

## **Fred Shamburg**

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**From:** F. Shamburg, Leanovations, LLC <info=leanovations.com@mail72.atl11.rsgsv.net> on behalf of F. Shamburg, Leanovations, LLC <info@leanovations.com>  
**Sent:** Thursday, April 17, 2014 9:00 AM  
**To:** fshamburg@leanovations.com  
**Subject:** Leanovations Announces Lean-ISO Workshop May 28

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Leanovations Announces Lean-ISO Integration Workshop



### **1-Day Lean-ISO Integration Workshop**

**May 28, 2014**

**AT: Leanovations University**

**Rowley Spring & Stamping Corp.**

**210 Redstone Hill Rd**

**Bristol, CT 06010**

**Date: Wednesday, May 28, 2014**

**Time: 8:00- 4:00PM**

**Cost: \$250/person or \$200/person with 3+ from same company**

**To Enroll in the workshop visit Leanovations website at:**

**[www.leanovations.com](http://www.leanovations.com) or send an E-Mail to [Info@leanovations.com](mailto:Info@leanovations.com)**

**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.**

Leanovations offers a 1-Day workshop to help organizations integrate the two systems, since the change will be required anyway.

Lean and ISO are both intended to improve processes, and it is wasteful to have two different systems, driven by two different departments, in the same organization attempting to drive toward the same objectives, while not being properly integrated.

Participants will learn:

The process approach will be a key emphasis in 2015.

- ISO 9001 and Lean have always encouraged a true process approach, or value stream approach. ISO 9001:2015 will emphasize it even more, providing an opportunity for organizations to develop a culture/spirit that integrates lean and ISO 9001.

Strategic direction and organizations ability to achieve the intended outcome(s) of its QMS will be key in 2015

- ISO 9001:2015, it states that an organization must determine “its strategic direction and what is affecting its ability to achieve the intended outcome(s) of its QMS. Top management needs to understand the relationship between the overlapping requirements of ISO 9001 and Lean's Hoshin Kanri approach (strategic deployment process).

ISO 9001:2015 will focus a great deal on risk management.

- Lean tools like SWOT, which stands for strengths, weaknesses, opportunities, and threats analysis, as well as QMS failure mode and effects analysis (FMEA) will need to be used to identify and mitigate these risks

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. Through Lean-ISO Team events, implementing Lean and establishing standard work supporting ISO, providing the ability to predict the outcome in time, quality and cost is the foundation that supports a Lean-ISO culture. A "Lean-ISO" culture pursues continual improvement focusing on creating a “Profitable Growth Strategy”.

**INSTRUCTOR: 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.

[www.leanovations.com](http://www.leanovations.com)

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