

# Quality Quest

[www.time2meet.com/asq1508/index.shtml](http://www.time2meet.com/asq1508/index.shtml)

April 2006 Volume 47 Issue 8

## ASQ Section 1508 St. Petersburg/Tampa

APRIL MEETING  
Monday, April 10, 2006

**Speaker: Mick Howk, Medical Device Manager, BSI Systems  
Review and History of Quality Management Systems**

### The Evolution and Development of Registration Schemes

Over the last 15 years the requirements of ISO 9001 have changed dramatically and have been modified for use by specific interest groups. The purpose of Mr. Howk's presentation is to provide a broad overview of the development of "spin off" standards, what they are and which industries are using them. A brief overview of the Who, What, Where and When of the following standards will be presented: ISO 9001, ISO 13485, ISO/TS 16949, AS 9100, BS 7799, OHSAS 18000 and TL 9000.

*Mick Howk is the Medical Device Manager for BSI Management Systems, covering the eastern United States and the Caribbean. He manages new and existing accounts for ISO registered companies in the region and CE marking of medical devices. Mick has over 30 years experience in the quality management field. He is a Professor of Quality Management for the University of Phoenix and holds degrees in Industrial Engineering and Management. Mick also holds certifications from the American Society for Quality in Quality Engineering, Quality Auditing and is a Six Sigma Black Belt.*

Submitted by Steve Babb, Programs Chair

## **A MESSAGE FROM YOUR CHAIR**

“We have only this moment,  
sparkling like a star in our hand....  
And melting like a snowflake.  
Let us use it before it is too late.”

- Marie Beyon Ray

We elected a new slate of officers (Chair, Treasurer and Secretary) at the March 13 meeting. The Section 1508 officers for the ASQ 2006-2007 year that runs from July 1 2006 to June 30 2007 are:

Steve Babb – Section Chair

Heike Johnson – Secretary

Glen Cavanaugh – Treasurer

Our latest workshop series continues to evolve according to the needs of our members. The remaining three workshops cover topics that are both timely and technically relevant. The workshops are described in the “News Flash” area of our web site and are included in this newsletter. Be sure to make a reservation with Alain Gaumier, our Education Chair for any workshop that interests you. Don’t let this opportunity to attend a free workshop pass you by.

We extend our thanks to Bob Rhyder, President, Rhyder Associates, Inc. for his presentation on Process Optimization via DOE & MRAT’s (Multiple Response Analysis Tables). His example of the use of DOE to improve the manufacturing process provided a striking example of how the use of this powerful statistical tool can indicate critical control factors that are not intuitively obvious.

We are still in need of new board members. The board meets each month at 4:30 prior to the regular meeting. No reservation for the Board meeting is required.

If you have a suggestion for a speaker or subject, or would like to assist with the meeting programs, please contact Steve Babb our 2006-2007 Chair elect and Programs chair.

Once again, this year marks the 50<sup>th</sup> anniversary of the founding of ASQ (originally ASQC). The society presently has a worldwide membership of nearly 100,000 members. Section 1508 joined the national ASQ in 1958 and will celebrate 50 years as a section in 2008.

Ed Pagnott

Section 1508 Chair for 2005 / 2006

**ASQ Section 1508 St. Petersburg/Tampa**  
**Next Meeting: *Monday, April 10, 2006***  
***Hilton Tampa Airport Westshore***  
***2225 North Lois Ave***  
***Tampa, FL.***

Due to the board meeting running from 4:30-5:30, Registration for the meeting will not start until 5:30.

**5:30pm**            **Registration**  
**5:30-6:00pm**   **Appetizers/Networking \*\***  
**6:00- 6:30**       **Pre-Dinner Topic**  
**6:30pm -7:30**   **Dinner**  
                         **Dinner Menu:** Jack Daniels Sliced Sirloin  
                                            Roasted Red Potatoes and Vegetables  
                                            Vanilla Ice Cream

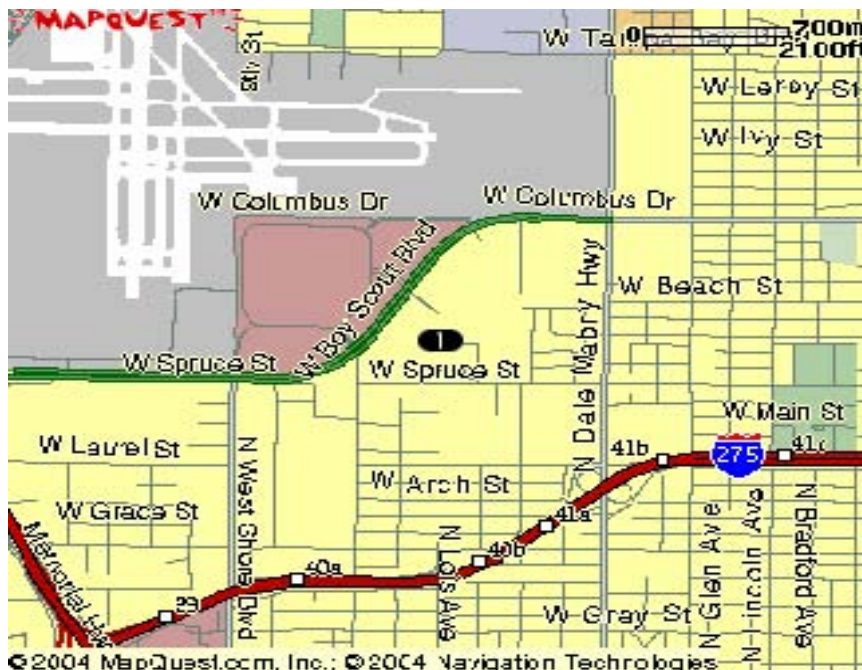
**7:30pm-8:30** – **Speaker**

**\*\* Appetizers are provided at no cost to members by the section. \*\***

**Directions :**

.FROM 275 NORTH TAKE EXIT 40B/LOIS AVE. WHEN EXITING TURN LEFT ONTO LOIS AVE. HILTON IS LOCATED 1/2 MILE ON RIGHT.

FROM TPA - FOLLOW AIRPORT EXIT TO SPRUCE STREET TO THE THIRD LIGHT- LOIS AVENUE. TURN RIGHT AND THE HOTEL IS ON THE LEFT.



**On-line Reservations: [www.time2meet.com/asq1508/index.shtml](http://www.time2meet.com/asq1508/index.shtml)**

**Reservations should be made by 4:00PM, Thursday, April 6, 2006**

**If you experience a problems using the website for making a reservation, send an e-mail with your phone number, company name and address to Heike.**

**[Heike @ e-imagestudios.com](mailto:Heike@e-imagestudios.com)**

Cancellations should be made by noon on the Friday before the meeting but every effort will be made to accommodate late cancellations. If you have a special dietary request - vegetarian or low fat. - please indicate this at the time you make your reservation. \$20.00 per member with a reservation or \$25.00 at the door for guests and members without a reservation. **Only cash or check accepted at the door.**

If you make a reservation and do not attend, the section must still pay for your meal.

In this event you should reimburse the section by sending a **check**, payable to ASQ, for \$20.00 to our treasurer,  
**Glen Cavanaugh, 9212 Rustic Pines Blvd. W, Seminole, FL. 33776**

## **Recertification**

### **Recertification Chair: Heike Johnson**

Please send all recertification packets to:  
Heike B. Johnson, ASQ 1508 Recertification Chair  
e-image Digital Studios, Inc.  
2106 Climbing Ivy Drive  
Tampa, FL 33618-1709

To contact Heike for questions, her e-mail address is as follows: [Heike@e-imagestudios.com](mailto:Heike@e-imagestudios.com)

## **CERTIFICATION EXAM DATES 2006**

<b><i>EXAM</i></b>	<b><i>EXAM DATES</i></b>	<b><i>APPLICATION DEADLINE</i></b>
CQE, SSGB, CSQE, CQA, CQIA, CCT, CQPA	June 3, 2006	April 7, 2006
SSBB, CBA, CRE, CQT, CMI, CHA, CMQ/OE	October 21, 2006	August 18, 2006
CQE, SSGB, CSQE, CQA, CQIA, CCT, CQPA	December 2, 2006	October 6, 2006

CBA - Biomedical Auditor Certification  
CCT - Calibration Technician Certification  
CHA - HAACP Auditor Certification  
CMI - Mechanical Inspector Certification  
CMQ/OE - Manager of Quality / Operational Excellence  
CQA - Quality Auditor Certification  
CQE - Quality Engineer Certification  
CQIA - Quality Improvement Associate  
CQPA - Quality Process Analyst Certification  
CQT - Quality Technician Certification  
CRE - Reliability Engineer Certification  
CSQE - Software Quality Engineer Certification  
SSBB - Six Sigma Black Belt Certification  
SSGB - Six Sigma Green Belt Certification

## Additional Section News

- Elections were held at the March General Membership meeting on March 13, 2006. Officers for the 2006-2007 year are as follows :  
Steve Babb (Chair)  
Glen Cavanaugh (Treasurer)  
Heike Johnson (Secretary)  
The remaining board positions are appointed.

\*\*\*The board is always welcome to new ideas and additional volunteers.  
If you are interested, please contact Steve Babb. \*\*\*

- A survey was taken at the meeting on March 13. Results will be presented to the board at the quarterly strategy meeting on March 27, 2006
- The Quarterly Board Strategy meeting also reviewed the budget for next year.
- Alain will attend the ASQ National meeting and leadership conference.

## ASQ Sponsored Workshops for 2006

The following workshops are being offered free of charge to ASQ members.  
Contact Alain Gaumier at [Algaumier@aol.com](mailto:Algaumier@aol.com) for more information or to sign up.

**All workshops will take place at the STAR Building,  
7887 Bryan Dairy Road, Suite 120, Largo, FL 33777.  
Tel: 727 541 8942.**

*People who would like to attend while not being ASQ members have a choice between joining ASQ prior to the workshop and attending for free, and being charged a \$25.00 fee at the door.*

Workshop	Instructor	Day	Date	Time	Deadline to Register
How to Conduct an Internal Audit	Mick Howk	Thursday	4.20.2006	5PM to 7PM	4.03.2006
PDCA & Other Methods of Process Improvement	TBD	Thursday	5.18.2006	5PM to 7PM	5.01.2006
Overview of Statistical Process Control	TBD	Thursday	6.22.2006	5PM to 7PM	6.05.2006

## **March's Pre-Dinner Presentation Summary**

**Bob Rhyder, President, Rhyder Associates, Inc.  
Process Optimization via DOE & MRAT's (Multiple Response Analysis Tables)**

The Section enjoyed an enlightening and extremely clear presentation from Bob Rhyder at the March meeting. Without having to get into nitty-gritty technicalities, Bob masterfully showed how to use Design of Experiments and Multiple Response Analysis to solve an actual problem of making 70 million bushings per year to very tight diameter and length tolerances!

Usually we go about process optimization by visualizing a single or a few inputs to each process step leading to an output. But more realistically, a process may have several inputs at each step that we aim to control (control factors), several outputs (quality characteristics), plus "noise" factors we do not control but DO affect variability of our outputs. To make the real situation even more complicated, each of the several control factors may be related to one or several quality characteristics, or vice versa. We would like to make such a real-world process "robust", meaning it hits targets accurately, with minimal variation, minimum cost, and especially that it is extremely stable even as uncontrolled factors vary.

Bob's example demonstrated how Taguchi methods were used to optimize each control factor to produce the desired quality characteristics, reduce variation through maximizing the signal-to-noise ratio, and reduce cost. Multiple Response Analysis puts all of the factor settings that produce the desired results in an easy to use data table that helps make the correct trade-offs. If you would like to learn more about the bushing example or another case study, please go to [www.RhyderAssociates.com](http://www.RhyderAssociates.com)

Bob, thank you, on behalf of Section 1508 for showing us the big picture on making a process truly robust.

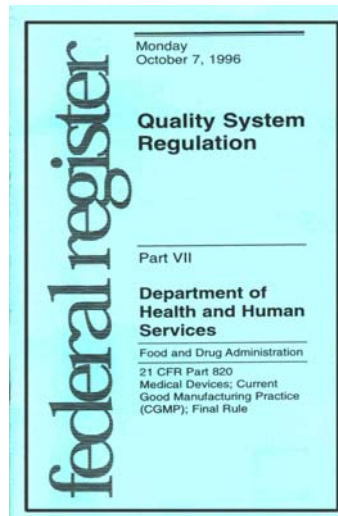
Bob Rhyder is President of Rhyder Associates, Inc., a Jacksonville-based firm that specializes in contingency-fee problem solving. An ASQ-Certified Quality Engineer, and an ASQ-Certified Six Sigma Black Belt, he is a graduate of Lehigh University with a BS in Mechanical Engineering. He has held numerous positions of responsibility in a variety of industries including VP of Quality for Hamilton Beach/ Proctor Silex Company. Prior to that position he was employed as the Director of Engineering, Quality, and R&D for Garlock Bearings, Inc., North America's largest manufacturer of self-lubricated bearings.

Submitted by Steve Babb, Programs Chair

# QARA Compliance Connection, Inc.

P.O. Box 448 \* Odessa, FL 33556 \* (813) 784-8457 \* [www.qaracc.com](http://www.qaracc.com)

## FDA QSR TRAINING



*An In-Depth 2-Day Seminar for:  
Executives, Managers, Engineers,  
Quality and Regulatory Professionals,  
Auditors, Documentation Specialists,  
and Compliance Specialists*

**Date: May 23<sup>rd</sup> and 24<sup>th</sup>, 2006**

**Time: 8:30 AM to 4:00 PM**

### COURSE EXPECTATIONS

Manufacturers of medical devices are mandated to implement and comply with the FDA's Quality System Regulation (QSR) codified under 21 CFR Part 820. This two-day course will provide medical professionals with an in-depth knowledge and perspective of the FDA's QSR and enable personnel to implement an FDA-compliant quality management system. The course provides an in-depth review of the QSR subparts in easy to understand language. It is ideal for those individuals responsible for complying with the regulations as well as those individuals involved in the development, implementation and maintenance of the organizations quality management system.

### Highlights

- ◆ CGMP/QSR History
- ◆ Organizational Benefits of Compliance
- ◆ Key Terms & Definitions
- ◆ Outline FDA's Quality System Inspection Technique (QSIT)
- ◆ In-Depth QSR Subpart Review
- ◆ General Auditor Questions
- ◆ Interactive discussion
- ◆ Real World Examples
- ◆ Tips for Compliance
- ◆ Participant Manual

### REGISTER NOW!

SAVE \$100 off the \$995 registration fee by registering before 4/15/06

#### CONTACT

QARA Compliance Connection, Inc.  
P.O. Box 448  
Odessa, FL 33556

Phone: 813-784-8457  
Email: [info@qaracc.com](mailto:info@qaracc.com)  
Website: <http://www.qaracc.com>



### SEMINAR/HOTEL INFO:

The seminar will be held at the:  
Wyndham Harbour Island Hotel  
725 South Harbour Island Blvd  
Tampa, FL 33602-5707  
Tel: (813) 229-5000 Fax: (813) 229-5322  
Web: [www.wyndhamharbourisland.com](http://www.wyndhamharbourisland.com)

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loisjordan@transformationtech.com

## Membership Statistics

Regular	427
Fellow	4
Senior	153
Associate	16
Student	10
Sustaining	2
Forum	1
	=====
Total	613