



Northeastern Illinois
Section

MAKE GODD GREAT™

JOIN US FOR OUR NEXT SECTION MEETING!

We cordially invite you to join us on Thursday, November 17, 2011 at the Arboretum Club, 401 W. Half Day Rd (Rt. 22 East of Buffalo Grove Road, across from Dominick's), in Buffalo Grove. Members and non-members are always welcomed.

E-mail registration: E-mail: asq1212reservations@yahoo.com

Pre-meeting Clinic 5:30 pm Networking/Dinner: 6:30 pm Main Meeting: 7:30 pm.

November 17 th Section Meeting Statistical Techniques and Validation

By Regina Fullin Section 1212 Program Chair



The November 17 ASQ Section a warm welcome to Dr. Wayne of Taylor Enterprises Inc. Dr. Taylor his expertise with the use of statistics regulated industries with a discussion definition of “Statistically-Valid.” He

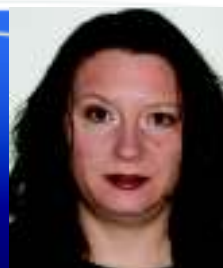
process validation in detail with a reprise of groundbreaking FDA the topic.

Taylor has a Ph.D. in Statistics from Purdue University and is a fellow of the American Society of Quality. He is founder, and chairman of Taylor Enterprises Inc. (www.variation.com), where he provides consulting and training on the Six Sigma approach and other quality statistical techniques. He authored the books

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The American Society for Quality is a leading quality improvement organization and a knowledge-based global community of quality experts with a passion to improve themselves and their world. ASQ advances global learning, quality improvement, and performance excellence with over 130,000 members worldwide.



***Our Program Chair,
Regina Fullen:***

Optimization and Variation Reduction in Quality and Guide to Acceptance Sampling. He has also authored five software packages, including *VarTran*®. The *VarTran*® software has enjoyed particular success as a component of many DFSS (Design for Six Sigma) programs at many companies. *VarTran*® was also adopted at Honeywell and the Six Sigma academy as an essential tool for design of high-quality products.

In 2000, Dr. Taylor retired from Baxter Healthcare Corporation after a 22-year career, where he was Director of Quality Technologies. In this role, he was responsible for the company's Six Sigma program, as he and his staff trained over 800 Baxter engineers as Six Sigma Black Belts. He is a fellow at the Royal Statistical Society and a member of the American Statistical Association.

PRE-MEETING CLINIC: What does “Statistically Valid” Really Mean? This presentation will elucidate the meaning of “Statistically Valid”, as viewed from the perspective of an FDA auditor, including the elements that make a procedure statistically valid, and the statistical rigor expected in documents such as process validations, release testing, trending and CAPA documentation.

MAIN PRESENTATION: Process Validation: A Lifecycle Approach. This presentation provides training on the latest FDA Guidance document on Process Validation, authored by Grace McNally, Senior Policy Advisor of the U.S. FDA. This document discusses the FDA's current thinking on process validation. Please come prepared to learn how to keep your validated processes in continual compliance!

Quality Quote:

“Progress is impossible without the ability to admit mistakes.” ~ Imai

LinkedINsurance is free! by ~ Stephanie R. Donato

Did you know there is a **free** insurance policy to keep you connected to your friends, coworkers and other local and global contacts? I found LinkedIn to be a tool in today's job market. You may be well established and secure in your career, but these days, for how long? LinkedIn can be a way to help others who need to build their network, and someday they may return the favor.

I discovered LinkedIn about four years ago when I was actively job searching. I wasn't having much success after several months, and realized that my method, using Internet job boards, produced an estimated 2 percent return on my time and effort. What was missing? Connections! I decided to start small, and find people by searching companies where I worked in the past. It worked.

- **Build your network! Introductions:** I found colleagues by looking through my contacts network, and asking for introductions or simply contacting them directly. (note: there is a limit with the free account for 5 active intros at a time.)
- **Join Groups:** There are hundreds of groups to join from Alumni to industry and special interests (i.e., ASQ, ASQ section 1212, and Women in ASQ are three related groups.)
- **Join a discussion or ask a question in a group:** I have found it very helpful and informative to ask a question and receive useful feedback. I asked about what certification was most marketable, and what references to use. It was

nice to find others who were like-minded, and offered their advice.

- **Stay up to date on trends and issues in your fields:** find potential resource.
 - **Think Global:** One aspect that I value greatly is the ability to reach out globally and expand my network. In a previous job, I was working with a third party testing labs in China. I received a LinkedIn contact from other global labs and got advice on testing. In my current role, a colleague contacted me from another continent. I didn't know we had an international location! He asked me to connect.
 - **See who is looking at your profile/ Number of views:** With the free account, you can see how many times your profile has been viewed. You can also see who those people are.
 - **Status Updates:** Tell people what you're doing or learning about professionally! It helps others to see your unique insights or activities, and may help you depending on your field of influence. You can choose to show your status updates to all, or to only your connections.
 - **List those ASQ Certifications/ Qualifications:** Located at bottom near Education to list any ASQ or other certifications you may have obtained.
- Research for interviews or new contacts:**
Depending on your objectives and interests, you may find it useful to either research people or companies.
- Meet someone new? Look them up

and study their background and interests, and group memberships.

- Follow a company and stay informed. It's standard industry practice now for recruiters and HR departments to look up candidates on LinkedIn, so keep in mind, you want your impression to be polished and professional, including your profile picture, status, or group comments.
- Control Your Settings: Once of the most important features to learn to use to control the information that others can access and view.
 - Public profile: how others will see you if they "Google" your name. Include as little or as much of your profile as you wish.
 - Profile info for others on LinkedIn: You can change the information others on LinkedIn will see, unless they are in your network, or one of your direct connections.
- Last but not least: Don't forget to list the LinkedIn "link" on your resume! You can count on your application being looked up online.
- Use the Smartphone app. It's a free app, and keeps you connected when you're on the go.

I hope these tips can be useful to reach your goals, and stay in touch. I find it's the best way to "pay it forward," now that I'm happily employed; helping others get connected with this rich resource. And it's FREE!

David Norby, Chair: dplmnorby@sbcglobal.net

Peter Larson, Vice Chair: twins0649@gmail.com

Jim Sohn, Treasurer: james.sohn@yahoo.com

G. David Spengler, Historian, Auditing: gdpengler@yahoo.com

Peter Larson Membership Chair: twins0649@gmail.com

Martha Kadas, Asst Membership: mkadas@sbcglobal.net

Jimsong Gong Internet Liason: jimsonggong@hotmail.com

Orville Krumdick, By-Laws: orvkrumdick@juno.com

Sandra Storli, Past Chair, Nominating Chair, Database: Sandra.storli@abbott.com

Willie Carter, SMP Chair:

wcarter@quantumassocinc.com

Jim Schlichting, Publicity: schlijp@sbcglobal.net

Regina Fullin, Certification, Lead Proctor: Regina.m.Fullin@ge.com

Merle Goddard, Recertification: Merle.Goddard@abbott.com

Dee Miranda, Assistant Recertification: dee_miranda@baxter.com

Virginia Gibbs, Award Chair: VirginiaG920@aol.com

Jeff Wright, Secretary: jwright@scotforge.com

Stephanie Donato, Asst. Secretary: srdonato@sbcglobal.net



On October 6, we continued to study ISO/DIS 3100, Risk management — Principles and guidelines on implementation. We are rating the sections of the standard as to how effective it would be in Managing risk. We completed Section 6.1 General and will start with Section 6.2 Communication and Consultation. Ron Bateman, Dave Spengler, Christine Rhodes, Regina Fullen and Dave Taylor attended.

In the round robin review:

Regina has a new manager at G.E. Healthcare.

Christine continues to do traveling for supplier audits. She has two trips left in 2011.

Dave S. is balancing various quality issues at his company as they still lack a

Quality Manager. And he is working with Dave Taylor to complete the conversion of the Quality Management System to The latest revision AS 9100

Ron 's company, which supplies equipment to Natural gas providers, has closed their fiscal year and almost doubled sales over last year!

Dave Taylor is working on an AS9100 (Aerospace Standard) revision to Rev. C at Dave Spengler's company. In addition, he performed a customer-supplier audit for a machine shop in Cary.

We plan to continue our review of ISO/DIS 31000, Risk management — Principles and guidelines on implementation from Section 6.2 Communication and Consultation.

The next ISO discussion group meetings are November 3 and December 1, at 6:00 PM. We will begin a review of ISO/DIS 31000 Risk management — Principles and guidelines on implementation.

At the New China Buffet: An enjoyable mouthwatering buffet will be served for \$5.00 (free for members searching for a position), the balance being funded by ASQ section 1212 Northeast Illinois. The public is always invited and we welcome your questions about Quality Management Standards. Let me know if you have particular subjects to discuss. Contact me, Dave Taylor at kolimat@yahoo.com. If you have any questions or need directions, just let me know.

Director of Quality

The Walstrom Group, Inc. (Medical Industry Search Experts)
- Greater Chicago Area

Job Description

Director of Quality

Client is the world's leading provider of injectable drugs and devices. Through its broad, integrated portfolio, Client is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is has approximately 14,000 employees.

Client seeks to attract a **Director of Quality** to be responsible for the oversight of device remediation.

DUTIES AND RESPONSIBILITIES

Reporting directly to the vice president Device Quality and indirectly reporting to the corporate vice president, Device Operations, this position will manage and represent Quality activities related to the remediation team (Team Remedy).

NIQC 2011 is Coming (November 14-15)

Participation in workshops and the Tuesday conference will each earn ASQ Recertification Units (RUs).

Please check web site (www.niqc.org) for a copy of the agenda, details and registration information.

Visit [ASQ's Career Center](#) to search for jobs, read articles and access career development resources. It is free to all job seekers and provides access to the best employers and jobs in the quality industry. Boxwood Technology, an external vendor, powers it so job seekers must register separately from the regular ASQ member site to apply for a position or post a resume. ASQ also offers an [unemployment benefit](#) to those unable to pay membership dues due to being unemployed. **Please join us on our LinkedIn discussion group [ASQ NEI Section 1212](#)**

“QUALITY QUOTE

“Business processes—the domain of the so called white-collar worker—hold the potential for quantum leaps in improvement.” ~ Lon Roberts



Adela Crandell

AdelaCrandell@me.com

Quality Beyond Compliance

If you spend a majority of your career in a regulated industry, you may find an interesting paradox. Your co-workers are keenly aware of the importance of quality as it relates to compliance with the regulations. In some cases quality may be considered a necessary burden, part of the overhead, and the cost of doing business. What people may forget is that quality makes good business sense. It is value-adding activity.

It should be obvious that our products must be safe and consistent. Most of us understand the importance of a good adverse events reporting system, with the ability to respond quickly by investigating root causes and implementing corrective action.

What about those other complaints; the ones that indicate some level of customer dissatisfaction? Funny odor, print too small, open seal, partially filled container, weird texture. These kinds of complaints could be a “gold mine” for the company. Slicing and dicing complaint data to reveal trends in manufacturing quality and correcting those

niggling issues can lead to increased customer loyalty and increased sales. A measurable problem in one product or product line, just might reveal a hidden problem in another product line. You may even come up with a solution that delights the customer. These types of solutions have a positive impact on the bottom line.

Not only might resolutions to non-health related complaints increase customer satisfaction, they just might be a signal to a larger issue looming, like insecticide [leaching from pallets](#); a real health problem lurking, undetected.

In order to take your company and your career to the next level, consider the positive impact your quality project will have on your company. Link the purpose to the company goals and objectives. Remember to put the economic impact in your proposal.

What You Missed Last Month

Tony Manos, of Profero, Inc. was our presenter for both Pre-Meeting Clinic and for the Main Presentation. His discussion focused on Lean. The Pre-Meeting Clinic discussed the new Lean Certification Body of Knowledge. This new certification is the most comprehensive Lean Certification in the industry, and is done cooperatively between ASQ and the Society of Manufacturing Engineers. The certification includes both an exam and project work.

The Main Presentation discussed a case study in a Lean workout for a Total Productive Maintenance blitz. The essential elements of this activity include assembling the appropriate team players, selecting the right project, getting close to the equipment, root cause analysis, and finding improvements that have the most impact with



Your Arrangements Chair:
djkrasowski@yahoo.com

the least effort. Be sure to attend in the future so you don't miss out on great content offered at monthly meetings!

Call to Action:

ASQ Section 1212 is searching for tech-savvy volunteers to coordinate monthly meeting attendance via teleconference. If interested, please contact Dave Norby (dplnorby@sbcglobal.net) or Regina Fullin (regina.m.fullin@ge.com) to discuss the project scope. This is an excellent opportunity for individuals to accumulate RUs toward ASQ recertification, and to network with fellow ASQ members.

October Attendance: 64

Door prize winners:

Dave Spengler
Jose de la Cruz
Karen Caplis
Amanda Jarzabek
Stuart Thomason
Jim Klinkowitz
Marion Menze

Education Program Opportunities

Your Education Chair: Dave Taylor



Class	Duration	Coordinator	Contact	Start date	Sign up ASQ	Exam
Certified Quality Engineer	40 Hours	Dave Taylor	kolimat@yahoo.com	9/17	10/14	12/3
Green Belt Certification	40 Hours	David Spengler	gdspengler@yahoo.com	9/17	10/14	12/3
Quality Auditor Certification	Two Days	Sandra Storli	sandra.storli@abbott.com	No date assigned	10/14	12/3

We can provide Training for All your quality-related needs.

Remember, all year around we offer all of our workshops (and can prepare and present almost any customized training you need) for in house presentations at an economical price for your company. There is NO quality-related subject we cannot provide for your training needs.

Our Section provides workshops for in-house presentations at a fixed price to your company - including these offerings and many others:

- | | | |
|---|--|-------------------------------------|
| CRE Review | Review Certified Reliability Engineer Review | Certified Software Quality Engineer |
| Review MSA/Gage R&R | 8D Problem Solving Methods | Quality Function Deployment |
| Six Thinking Hats (Team Building) | Successful Acceptance Sampling | Lateral Thinking |
| Improving Team Performance With Quality Tools | QS-9000 Continuous Improvement Tools | Robust Tolerance Analysis |
| Short Run SPC | Upgrading to ISO 9000 to QS-9000 | Statistical Thinking |
| The Illinois Lincoln Award | Lean Office Simulation | Lean Office Training |

Contact Dave Taylor at: kolimat@yahoo.com for details!

Mark your Calendar

For the extended calendar, please go to our website: <http://www.asq1212.org/>



Anything is possible if we expand the reach of quality.
Please go to <http://wcqi.asq.org> for more information on this opportunity to benchmark, network and learn.

Your chair, David Norby

September 15 2011	Project Management Principles by Manu Vora	Project Management for Organizational Excellence by Manu Vora
October 20 2011	Lean Learning Game Exchange by Tony Manos	Lean by Tony Manos
November 17 2011	Two Programs: (1.) FDA Guidance and (2.) GHTF Guidance by Wayne Taylor (author of the document)	
December 15 2011	Quality Celebration	ASQ's Futures Study: 2011 Forces of Change – Shaping the Future of Quality by Paul Borawski
January 19 2012	Annual Business Meeting	
February 16 2012	Two Programs: (1.) FDA Guidance, and (2.) Risk Communication by Michael S. Wolf, Ph.D., M.P.H. of the Risk Communication Advisory Committee to the FDA	
March 15 2012	Plant Tour TBD	
April 19 2012	Statistic Free Six Sigma by Praveen Gupta	Innovation Competencies by Praveen Gupta
May 17 2012	Getting Your Certification – How to Take the Exam By Dave Taylor and Dave Spengler	Recert & Packet Info By Merle Goddard
June 21 2012	Putting Contest and Statistics By Dave Taylor	Quality Tools: By Wayne Taylor

Please ensure that your email address with ASQ is current. The section recommends that you use your home email address for ASQ mailings, that way you will never miss an ASQ or section mailing due to screening of the company email or changing jobs