

# Quality Quest

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

June 2004 Volume 46 Issue 10

**ASQ Section 1508 St. Petersburg/Tampa**

**JUNE MEETING  
Monday, June 14, 2004**

**SPEAKER: MR. BRYCE CARSON**  
**Vice President of Quality Paradigms Training & Consulting, Inc.**  
**“ISO 9001-2000: A New Paradigm for Healthcare”**

It's no secret that US healthcare organizations find themselves in difficult times. These circumstances include government cutbacks on Medicare; rising cost of malpractice insurance; enhanced, new, and ever changing regulations that erode organizations creativity; difficulty in attracting, and keeping qualified professions; overworked staff; enforcement, and compliance requirements that tend to choke organizational effectiveness, and requirements for accreditation where the rules of the game constantly change; what was acceptable three years ago is no longer acceptable. It is for these reasons than implementing an effective, and efficient ISO 9001-2000 process management system is not only advisable but also necessary. Such a management system can increase operational efficiency, and enhance financial effectiveness. In addition, newly educated healthcare professionals, and experienced highly motivated people want to work in an environment that is progressive, and willing to try new initiatives. They seek out organizations, that have adopted a fresh approach to healthcare service delivery processes.

This presentation will describe how the healthcare organization can identify its key processes by building on existing policies, guidelines, and management control systems. This will enable the development of a quality management system that is suitable for and is structured to reflect, the scope of services it supplies, and the processes, and specific practices it employs.

Mr. Carson is author of the books entitled, “ISO 9001-2000-A New Paradigm for Healthcare” published by ASQ Press, and “Quality Management Systems for Assisted Reproductive Technology-ISO 9001:2000”, published by Taylor and Francis.

He is a former Chair of the American Society for Quality, Healthcare Division Standards Committee. Bryce is a Registrar Accreditation Board (RAB) Certified Quality Systems Lead Assessor, and Senior Graded Assessor under the International Association of Training and Certification Association (IATCA). His firm has consulted and assisted five hospitals achieve ISO 9001 certification.

Bryce holds degrees in Industrial Engineering, and Quality Management.

Carl G. Wilkerson-Sr. Mfg. QE  
ASQ Programs Chairman  
See you at the meeting!

## **A MESSAGE FROM YOUR CHAIR-ELECT**

With one meeting left until our Summer break, we need to look forward to our activities for next year. As we look forward, it is important to recognize that a majority of our board members will continue to serve us for the next year. All of our section positions are served on a voluntary basis and I am honored to work with this great group of people. That said, I'm sure that they all will agree that we could use additional help. We hold board meetings starting at 4:30PM on the days of our monthly meeting. Anyone interested in volunteering for one of our committee positions is invited to join us for our board meeting (check last month's newsletter at <http://weiquality.com/asq1508/index.shtml> for descriptions of board positions). We are looking for new ideas in all areas.

As part of our attendance initiative, at the June 14 meeting, we will recognize any of our members who have a perfect attendance record for the 2003 / 2004 year. We will also be conducting a summer board meeting in late July or early August to review progress on our Section Management Plan prior to submitting it to our Regional office. At the summer meeting we will also be developing a new SMP for the 2004 / 2005 year.

I look forward to seeing all of you next month and at next year's meetings.

Ed Pagnott  
Section 1508 Chair for 2004 / 2005

**Elections of Section Leadership roles were held at the May meeting  
There were no additional nominees, the following is the  
2005 Leadership team**

**Section Chair Ed Pagnott  
Treasurer Glen Cavanaugh  
Secretary Robert Cavanaugh**

**ASQ Section 1508 St. Petersburg/Tampa**  
**Next Meeting: *Monday, June 14, 2004***  
***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>**

**Reservations should be made by 4:00PM, Thursday, June 10, 2004**

**If you prefer you can still e-mail your reservations, with your phone number ,company name and address to Sophie and Heike.**

[Sgarancher @ Transitions.com](mailto:Sgarancher@Transitions.com)

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

**The Reservation hotline phone number is being discontinued. If you do not have access to e-mail, you may phone Sophie with your reservation: (727) 545-0400 X2211**

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**

## May Speaker

Mr. Kelly G. Curtis-CWM, CFMA, MFP  
President and CEO, Curtis Wealth Management Group, LLC.

### “The Global Market and Industry Trends, Global Events and Markets, and Momentum Investing Models”

Kelly began to aggressively explain and decipher the vast input of information released to the public weekly concerning the rosy or gloomy economic picture. First on the positive side, Kelly mentioned that we now have some of the lowest interest rates, and inflation in history. Short-term interest rates like the Federal Funds and the 6-month T-Bills hover at 40+ year lows. Federal Funds are at 1%, and the 6-month bill quote as of the end of the last quarter was .87%. The Bond Market Association reports that total outstanding Public and Private Debt was \$21.6 trillion at the close of the Third Quarter 2003. The U.S National Debt was reported to be \$6.951 Trillion as of December 27, 2003. As you know, this is the portion of total debt that is owed by the government. According to the Treasury, as of December 1998, 41% of the national debt is owed to the Federal Reserve Bank. That means that part of debt that is owed by one part of the government to another. So roughly 60% of the National Debt is privately held.

So, is this the good news? Kelly stated that in reality, the record low interest rates have really subsidized the heavy indebtedness. That is what he called the Robin Hood syndrome. The record low rates steal from the rich (savers), and gives to the poor (spenders). Due to this, many retirees never anticipated the earnings on their savings would yield this low of a return. Just think about how corporations are able to increase earnings just from the positive effects of restructuring debt. Households, Municipalities, and the government have been huge beneficiaries of the Federal Reserves aggressive stance on reigniting the economy. The bottom line is that the low interest rates provided by the Federal Reserve, and the stimulus provided with the new tax code will increase disposable income.

Kelly mentioned to us that one of the early signs of a potential economic downturn was a weak dollar. In the short run, a weak dollar makes our products and services cheaper in the global marketplace. This weak currency should have a very positive impact on corporate earnings for the next few quarters and further stimulate GDP. The concern regarding the weak dollar is usually centered with interest rates.

Kelly passionately pointed out one major issue on the balancing act was the Manufacturing sector. **The U.S. as well as the world, is losing manufacturing employment. Unions, Government regulations, and outrageous employee benefits are forcing manufacturing jobs to lower wage, and less restricting countries.** The most uncompetitive countries with regards to manufacturing cost structures are in Europe. GDP for the third quarter in the Euro area for the third quarter was 1.5% versus our 8.2%. Evidence of Europe problems are the current level of unemployment. Germany’s unemployment now stand at 9.3% and France is even worse. The weak dollar is going to make things very difficult for Europe for the next couple of quarters, and pressure Euro areas to reduce interest rates in order to weaken their currency. In many respect, we are in much better shape than Europe. However, Kelly made clear that he found it difficult to imagine that the U.S is going to be a net beneficiary of manufacturing jobs because of Europe.

He concluded, in short-term we are looking at a recovery that should drive the markets up. Look for signs that yields are rising to finance the deficit as well as foreigners dumping Treasuries. Portfolios should benefit from a rising as well as a declining market. And finally, eliminate or fire your Broker. Do you really need them? But that’s another summery all in itself.

From the Tampa Bay ASQ chapter 1508, Thanks Kelly!

Submitted By:  
Carl G. Wilkerson-CFI  
ASQ Programs Chairman

## CERTIFICATION EXAM DATES 2004

<u>EXAM</u>	<u>EXAM DATES</u>	<u>APPLICATION DEADLINE</u>
CQE/CQA/CSQE/CQIA/CCT	June 5, 2004	Past
CQT/CRE/CMI/HACCP Biomedical Certified Quality Manager Six Sigma Black Belt	October 16, 2004	August 20, 2004
CQE/CQA/CSQE/CQIA CCT	December 4, 2004	October 1, 2004

### **Recertification**

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

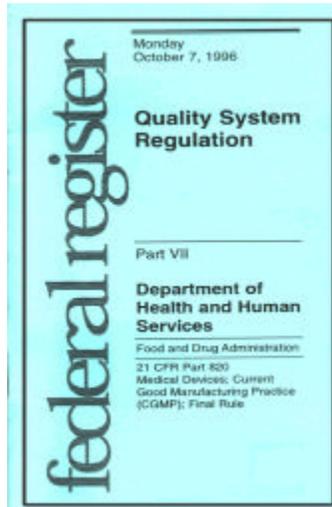
Please send all recertification packets to:  
Heike B. Johnson  
ASQ 1508 Recertification Chair  
e-image• Digital Studios, Inc.  
2106 Climbing Ivy Drive  
Tampa, FL 33618-1709

To contact Heike for questions, her e-mail address is as follows:

Heike@e-imagestudios.com

# QARACC News

## FDA QSR TRAINING



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

**Date: September 13<sup>th</sup> & 14<sup>th</sup>, 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
- ◆ Benefits of Compliance
- ◆ Key Terms & Definitions
- ◆ Outline FDA's Quality System Inspection Technique (QSIT)
- ◆ In-Depth QSR Subpart Review
- ◆ General Auditor Questions
- ◆ Interactive Discussions & Exercises
- ◆ Practical Examples
- ◆ Tips for Compliance
- ◆ Participant Manual

### REGISTER NOW!

SAVE \$100 off the \$995 registration fee by registering before 07/16/04

#### 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>



The seminar will be held at the:  
Wyndham Harbour Island Hotel  
725 South Harbour Island Blvd  
Tampa, FL 33602-5707  
Tel: (813) 229-5011  
Web: [www.wyndhamharbourisland.com](http://www.wyndhamharbourisland.com)

**Call early for the discount rate!**

## Quality Quote

**The difference between people who exercise initiative and those who don't is literally the difference between night and day.**

**Covey**

## Newsletter News

If you have an article you want published, please send it to Camie by the deadline, Friday following the regularly scheduled meeting. Camie's e-mail is: [c4cwill@aol.com](mailto:c4cwill@aol.com)

## Advertising Policy

All advertising must be paid for in advance of publication  
(Advance payment may be waived at the discretion of the newsletter chair and/or Treasurer)

All ads are charged for with two exceptions:

- Section members placing an ad seeking employment...limited to business card size ad, maximum of 4 placements per fiscal year.
- Local businesses seeking applicants in quality-related fields.

All others are charged (including headhunters).

Calculation used for pricing: calculated once a year based on the average monthly cost of producing the newsletter (including postage, mail house work, printing, etc.). Average monthly cost is divided by the number of pages to obtain the cost of a single page ad. Minimum charge is for a quarter page ad.

Prices are currently:   \$80   full page ad,  
                          \$40   half page ad  
                          \$20   quarter page ad



Attn: J. Conrad  
 19824 Wyndham Lakes Drive.  
 Odessa, FL 33556

**NONPROFIT ORG  
 U.S. POSTAGE PAID  
 PERMIT # 2292  
 TAMPA, FL**

Quality Quest is published monthly by the Tampa/St. Petersburg Section of the American Society for Quality.

## Board Members

Section Chair

**Mark Puetz**

E-mail: 1508asq@tampabay.rr.com

Treasurer

**Glenn Cavanaugh**

E-mail: glenc@tampabay.rr.com

Secretary

**Robert Cavanaugh**

E-mail:

Robert.Cavanaugh@certegy.com

Programs

**Carl Wilkerson**

E-mail:

Carl\_G\_Wilkerson@raytheon.com

Newsletter

**Camilla Williams**

E-mail: c4cwill@aol.com

Internet Liason

**John Conrad**

E-mail: John@weiweb.com

Education Chair

**Alain Gaumier**

E-mail: Algaumier@aol.com

Arrangements Chairs

**Sophie Garancher**

E-mail: SGarancher@Transitions.com

Recertification/Arrangements

**Heike B. Johnson**

E-mail: Heike@ e-imagestudios.com

Examining Chair

**Debbie Holt**

E-mail: holtd@baxter.com

SMP Chair

**Ed Pagnott**

Epagnott@aaronmed.com

Placement Chair

**Guerry Thode**

E-mail: Thode@knology.net

Audit Chair

**Mark Anderson**

E-mail: Manderson@gaf.com

Publicity Chair

**Jim Triller**

E-mail: Jimtriller@earthlink.net

Membership Chair

**Paul Racine**

E-mail: Paul\_D\_Racine@raytheon.com

### Membership Statistics

Members	603
Fellows	3
Seniors	32
Students	17
Sustaining	1
	=====
Total	656