

Leanovations ASQ Southern & ASQ New Haven Joint PDM

For April 16, 2014



ISO 9001:2015 Requires Embracing a Lean-ISO Culture to enjoy Profitable Growth

Based on the draft version of ISO 9001:2015, the new revision to ISO 9001, will contain many major changes. The new standard will be much less prescriptive and references several Lean management principles and tools creating a need to "Integrate" Lean-ISO by merging Lean practices into the QMS/ISO Procedures. Too often in organizations it appears the Lean and ISO efforts are at best not connected, at worse bringing conflict and complexity into an organization.

So what is Lean-ISO? Lean-ISO means an organization becomes efficient and effective by managing its way of doing things through systemizing its processes. Following a Lean-ISO process ensures that nothing important is left out and that everyone is clear about who is responsible for doing what, when, how, why and where.

To implement a "Lean-ISO" culture of pursuing continual improvement, an organization must focus on creating a "Profitable Growth Strategy". Through Lean-ISO Team events, implementing Lean and establishing standard work, where you can predict the outcome in time, quality and cost is the foundation which supports a systemized Lean-ISO process.

Lean-ISO is all about meeting what the customer values in quality requirements and applicable regulatory requirements to enhance customer satisfaction, in the most efficient and cost effective manner to enjoy profitable growth.

The International Organization for Standardization (ISO 9001-2008) introduced a revised Quality Management standard based on an emphasis on measuring customer satisfaction along with a compatibility with ISO 14001 - Environmental Management Systems.

Leanovations (where Leanovations stands for Lean + Innovations) has been teaching, coaching and guiding companies through our "Lean to Green (L2G) Process" helping companies with implementing business sustainability, in support of the ISO9001-2008 and ISO 14001, that has a positive impact on 3-P's; the People, Planet and Profits.

Come to this PDM and learn more about how Lean and ISO complement each other and see how embracing a Lean-ISO Culture at your organization with create "Profitable Growth".

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Presenter BIOs

Fred Shamburg / President

The founder and President of Leanovations, LLC was introduced to lean by one of the originators of the “Toyota Production System”, and very quickly developed a passion for teaching and applying lean principles to the total business enterprise with over 25 years’ experience in leadership and executive level positions for multinational corporations. Experienced working with organizations in diverse industries that include aerospace, medical, automotive, chemicals, government and service organizations. The Board of Examiners for the National Shingo Prize selected Fred, as a Shingo Prize Examiner in 2007. A frequent guest speaker at business and government conferences, Fred has taught Lean worldwide and in all regions of the U.S., with experience in over 20 countries and 30 states. Recognized as an international leader in successfully implementing Lean and Innovations, where Lean plus Innovations equals Leanovations.

Kimberly Cunningham / V.P. Lean-ISO Integration

Kim has over 15 years of experience in Lean and Quality as a Lean-ISO Quality Consultant, ISO quality assurance auditing, Quality Manager and Manufacturing Engineer. She has a broad spectrum of experience with multiple standards and regulations across various industries. Kim has implemented and improved Lean-ISO Quality Management Systems in support of a Lean transformation with numerous companies. Her work has included guidance through certification process, on-going ISO maintenance documentation development, Lean/ISO training, process mapping, process validation, internal auditing, supplier auditing, and standard work development. Kim’s manufacturing and healthcare background and problem-solving skills complement her quality experience in evaluating companies and identifying areas of improvement. Working with organizations with implementations and certifications of ISO9001, ISO13485, ISO14971, ISO17025, AS 9100, and ISO/TS 16949 along with providing Internal auditing and training to the ISO9001, AS9100, ISO13485, FDA CFR Title 21 Part 820 and 211, ISO14971 and GMP requirements.

