



**Worcester
Section**

Let's Talk Quality!

www.asqworchester.org

APRIL 2008 Newsletter
Amy Powers, Editor
apowers@essilorusa.com

Cost: \$25.00
\$15 for
Unemployed/students
Reservations:
Please go to our
website
www.asqworchester.org

April Dinner Meeting

*Thursday,
April 17, 2008
Leo's Ristorante
11 Brackett Court
(off Shrewsbury St.)
Worcester, MA
Dinner Menu: Buffet*

5:30pm-6:15pm
Social & Networking
6:30pm
Dinner
7:30pm
After-Dinner Topic

Pre-Dinner Social & Networking

Come and "spring" into our April Dinner Meeting with time to socialize and network with your fellow ASQ Worcester Section Members. Bring a friend!

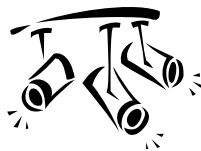
After Dinner Topic **Successful Inspections: ISO 13485 and FDA** **By Art Rankis**

Executive Management measures the success of Quality Systems and Quality Departments in various ways. Success in certification and regulatory inspections is always a primary measure.

This presentation is built upon the experiences, successful and unsuccessful, of companies manufacturing Medical Devices, and their suppliers. It contrasts ISO 13485 and FDA inspections, and examines the key success factors for each.

Bring your recent ASQ Certification for FREE dinner, FREE framing and recognition at the April ASQ Worcester Section Dinner Meeting!
If you're interested in participating, register for the April Dinner Meeting on our website at www.asqworchester.org

For information on Programs contact
Carol Beauchesne
cbeauchesne@fostercomp.com
860-928-4102



Speaker Bio



After Dinner



A. Arthur (Art) Rankis, President of A. A. Rankis & Associates, Inc., has over 25 years of US and international Medical Device experience in Quality and Regulatory Affairs. He has been consistently at the forefront of implementing new regulatory and quality requirements: the original US GMPs, MDR, ISO 9001, QSR, MDD-CE, ISO 13485, CMDCAS and others. Art has extensive experience in: quality system implementation, improvement, and repair; interacting with regulatory agencies; auditing and being audited; supplier management; regulatory strategies and submissions (510Ks, Technical Files, etc.); and has successfully guided many companies through FDA, CE and other international inspections, issues, and regulatory approvals.

Art uniquely brings practical and workable solutions to Quality and Regulatory challenges working with companies that range from 2 person startups to multinationals. He also teaches companies in areas such as Managing FDA and CE inspections, Auditing, Quality and Regulatory Fundamentals for Medical Device Companies, Design Control, Validation, Risk Management, Sampling Plans-SQC, and other subjects.

Prior to establishing his consulting practice, Art held the leadership position in Quality and Regulatory for Bausch & Lomb Inc., Millipore Corp., Smith & Nephew Inc., HemaSure Inc., Cytoc Corp., and Insulet Inc.

Art is a senior member of ASQ, founding board member of the ASQ Biomedical Division's New England Discussion Group, is on the Independent Certification Board of NQA-USA, a US based Quality System Registrar, was on the Board of Examiners for the Malcolm Baldrige National Quality Award, was a member of the AAMI-Blood Filtration Committee, and is a long time active member of RAPS, AAMI, and ASQ. Art has a B.Sc. degree in General Science and Education from the Vermont State College at Lyndonville VT, an Associates degree in Quality from the Ryerson Polytechnic Institute in Toronto, Ontario and he is an ASQ certified Quality Engineer.

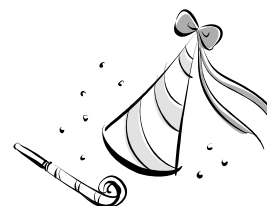
Art is often requested to speak on various areas of his expertise, and has authored several publications.

The ASQ Worcester Section has Achieved the Total Quality Level 2006-07 Section Management Process

By achieving the highest level of the SMP (Section Management Program), our section has achieved the Total Quality Award for 2006-2007! Our Chair for 2006-2007 was David Potty.

You have all helped make ASQ what it is today!

Congratulations ASQ Worcester Section!



March Dinner Meeting Wrap-Up

Before dinner, Jack Reardon, Senior Consultant for Quality and Productivity Solutions, spoke to us about DMAIC Process. DMAIC process is the best way to achieve breakthrough results.

He explained DMAIC vs. PDCA (Plan, Do, Check, Act Cycle). DMAIC is better for complex, difficult problems. PDCA probably will not achieve the breakthrough improvement that DMAIC does. Improvements made following the PDCA process are usually incremental and PDCA is usually more reactive.

DMAIC steps:

Define: Define the problem that is being addressed.

Measure: Establish a baseline – what is the cost?

Analyze: Use statistical tools to analyze the problem and research solutions.

Improve: Incorporate improvements and verify results.

Control: Once problem is resolved, controls are put in place to make sure the process stays in control and improvements are sustained.

Jack reviewed the tools used at each DMAIC phase and talked about some of the improvements made in the companies he's worked with. In conclusion, he emphasized the importance of management support. Without buy-in from management, it is difficult to make and sustain improvements. He also stressed how important lean/six sigma is to companies in order to be competitive with China.

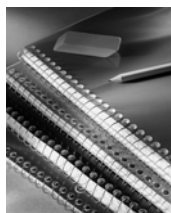
After dinner, David Potty, Principal Consultant, Value Added Quality Services and Senior Consultant for Quality Support Group, spoke to us about getting people to use quality tools.

David's presentation was inspired by two books: *It's Your Ship* by Capt. D. Michael Abrashoff and *Seeing David in the Stone* by James E. Swartz and Joseph E. Swartz.

David identified some steps to take when trying to get people to use quality tools. It's important to *choose the correct tool*. If you're not using the right tool, you're wasting your time. Some things to consider when choosing tools are to determine which tool will add value, which tool do people know how to use, and if it make sense to use that particular tool.

It's also important to provide leadership and take command by remembering it's important to treat people with dignity. People need to be encouraged. Also, remember that it is important to always have fun. A person needs to lead by example. If you're not using quality tools, you can't expect anyone else to.

In conclusion, it's important to use the right method for getting people to use quality tools. A popular, but unfavorable, method is forcing people to use them. No one likes to be forced to do something. It just doesn't work. Remember, we're all in this together. One solution could be to tie in using these tools into the quality objectives or make it part of yearly reviews. The best and most effective method of getting people to use quality tools is to mobilize support – involve others. There are three types of people. The first type is those who are eager stakeholders and support what they create because they're involved in decision-making. The second type is cautious stakeholders that like things the way they are. The third type is the opposers who don't want any part of change. Consider the tools and methods to be used in being successful with implementing the use of quality tools in your organization.



**WORCESTER SECTION
RICHARD C. OLSON
SCHOLARSHIP AWARD PROGRAM**



Applications are now being accepted for the Worcester Section Richard C. Olson Scholarship Award. The award is a \$500 scholarship.

Eligibility:

1. Each candidate must be accepted for enrollment or currently enrolled in an accredited college, university, or technical school in which the completion of studies will result in a two year or four year degree or certification.
2. Each applicant must be sponsored by and be a direct family member (child, stepchild, spouse) or a fully supported dependent of a current member of the Worcester Section, ASQ.
3. Applicants cannot be sponsored by a member of the Worcester Section Scholarship Committee or Committee Chairperson nor can they be a relative, family member, or other dependent of this committee or Committee Chairperson.
4. Graduate students are not eligible for this award.

Procedure

Request an application form and submit it along with

- a copy of the most recent school transcript or scholastic record
- a copy of the acceptance letter from the educational institution (for entering freshman)
- a photocopy of both sides of the sponsoring ASQ member's membership card
- an original essay (from 250 to 500 words, type written) on the topic of "Quality" as it relates to the applicant's daily experiences, career, life style, or philosophy.

Incomplete applications will be accepted but will be penalized by the scoring procedure.

Applications must be postmarked no later than June 30, 2008.

Request applications from or direct any question to:

David Potty
72 Stoney Brook Drive
Whitinsville, MA 01588
Phone (508) 344-7113
Email: dpotty@charter.net



**Worcester
Section**

Welcome New Members!



**Tray Collins
Bijal Doshi
Matthew Garvey
Peter Hopkins
Arthur Laman
Chad Percival
Jennifer Sullivan
Stephen Woodworth**



***If you have not been attending monthly dinner meetings
contact us and let us
know what we can do to help!***



www.asqworchester.org



**Coming to the ASQ Worcester Section in
May!**



Plant Tour – Foster Corporation, Putnam CT

For nearly 20 years, Foster Corporation has been at the forefront of developing and manufacturing state-of-the-art material solutions based on extremely precise polymer technologies, with a special focus on serving the medical, pharmaceutical delivery, and bio-technology sectors worldwide.



ASQ Worcester Section Refresher/Prep Classes for April to June 2008

Start Date	Schedule	Location	Instructor	Cost	Exam Date
April 8, 2008	Six Sigma Green Belt <i>Tuesday</i> <i>Nights for 8</i> <i>weeks -</i> <i>5:30p.m to</i> <i>8:00p.m</i>	Bose Corporation – 1 New York Ave, Framingham, MA	TBD	\$425.00	June 7, 2008
April 9, 2008	Quality Improvement Associate <i>Wednesday</i> <i>Nights for 8</i> <i>weeks -</i> <i>5:00p.m to</i> <i>7:00p.m.</i>	Bose Corporation – 1 New York Ave, Framingham, MA	Al Scorza	\$400.00	June 7, 2008
April 9, 2008	Quality Auditor <i>Wednesday</i> <i>Nights for 8</i> <i>weeks -</i> <i>5:30p.m to</i> <i>8:00p.m</i>	Future Electronics Bolton, MA	Dave Potty	\$425.00	June 7, 2008
April 8, 2008	Software Quality Engineer <i>Tuesday</i> <i>Nights for 8</i> <i>weeks -</i> <i>5:30p.m to</i> <i>8:30p.m.</i>	Bose Corp 1 New York Ave, Framingham, MA	Darin Kalashian	\$525.00	June 7, 2008

Information regarding registration to these refresher/prep classes and certification exams can be found on next page.

<p><u>Recertification Reminder</u></p> <p>Do you have a recertification due?</p> <p>Do you have more than one certification that you would like to synchronize?</p> <p>Please contact me with any questions and your recertification packages.</p> <p>Tom Murtagh 1024B Waverly St Framingham, MA 01702-8425 E-mail: tmurtagh99@aol.com</p>
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Register for Certification Refresher/Prep Classes:

Two ways to register for Certification Refresher/Prep Classes:

- Register on Line at www.asqworchester.org/certification/
- Download and print the ASQ Worcester Section Registration form found on our web site at www.asqworchester.org under certification.

Make check payable to ASQ Worcester and mail to:

Al Scorza

P.O.Box 136

Uxbridge, MA.01569.

Two ways to register for Certification Exam:

- Register online at <http://www.asq.org/certification/apply.html>
- Call 1-800-248-1946
- Each student is responsible for filling out their own certification application form and registration for the exam.

*Please Note: The Certified Quality Manager Certification is now called *Manager of Quality / Organizational Excellence*



ASQ Worcester Section Elected Executive Leadership Committee 2007-2008			
Name	Position	E-mail	Business Phone
Kim Rice	Chair Placement Chair	RiceSunnyg@aol.com	---
Diane Dixon	Chair Elect SMP Chair Program Committee	Diane.Dixon@future.ca	978-779-3000 ext. 3859
Amy Powers	Vice Chair Newsletter	apowers@essilorusa.com	508-943-3860 ext. 484
Chester L. Kruegar Jr.	Secretary Auditing Contact Person	ckruegar@hydertools.com ckruegar@charter.net	508-764-4344 ext. 2271
Roger Carl	Treasurer	carlr@tycoelectronics.com	978-442-4053