



Quality Quest

<http://www.weiquality.com/asq1508/>

November 2003 Volume 46 Issue 3

**ASQ Section 1508 St. Petersburg/Tampa
NOVEMBER MEETING
Monday, November 10, 2003**

**SPEAKER: Mr. Mick Howk CQE, CQA, CMI
Account Development Manger for Florida and the Caribbean
BSI, Inc.**

"The Process Approach to Quality Management System Design"

Mick Howk has over 25 years experience in the quality profession. His career has spanned the Aerospace, Defense, and Automotive industries. Mick has worked as a national trainer and consultant for organizations seeking laboratory accreditation to ISO 17025. He recently designed, and implemented a quality management system compliant to ISO 9001:2000 for a local Defense Contractor.

Mick holds a Bachelors Degree in Industrial Engineering Technology and a Masters Degree in Management.

An outline of November's topic will include:

- Defining and Documenting your processes
- Understanding process interrelationships
- Using Six Sigma tools for Process Improvement
- Controlling the process through Auditing
- Establishing process Goals and Measurements

See you at the meeting!

Carl G. Wilkerson-Sr. Mfg. QE
ASQ Programs Chairman

Message from Your Chair

Mark E. Puetz

WHO BEARS THE RESPONSIBILITY FOR EFFECTIVE COMMUNICATION?

How many times have we insisted someone apologize for saying something out of line, when it was really not so much what was said but how it was interpreted that made it so out of line? How many times have we insisted that the presenter reframe his message so it might be more easily understood? It seems we often hold the speaker responsible for the message. Does the listener bear any responsibility here?

Sometimes we admonish ourselves to be very clear when we make our points. This is effective communication. To be fair, there are other times, when we tell ourselves we need to listen more effectively. This is effective communication. Which is it? Is it some combination of both? There are mantras and formulas or each, of course. Certainly you can think of a few.

The Japanese make a distinction between “Speaker Talk” and “Listener Talk.” The person who actively engages in *sasshi* (guessing what the other person is thinking) is a good communicator. Those who do not are bad communicators. The responsibility for effective communication, then, lies with the audience! This is “Listener Talk.”

“Listener Talk” requires the recipient to think about the real message being conveyed, and not so much about the words or gestures used to convey it. It requires us, AS LISTENERS, to go beyond the medium, to the message. How often does poor “Listener Talk” cause us to miss the whole point ... losing a great idea?

As a final thought:

“Consider your audience” is “Speaker Talk.”

“What does he REALLY mean by that?” is “Listener Talk”

Your thoughts?

Should you have ideas or concerns, please feel free to contact me at 1508asq@tampabay.rr.com

October's Speaker

Presenter: Kerri McManus
Interim Director
The Professionals Network of Tampa Bay (Pro Net)

In these times of economic uncertainties, many of our ASQ members are transitioning to and from the professional career ladder. From an ASQ member survey, a need and interest for professional career advisement, information, available options, and encouragement was requested. It came from the Interim Director of **Pro Net** Kerri McManus, and her guest assistant.

Kerri immediately provided our section with an update on effective networking skills, which includes; Planning, Research, Self Promotion, Communications, Thinking Creatively, Follow Through, and Record Keeping. Kerri explained in her Thinking Creatively stage that "rarely does an answer present itself in black and white". You have to assemble it, create it, and think it through. You've got to solve problems, and maximize opportunities with innovative ideas. Kerri mentioned that real Networking is about building bridges. Ask for help. Kerri shared with us that too many times we just don't ask for help. If you need help, ask! Your closest associates often wont help you, simply because they are not aware that you need it.

With the help of her assistant, some additional tips for successful networking were shared, including; Defining who makes up your Network (don't forget family and friends), suppliers, and professionals in your field. You may not work directly with them, but you may share the same career choice. Volunteer Groups: One of the most prevalent reasons people volunteer is to meet others and to feel a part of something. Kerri's assistant emphasized that getting to know fellow volunteers, clients, Co-workers, and acquaintances a little bit better, could be key.

Members and guest of ASQ section 1508 left with questions answered, information to consider, and a real understanding of local resources such as The Professionals Network of Tampa Bay (Pro Net). Thanks goes out from all of our members for a great presentation by the Pro Net team. And remember, "Everyone in your life is part of your Network".

Submitted by: Carl G. Wilkerson
ASQ Programs Chairman

ASQ Section 1508 St. Petersburg/Tampa
Next Meeting: *Monday, November 10, 2003*
Tutto Favoloso Restauarant
1469 South Belcher Rd.
Clearwater, 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
7:30pm-8:30 – Speaker

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

Directions to Tutto Favoloso (located in the city of Clearwater):

From Tampa, go over the Courtney Campbell Causeway to your 7th traffic light, this is Belcher Road, make a LEFT go 3/4 of a mile Restaurant is on the left if you pass Nursery Road or Bellair Road you went to far.

From St. Pete., take US19 North to you see Nursery Road at this traffic light you make a Left, go to your first traffic light make a Right onto Belcher Road, then make a Quick Right into the strip-mall parking lot.

On-line Reservations <http://weiquality.com/1508res> to make a reservation

Please e-mail your reservations, with your phone number and company name to Sophie and Heike.

SGarancher@Transitions.com

Heike@tampabay.rr.com

If you prefer you can still call the ASQ Reservation Hot Line at:

(813) 872-1500 x 5557

Before 4:00PM, Thursday, November 6, 2003

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**

ASQ would like to thank **Electric Supply of Tampa** for their continued support providing the reservation hotline.

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2003 CERTIFICATION EXAM DATES

<i>Exam</i>	<i>Exam Date</i>	<i>Application deadline</i>
CQE/CQA/CSQE/CQIA CCT	December 6	Passed

** Note: The CQA Body of knowledge is changing starting with the June 5th, 2004 exam. The exam will be 5 hours with 15-20% (25-30 questions) devoted to case studies. For a comparison of the old vs. new BOK, please see the asq website at www.asq.org/portal/ **

Approximately 20 people sat for the exams on October 18th.
Special Thanks to Dave Vanoverbake and Debbie Barrick for volunteering as Assistant Proctors.

Recertification

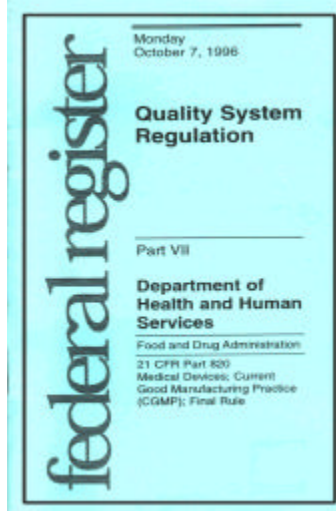
Recertification Chair: Heike Johnson

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

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FDA QSR TRAINING



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

Date: February 23rd and 24th, 2004

Time: 8:00 AM to 4:30 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 \$895 registration fee by registering before 12/31/03

CONTACT

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P.O. Box 448
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Phone: 813-784-8457

Email: 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

Call early for the discount rate!

FMEA FEVER!!!



By Sandra Werwega
President, Quality Systems Engineering

Symptoms: severe headaches; depression; moody and/or irritable behavior;

Cause: ISO/QS-9000, FMEA processes, APQP processes, PPAP processes

Does your engineering department suffer from “**FMEA-Fever**”? “Time-Consuming... tedious...confusing...and agonizing”, said engineers when asked about their Risk Management processes and procedures. In fact, just whispering the word “FMEA” will grimace the face of engineers causing them to retreat to their work-cells and develop a plan of immunity! As one QA Manager put it, “FMEA’s?...I don’t understand them...for me, it is a system of dodging and delegation!”

Risk Management, regardless of its unpopularity, is important and necessary. How necessary? Just ask the CEO’s of Firestone Tires®, Dow Corning Plastics®, and/or Johnson & Johnson®. These fallen comrades have paid a heavy price for breakdowns in their Risk Management controls and processes. And sadly, sometimes the “heavy price” is not just measured in dollars and cents; it is measured in disease, fatal accidents, and other atrocities.

My name is Sandra Werwega, and I am a Quality Consultant. I have worked, trained, and consulted for various companies in the discipline of Risk Management. In my experience, companies have good intentions when developing Risk Management processes. However, they lack the proper tools to perform the FMEA / APQP process in an efficient manner. For that reason, I have developed software that simplifies the FMEA / APQP process, and properly utilizes **Risk Management reporting, the most valuable part of the FMEA process.**

Our QSE-FMEA/APQP Solution software demonstrates the **power of risk evaluation** and process/product verification. Further, it does so in a logical interrelated sequence that parallels the ISO/QS-9000, TS-16949 basic requirements. Our software breaks down the FMEA / APQP quality documents into 5 simple chapters. These chapters are exemplified in the QSE-Training Manual.

Unique user friendly software features include:

- Enter data once to produce over 12 quality documents.
- Excel files Import and Export to and from QSE-FMEA/APQP Application
- Automatic Color-Coded (High (red), Medium, (yellow), Low (green), Risk Management Reporting.
- Automatic RPN Reports
 - Overview of Failures / Preventive Analysis / Summary of RPN’s
- Drop Down Editable Menus (in every field).
- Editable Common Terms and Guidelines / Search / Replace / Find feature in every field.
- Team Tracking, Gage and Error Proofing printout, Reaction Plans, Operator Instruction and Comments Attachments
- **The Application and Manual ASQ (American Society for Quality) wanted to publish.**
- **Manual & Application has rewrite Permission from the AIAG - DaimlerChrysler, Ford, and General Motors FMEA-Manual Task Force.**

The QSE software system will reduce the need for costly consultants and training programs. It is user-friendly, fast, efficient, cost-effective, and provides automatic risk management reporting.

The cure for “FMEA-Fever” is here in Spring Hill, Florida - 1-352-683-7301

For more information visit: www.QSEprocess.com or Call 810.499.1015.



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Fellows	3
Seniors	31
Students	18
Sustaining	1
	=====
Total	610