



Jodi Sutherland <jodilynsutherland@gmail.com>

Please join ASQMV and Masy Systems Inc, Keith Kelly, John Coolidge and John Masiello for an Operational Overview - March 6th at the Alpine Grove, Hollis, NH

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ASQMV Quality News



March 2014



Merrimack Valley
Section
ASQ The Global Voice of Quality™

March ASQMV Meeting
Thursday, 6 March 2014
Guests Welcome!

www.asqmv.org

February Section Meeting Summary

Carousel Brainstorming

Results

How do we grow our section?

J. Kulungian and J. Hamilton

1. How do we increase section meeting/workshop attendance?

- Provide incentives
- Change locations
- New audiences
- Communications
- VOC topics

2. What new topics or programs are of interest to the members?

- Quality Management
- Soft Skills
- Quality Tools
- Standards
- Process Quality
- Quality Audits

3. What is the best method of communicating?

- Outlook Calendar
- Email reminder
- Social Media
- Create an App

4. Why do we have 120 unpaid members?

- Ensure contact information is clear
- Manage renewal process
- Get companies to pay
- New pricing techniques
- Establish special status

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Creating?
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Masy Systems Inc.
Biorepository Operation Tour

Quality is an integral partner in every aspect of Masy's biorepository operation, from equipment calibration and process validation to product handling and storage environment. Keith Kelly will review a few of the key roles and techniques used by the quality department in supporting these activities.

Calibration and Validation are key components in the biorepository operation. John Masiello will discuss training, standards, traceability, tolerance, interval and reporting.

Day to day operations and processes in the biorepository will be discussed by John Coolidge. Topics will include work instructions, training, product handling, temperature excursions, customer notification and audits.

Speaker Biographies

Keith Kelly

Keith's formal education is in Computer Science from the University of Massachusetts in Lowell. He started his career in applications development for a temperature monitoring and recording manufacturer, where he gained his first experience with equipment calibration and chamber validation principles. From there Keith progressed into project management and product development until, in 2000, he transitioned to the role of Quality Assurance, and has worked in this profession ever since.

Keith is the Vice President of Quality at Masy Systems, Inc. where he has worked for over twelve years. He is a senior member of the American Society for Quality (ASQ), and is an ASQ certified Manager of Quality/Organizational Excellence (CMQ/OE) and certified Quality Auditor (CQA).

John Coolidge

John Coolidge is the Biorepository Manager at Masy Systems. He has been at Masy for over 5 years and has overseen the development of the Biorepository since its beginnings. He wrote procedures, participated in audits, and grew the biorepository to a staff of ten. The Biorepository is a controlled temperature storage facility that provides cGMP storage to the pharmaceutical and life sciences industry at a range of -196°C to 60°C. John has a degree in Chemical Engineering with Nuclear Engineering interests from Worcester Polytechnic Institute in Worcester.

John has participated in industry conferences and shared best practices by speaking at the Annual Biorepositories and Sample Management Conference, the Annual Biobanking Americas Conference, and the Pharmaceutical Packaging Leadership Summit.

John Masiello

John Masiello is the founder and Executive Vice President of Masy Systems Inc., which provides Validation and Calibration services,

Leadership Team!
For more information:
[EMAIL US.](#)

ASQMV

Leadership Committee 2013-2014

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monitoring systems, equipment rentals and biopharma storage services. He is a recognized industry expert in thermal mapping and chamber validation, and has been in these industries since 1988. He has provided training, consulting, Validation and Calibration services to many major pharmaceutical, biotech, medical device and validation companies throughout his career.

John was educated at Wentworth Institute in Boston with a degree in Electrical Engineering. He currently serves as a Member at Large in the New England Parenteral Drug Association (NE PDA) and has been a member since 1991. He has been a long- standing member of other industry organizations such as the International Society of Pharmaceutical Engineers (ISPE), Instrument Society of America (ISA), and the National Conference of Standards Laboratory (NCSL). John volunteers in his hometown on the Economic Development Advisory Committee (EDAC) whose purpose is to stimulate business growth in the area.

Register Here !!

Cost: \$25

Schedule

Registration will open at 6pm and buffet served at 6:30pm at Alpine Grove in the Skylight Room.

Location

Alpine Grove
19 S Depot Road
Hollis, NH 03049

Directions

From Route 3 North or South
Take Exit 5W (Route 111 West)
Follow for 4 miles
After entering Hollis, take a left onto Route 111A (at the light)
The entrance to Alpine Grove is your second right turn

Buffet Dinner Menu

Warm rolls and butter
Garden salad
Stuffed chicken roulades with veloute sauce
Roast top round of beef with espagnole sauce
Fresh vegetable of the day
Red bliss garlic mashed potatoes
Chef's choice of dessert
Coffee and tea service

Leadership Team New Member Introduction *Jeff Johns*

The ASQMV Leadership Team is pleased to welcome Jeff Johns and introduce him to the ASQMV section.

In his assignment Jeff will serve as Voice of Customer Chair and promote member unit and society research opportunities, participate in

Calendar

Section Meeting Dates

6 March 14

3 April 14

12 May 14

5 June 14

Exam Dates

1 March 14

7 June 14

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questionnaire development and conduct VOC analysis which will provide useful and applicable information to the section and the Society in support of our growth.

Jeff is an ASQ Certified Quality Engineer (CQE), Auditor (CQA), and Six Sigma Black Belt (CSSBB) with over 25 years of experience working in medical devices with companies like USCI, Becton Dickinson, Boston Scientific, and Medtronic. He has focused his career on helping companies meet FDA and ISO 13485 regulatory requirements by improving their quality systems to meet compliance but to also add value to the company and customers.

His most recent position was with Infraredx, a start-up coronary imaging company, where he used customer complaint analysis to drive product reliability improvements.

Jeff has a B.S. in Environmental Science, and before going back to school to work on a MA in Biology, briefly worked for the Boy Scouts of America as a district executive.

Jeff's favorite pastimes are hiking (NH 4,000 Footers Club), nature photography, and sailing on Lake Winnepesaukee.

Merrimack Valley Quality Professionals,

Please provide your feedback on this newsletter as we continue to evolve it into a primary communication tool.

Please send any of your feedback to asqmv@asqmv.org.

We look forward to seeing you March, February 6th at the section meetgin.

Regards,
John Kulungian
ASQMV Chair

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