

# Let's Talk Quality!



Worcester  
Section

EDITOR: BARBARA BUTRYM (BARBARA.BUTRYM@VERIZON.NET)

February 2010 Edition



The Leadership Committee would like to apologize for the technical difficulty with the web site. Please bear with us through this difficult time as we improve the site performance

## February Dinner Meeting Thursday, February 18, 2010 Marlboro Marriott Courtyard.

5:30pm  
Pre-Dinner Topic

6:15pm  
Dinner

7:30pm  
After-Dinner Topic

Cost: \$25.00

Unemployed/Students: \$15.00

Reservations:

Please go to our website [www.asqworchester.org](http://www.asqworchester.org),  
call 774 854-0681 or e-mail- [tombilodeau@azz.com](mailto:tombilodeau@azz.com)

### **NOTICE: The Worcester Section of the American Society for Quality purchase/refund policy:**

You may cancel your prepaid registration by email prior to noon of the Monday preceding the event and receive a credit toward admission to the following meeting. No refunds are issued and no credit toward the following meeting is made after noon of the preceding Monday because attendance/payment commitments to vendors have been finalized.

You may cancel your pay at the door registration by email prior to noon of the Monday preceding the meeting. For cancellations after noon of the Monday preceding the meeting and "no shows", an invoice for the cost of the dinner will be sent to the registrant.

## **Before Dinner February: Management Review in the Medical Device Industry**

Betty Lane has over 20 years experience in Medical Device quality assurance and regulatory affairs. She has established or updated quality systems for numerous small and medium sized medical device and diagnostic companies. Her accomplishments enabled these companies to manage their business in compliance with FDA and ISO 13485 requirements, allowing worldwide sale of their products. Her background in digital systems engineering, enables her to understand and communicate with technical individuals on design controls, process validation, and software validation.

## **After Dinner February : Battling Burnout**

Successful quality initiatives depend on employees. Without their participation, support, and implementation assistance, a quality program can stall in its tracks. In this case study presentation, we will look at what one company did to engage employees amidst tumultuous circumstances. The company needed to retain 250+ employees that had been given tentative layoff dates up to 12 months into the future. Additionally, the company had to maintain employee cohesion, productivity, and focus while shutting down an entire division of its business. We will identify how the company maintained 98% retention, increased commitment to customer

service, and shared years of collective knowledge with the new service provider who, in essence, was taking their jobs. We also look at how the technology group implemented quality standards in software development during its own challenging layoff process. Participants will gain practical, proven tools for engaging employees during difficult times.

**About the presenter: Maya Townsend**

Maya Townsend, founder of Partnering Resources, helps clients form an accurate picture of current challenges, imagine possibilities for the future, and mobilize energy for change. She specializes in helping technology leaders identify the hidden web of relationships that drive organization performance, build internal and external alignment, and reach across the white spaces to develop solutions that stick. A presenter and author on organizational complexity, Maya believes that today's organizations require different thinking and competencies than in the past



**WELCOME NEW MEMBERS!**

- Tarah A. Bushee
- Jay Chou
- Jenny Fern
- Shane D. Gerson
- Carol Graves
- Deborah M. Hervieux
- Laura F. Ouimet
- Stacie A. Partlow
- Michael R. Pousland
- Raj Rangaraj
- Christian Andrew
- Svejk

**Special Congratulations to our new Senior members:**

- Michael Butkus
- Matthew Jennings
- William Martin
- Kashif Sheikh
- Firmin Sillo
- Sam Stimson
- James Worth

**Tips for New Members**

**Bring a colleague to the meeting**

**Share the newsletter with your company**

**Suggest a topic for a training event at your facility, get a free seat.**

**Reap the Benefits, Share the Successes**

**Volunteer**

## ????????????? Quality Question of the Month ??????????????????

Well, it's time again for the questions to begin, hope you have some saved up from the summer newsletter break. Send them to me at [Barbara.butrym@verizon.net](mailto:Barbara.butrym@verizon.net). The topic is up to you. This is your column. I look forward to the input. Let's see if I can drum up some interest.

**Barb, I just started a new job in a small medical devices company. They are due for their surveillance audit the end of the month. They haven't had anyone watching the store for almost a year. Where do you suggest I start to get the best bang for the buck?**

**Thanks, Stephen**

Well, Stephen, basically, you will need to take the medical device standard, and do a strong internal audit. Concentrate on stuff that has occurred in the past year especially invasive equipment. Write up a full detailed report and issue corrective actions. Then chip away at any majors/system breakdowns.

This will do a couple things, it will give the auditor confidence that you will be on top of things now that you are there. It will show commitment on your part. It will also allow you to prioritize your findings. It may even drop a major to minor, or a minor to an observation. How much will be auditor dependant.

Take the last registrars audits and determine what areas have not been audited in the last 2 visits. You can almost ensure they will be audited this time. Audits, Management Review, CA/PA, continuous improvement, customer complaints and probably risk management are usually a given as well. Pay attention to those first.

Hosting it will be the key. You need to set the tone. Hospitality and Honesty will go a long way. Leave your dancing shoes at home. Be humble and accepting. Tell the auditor up front that you are new, and have "great plans" for improvement. Tell him you are looking forward to learning from him. Tell him you've done a round of audits to get a handle on things and found some issues but you are proactive and have a plan, and there is a lot of work to do but you are up for the challenge and actually look forward to it. Be sincere. This is my advice, having been on both sides of this situation. Without knowing what problems you run into there isn't much more I can offer except make the system work for you. You may be pleasantly surprised. A good system can sustain even without a watch dog.

.....Till next time, *Barb*



## UPCOMING ELECTIONS

### Nominations for 2010/11 Worcester Section ASQ Officers

The Worcester Section ASQ Nominating Committee presents the following slate of candidates for 2010/11:

Chair – Bill Hackett  
Chair-elect – David Potty  
Vice chair – Barbara Butrym  
Treasurer – Roger Carl  
Secretary – Chet Kruegar

Nominations for these elected positions may be presented by the general section membership. General section membership nominations require the submission of a nomination petition to the section secretary, Carol Beauchesne, prior to February 18, 2010. The petition requires a minimum of 10 (ten) signatures from Regular Members.

ASQ Worcester Section Contacts 2009-2010		
Position on the Board	Email	Phone
<b>Chair</b> Chet Kruegar	<a href="mailto:ckruegar@hydertools.com">ckruegar@hydertools.com</a>	508-764-4344 Ext. 2271
<b>Chair Elect</b> Bill Hackett	<a href="mailto:billhackett@vpsi-ma.com">billhackett@vpsi-ma.com</a>	508-753-2900 Ext. 1322
<b>Vice Chair</b>		
<b>Treasurer</b> Dan Daigle	<a href="mailto:dan.daigle@metso.com">dan.daigle@metso.com</a>	508-852-0215 Ext. 2372
<b>Secretary</b> Carol Beauchesne	<a href="mailto:cbeauchesne@fostercomp.com">cbeauchesne@fostercomp.com</a>	860-928-4102 Ext. 157

### **Recertification Reminder**

Do You Have a Recertification Due?

Do you have more than one certification you'd like to synchronize?

Please contact me with any questions and send me your recertification packages

Tom Murtagh

1042B Waverly Street

Framingham, MA 01702-8425

Email: [tmurtagh99@aol.com](mailto:tmurtagh99@aol.com)

## Letter from the editor

Well we're into another year. Where does the time go? January was gone in a flash. Even looking back at it seems like it was over in 7 days instead of 31. Seems like the whole month was spent in my office or sleeping. Of course there was a reason for that ...we had our AS9100 registration audit the first week in February. We were successful...so it was all worth it.

Funny how things creep up on you. DEADLINES

As stressful as they are, they drive me. Without a deadline I have no drive, just go through the motions. Why is that? I remember as a kid I always waited till the last minute too. One particular time I did a wind machine, had weeks to do it...BUT I chose to do it 9pm the night before it was due with stuff hanging around the house..... much to my mother's dismay..... She said I would get the failing mark I deserved...but I got an A. Talk about copping an attitude!!!!

I have gotten better over the years, lost some of my attitude and now I don't wait till the witching hour, but I still love the deadline. If I don't have one, I'll give myself one and make a game of beating it. Wonder why I do that? Am I alone?

### "The Funny Side" By Roger Simmons

