



# American Society for Quality Southern CT Section 301 October 10, 2018



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**Wednesday October 10, 2018**

## **How to Plan for Reliability Growth throughout NPD**

**Location:** Blue Goose Restaurant – 326 Ferry Blvd (CT 130) in Stratford

**Directions:** *From the South:* Take US 95 to exit 32, keep right at end of ramp, left on Main Street, then immediate right turn, continue to stoplight, then left turn onto Ferry Blvd, restaurant will be a short distance on your right.

*From the North:* Take US 95 to exit 34, follow Post Road west (US 1) about 1.5 miles to merge with CT 130 (Ferry Blvd), restaurant will be on your left

5:30pm. - Informal Networking

6:30 p.m. - Dinner

7:30 p.m. - Presentations

Cost: \$ 25

RSVP by October 9th to [tomane723@aol.com](mailto:tomane723@aol.com)

Summer is over, so it's time to do a little personal development and have one of the Blue Goose's outstanding meals. I usually go for the prime rib but, there are other, and perhaps healthier, alternatives. See you there!

## *About Our Meeting*

I will go over how we implemented a Reliability Growth Test Strategy on our Signia™ Powered Stapling products. I will talk about the culture shift that we encountered when Medtronic decided to go from single use disposable stapling products to re-usable products. What is needed for a good Reliability Strategy to be successful and finally what we planned vs. what we actually did. I will also bring some product for demo purposes

## *About OUR Speaker*

Michelle Grasso brings 20+ years of Reliability Engineering and System Integration and Test Experience from Pitney Bowes where she worked on highly complex serviceable mailing machines and inserters. For over 6 years, she has been with the Medtronic Surgical Innovations group where she has been growing the Reliability Engineering department in North Haven, Connecticut. To further raise awareness of the importance of Reliability Engineering, she has taught multiple courses for her peers. She has orchestrated the development and implementation of tools such as issue tracking and test tracking at both Pitney Bowes and Medtronic to improve the New Product Development process. Michelle has a B.S. in Industrial Technology and has held her ASQ CRE since 1998.

## *ASQ Transformation*

Check out the video at <http://media.asq.org/105051/web.mp4>

Mike D'Onofrio

## *Programs*

*Locations and dates, usually the second Wednesday, subject to final confirmation in monthly newsletters)*

## *ASQ Certification*

Certification prep courses run in the fall, winter, and spring. For details on certification, see [www.asq.org/certification/](http://www.asq.org/certification/) to confirm dates and register for the certification exams.

For further information, please contact Mike D'Onofrio at

[mikedonofrio301@yahoo.com](mailto:mikedonofrio301@yahoo.com), or 203-570-3657

## *Section News*

Nominations for Leadership positions for next year are due. If anyone is interested in serving the section, October would be a good time to speak up show up. It can be a rewarding experience

## *Standards Update*

September 15 is come and gone and most people have been navigated the conversion to ISO 9001:2015 and ISO 14001:015. Overall, it was reported that there was a 5% reduction in the number of ISO 9001 certificates worldwide.

The announcement by the FDA that it will use ISO 13485 in replacing its [current quality system regulation](#), is an important next step in the recognition this standard has already gained globally. Wil Vargas of the Association for the Advancement of Medical Instrumentation ([AAMI](#)), and Secretary of ISO/TC 210, said “this announcement will take global harmonization of regulatory requirements in the medical devices sector to a next level”.

[ISO 19011:2018](#), Guidelines for auditing management systems has been released. Denise Robitaille, Chair of the ISO project committee<sup>D</sup> that revised the standard, said it was updated to ensure it continues providing effective guidance to address changes in the marketplace, evolving technologies and the many new management system standards recently published or revised.

## *Development Opportunities*

Did you know that ASQ has created a library of videos answering the quality questions you face every day? Free for members, [ASQTV](#) covers organizational excellence, quality standards, team success, lean, and much more. Listen to an expert speak on changes in quality from the convenience of your office or home, on any computer or mobile device!

APICS New Haven, a joint meeting with ASQ New Haven. "Artificial Intelligence & The Supply Chain" presented by Dr Dave Cadden and John Sawyer. Wednesday October 17, 2018 from 5:00 PM to 8:00 PM EDT at Honeywell Fire Safety 12 Clintonville Road Northford, CT 06472. Go to their website for details



## ***Achieving and Sustaining a Culture of Excellence in a Global Environment***

Royal Plaza Hotel & Conference Center

This year, the 62<sup>nd</sup> ASQ NEQC Conference meets in Marlborough, MA on ***October 23-24, 2018***.

At this conference, you will enjoy four tracks each day, covering a wide variety of topics:

- Leadership
- ISO
- Process
- Special Communications
- Improvement
- Tools
- Excellence
- Medical/Pharma

*Sign up for the pre-conference seminars on Monday, October 22nd:*

- **Course 101: Medical Device Audit MDSAP and ISO 13485:2016**
- **Course 103: Implementing Risk-Based Thinking Simplified**

This year's conference theme is "Achieving and Sustaining a Culture of Excellence in a Global Environment." NEQC is pleased to bring speakers and trainers to our conference to help professionals and practitioners find what it takes to improve performance in this ever-changing global economy. Our speakers are experts by whom you will be inspired, and their motivational messages will guide you on a path of innovative improvements of endless possibilities. Time is running out to register.

**Don't miss it!!**

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