality management solely as a means to comply with regulations. With this view, companies place less emphasis on the safety of products and the opportunity to continually improve manufacturing processes; two of the key benefits of a sound quality management system.

Today's manufacturing industry is gradually moving away from a siloed approach to quality management. Lean, fully integrated systems afford manufacturers the benefits of reduced waste, increased visibility to pinpoint nonconformances earlier, more efficient business processes, and continuous process improvement. Essentially, developing a quality management system serves as a means for companies to reinvent themselves with a focus on adopting lean principles to keep pace with competitors.

The challenge of document control alone necessitates deploying an enterprise-wide quality management system. For instance, ISO standards focus tightly on document control processes. Inadequate documentation practices remain one of the top reasons manufacturers do not meet ISO standards. As enterprises continue to expand multinational partnerships, controlling massive amounts of quality system documentation will become even more critical in the coming decades.

HOW TO DEVELOP A QUALITY MANAGEMENT SYSTEM.

Using ISO 9001 as a starting point, quality management systems must adhere to a process-centric approach. The specific details of how to implement such a process-centric system are difficult to pinpoint due to the high amount of variability within manufacturing industry verticals. For example, the Advanced Product Quality Planning (APQP) challenges of the medical device industry differ substantially from those facing the automobile industry. However, the following general guidelines may serve as a baseline.

First, corporate governance must make a commitment to quality management, whether via lean principles or Total Quality Management (TQM). One pitfall to avoid is allowing organizational changes to dictate changes in processes. Ideally, business decision makers should create a map of current business processes to identify and quantify areas of vulnerability, or of waste if companies commit to lean principles. Manufacturers can then compare this “blueprint” of the proposed quality management system against current processes.

Taking one component of the new or updated quality management system at a time affords manufacturers the benefit of flexibility. The impulse to implement wholesale changes to processes can lead to the problem of locking in unforeseen nonconformance issues. As a good starting point, document control should be a priority, since certifications rely so heavily on viable document control processes. One way to overcome the challenge of document control is to adopt a pyramidal structure that prevents lower-level documentation from superseding upper-level documentation.

Certainly, the intricacies of a quality management system are voluminous. However, the benefits of building a sound quality management system are worth the risk.

Running a successful business requires several key components including innovation, collaboration and cooperation. Chief among the components a business should have in place is a sound QMS.



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