Six Sigma Is No Replacement for a Quality Management System

Integrating the tools in your QMS is essential for success.

by Mike Micklewright

I'm a huge proponent of both Six Sigma and lean manufacturing. I've been teaching the tools used in Six Sigma for more than 15 years, and I make a portion of my living from consulting and training in these areas.

However, Six Sigma and lean manufacturing are business improvement processes that should be viewed to be part of a continually improving quality management system (i.e., ISO 9001). Six Sigma and lean are not replacements for your quality system; they must be fully integrated into your quality system to make them more effective.

As more companies embark on a Six Sigma, lean manufacturing or lean Six Sigma journey, they either forget about their ISO 9001-registered quality system or bypass building a quality system altogether. ISO 9001 seems to be losing steam as Six Sigma and lean are gaining in popularity. In fact, according to the American Society for Quality, attendance at the annual ASQ Six Sigma Conference has increased from 223 attendees in 2002 to 333 in 2004, whereas attendance at the annual ASQ ISO 9000 Conference had less than half the number of attendees (152) in 2004.

Why is this happening? One possibility, at least for those who are ISO 9001:2000-registered, is that companies haven't seen the positive financial impact of being registered. Now they are looking at the latest craze to bring home the returns.

Well then, why have some companies not enjoyed a positive financial return from being ISO 9001:2000-registered? That's an easy one. Let's face it, many companies are focused on the certificate hanging in the foyer of their headquarters, rather than living the true spirit of ISO 9001:2000, as defined in ISO 9004:2000 ("Guidelines for Performance Improvements").

A prime example of this is when I work with companies that have been registered to an ISO-based standard for a number of years. Whether performing an internal audit for the client, preparing to teach them about problem solving using their in-house examples or, in the recent past, when helping the client convert their quality system from the 1994 version, I witnessed an awful execution of their corrective and preventive action process. This is most evident in the inadequate determination of the root cause of a problem, which then leads to an inadequate action that only addresses the symptoms, and not the underlying reasons, as to why the problem occurred in the first place. In many cases, people get blamed and the effectiveness of the quality system is not improved.

If a company still doesn't know how to implement effective corrective and preventive action through the use of root cause determination—leading to improving the effectiveness of the system—then this company is not living the true spirit of ISO 9001.

How is Six Sigma a subset of an ISO 9001-based quality system?

The two main elements of Six Sigma are:

- Business process management (the "Big Picture")
- The methodology used to attack DMAIC issues (define, measure, analyze, improve and

control)

Business process management provides for management accountability of cross-functional processes so process goals can be attained while business objective responsibilities remain clear.

How does this relate to ISO 9001:2000?

ISO 9001:2000 states:

- 4.1 "The organization shall a) identify the processes needed for quality management system and their application throughout the organization, b) determine the sequence and interaction of these processes."
- 8.2.3 "The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results."

From this, we can deduce that ISO 9001:2000 requires business process management as defined in Six Sigma terms. Six Sigma provides us with specific guidelines on how a company might choose to achieve the requirements of ISO 9001:2000.

DMAIC is a process for continual improvement that provides us with the methodology we can use to attain our process goals.

Have you ever noticed that section 8 of ISO 9001:2000 is entitled "Measurement, Analysis and Improvement" and that this is also the "MAI" of DMAIC? If three-fifths of DMAIC is addressed in section 8 of ISO 9001, where are the "Define" and "Control" steps?

I have another question for you first. Have you ever read ISO 9004:2000? If you did, you may have noticed that the last sentence of the last section (8.5.4), "Continual Improvement of the Organization," refers the reader to annex B. Annex B is entitled "Process for Continual Improvement"—the same words used in the definition of DMAIC. Anyone who knows anything about Six Sigma should read this annex and observe the extremely strong relationship between it and DMAIC. If a company followed the true spirit of ISO 9001:2000, it would read ISO 9004 and this annex, put it into practice, improve quality, lead-times, processes and their system, and develop its own version of DMAIC and Six Sigma. It may even be able to copyright its own methodology, certify employees with different colored clothing and infiltrate the consulting industry with new experts.

"Define" is probably the least addressed step in ISO 9001:2000, but it's easily learned and applicable. ISO 9001:2000 most closely addresses "Define" in the "Analysis of Data" (8.4) section, which states, "the organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made." This input then is used in the definition of the project as would be stated in the team charter.

The "Control" step is stated throughout the ISO 9001 standard. Because the standard was written in a cyclical fashion, the outputs of the last section of the standard "Measurement, Analysis and Improvement" should be the inputs into the first section of the standard "quality management system." Similarly, after the "Improvement" step of DMAIC is complete (section 8), a company should "Control" the gains (section 4). "Control" is addressed in Section 4 of ISO 9001 as follows:

- 4.1 "The organization shall c) determine the criteria and methods needed to ensure that both the operation and control of these processes are effective, d) ensure the availability of

resources and information necessary to support the operation and monitoring of these processes″

- 4.2.1 ″The quality management system documentation shall include documents needed by the organization to ensure the effective planning, operation, and control if its processes″

This should offer proof that Six Sigma is part of ISO 9001:2000 and that Six Sigma can provide us with the ″how″ in answering the question, ″How does a company comply with the 'true spirit' of ISO 9001:2000 as explained in ISO 9004?″

How is lean part of an ISO 9001-based quality system?

A value stream defines all the actions (both value-added and nonvalue-added) currently required to bring a product through the main flows essential to every product—the production flow of raw material into the arms of the customer and the design flow from concept to launch. The purpose of value stream mapping is to highlight sources of waste and eliminate them by implementing a future-state value stream that can be a reality within a short period of time. There are two types of values streams: the current state map and the future state map.

Building a lean manufacturing system first requires the development of a current state map (a map of the current production system) and then proceeding toward a much more efficient future state map (a map of what the production flow will resemble after lean manufacturing improvements are implemented), while achieving major cost, inventory and lead-time reductions. ISO 9001:2000 also requires the building of a current state map.

The organization shall a) identify the processes needed for quality management system and their application throughout the organization and b) determine the sequence and interaction of these processes.

With regard to the development and progression toward a more efficient future state map, one would have to delve into the spirit of ISO 9001:2000 by reviewing the requirements of ISO 9004:2000. Some of its sections strongly imply the use of lean techniques to increase the efficiency of the quality system:

- 7.5.1 ″Reducing waste″
- 7.5.4 ″Management should involve suppliers and partners in defining and implementing effective and efficient processes to protect purchased materials.

Lean manufacturing is a subset of ISO 9001:2000 that can show us with how to comply with some of the most important components of ISO 9001:2000.

Why should Six Sigma and lean be integrated into an ISO 9001-based quality system?
Simply put, Six Sigma and lean don't offer or mandate the systems to maintain the gains and controls as ISO 9001:2000 does. The last step of DMAIC is ″Control,″ and it teaches us that we must put controls in place to maintain the gains from a project. However, there are no systems mandated to ensure those controls are permanent.

If a company follows the spirit of ISO 9001:2000, the following controls should ensure the gains are permanent:

- Management review
- Control of documents
- Control of records

- Determining competency
- Design and development controls
- Control of monitoring and measurement devices
- Internal audit

These controls are absolutely necessary to maintain gains. This is the main reason why Six Sigma and lean should be integrated into your ISO 9001-based quality system.

Another reason is to clear up any confusion your employees may have regarding which directive they should follow to improve the company. In many cases, a company has been registered to an ISO 9000-based quality system prior to embarking on a Six Sigma or lean initiative. Employees then learn they will take part in projects to improve their processes through Six Sigma and lean. They may be confused as to when they should use the company's corrective and preventive action procedure and when they should use Six Sigma or lean. Worse, they may assume these initiatives are replacements for ISO 9001 and ignore the established quality system. Or, worst of all, they may think Six Sigma or lean is the next "flavor of the month" replacing the "old flavor of the month" (ISO), which lessens the credibility of all systems.

Not integrating Six Sigma and/or lean into your quality system can be destructive to your quality system, Six Sigma and lean.

How should Six Sigma and lean be integrated into an ISO 9001-based quality system?

Many ISO 9001-registered companies have a difficult time proving to their registrar auditors that they perform preventive actions. And yet, Six Sigma and lean initiatives both result in a wealth of preventive actions.

Isn't it ironic? The resources that teach us how to use Six Sigma and lean are prevalent. If we only learned about them and made them a permanent part of our quality system, we would improve our ISO 9001-based quality management system.

The following steps should be taken to fully integrate Six Sigma and/or lean into the company's quality system:

1. Write procedures and work instructions, and develop forms to describe the specific methodologies your employees will use to employ Six Sigma and lean techniques.
2. Update your corrective and/or preventive action procedure to reference these procedures and make it clear when the company's corrective/preventive action report will be used and Six Sigma or lean will be initiated. Define responsibilities and criteria within the procedure to identify which path to take.
3. Modify the design control procedure (for both products and processes) and/or the design change procedure to reference when to use design for Six Sigma and lean. Do the same for your quality planning procedure or other related documents.
4. Modify the training procedure and job descriptions/position qualifications to address competency requirements for Black Belts, Green Belts and lean experts.
5. Update the company's objectives and goals to include not just quality objectives, but also business process objectives (i.e., those that directly address future revenues and major costs).
6. Update the management review procedure/process to include status updates of lean projects and tollgate reviews (which should occur at the conclusion of each major step in DMAIC). The purpose of the review is to ensure the Six Sigma team is on the right track to achieving the original objectives and goals as defined in its project charter, to challenge the team in its data, analysis, assumptions and direction, and to ensure they have the proper

resources to continue moving forward.

7. Modify your internal audit procedure so your auditors are truly looking for opportunities to improve the effectiveness of the system in accordance with ISO 9001:2000. Use your audit procedure to determine if the controls put into place, as a result of DMAIC, are truly effective.
8. Modify your process sequences to greater specificity in the direction of a future state map.

Where do we go from here?

Obviously, it's your company's decision on how to proceed from here. As your company ponders whether it should pursue a Six Sigma or lean initiative, the first step might be to understand the potential of your company's quality system.

There are plenty of resources that explain Six Sigma and lean. Read and/or obtain training and then determine how they might fit into your quality system and company culture. Develop a plan that includes training and integration of Six Sigma and/or lean into your system.

Always remember and focus on the spirit of what is in print, whether it is ISO 9001:2000, Six Sigma or lean. As we learned from ISO 9001:2000, a certificate itself doesn't do anything for the company except cover up a blank space on the wall. This also applies to those coveted certificates held by Black Belts and Green Belts. If quality and customer satisfaction isn't increasing and lead times, inventories, waste and costs aren't decreasing, it doesn't matter if a company has five, 10 or 50 certified Black Belts and hundreds of certified Green Belts.

About the author

Mike Micklewright is president of QualityQuest Inc., a consulting, facilitating and training company based in Arlington Heights, Illinois, that specializes in the integration of Six Sigma and lean manufacturing into ISO 9001-based quality management systems. Micklewright has developed and sells video training programs entitled "The ISO Auditors Are Coming!" and "Auditing Nuts and Bolts." Micklewright holds a degree in engineering from the University of Illinois and is an ASQ-certified Six Sigma Black Belt, CQMgr, CQA and CQE.

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