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News from the Northeastern Illinois Section
American Society for Quality www.asq1212.org



Sailing into the Future



February 2010

Volume 40, Number 2

February 18th Section Meeting: Understanding GMP/QSR as a Concept

By Marlyn Hyde, Section 1212 Program Chair

Does your job as a Quality Professional require you either to investigate quality problems or review those investigations? Do you ever wonder if you've taken it far enough? How much investigation is required? Do you always need analysis on returned product? What analysis should you request? How do I decide if the issue has been satisfactorily resolved? Tonight's presentation will offer some insight and food for thought. This will not be step-by-step presentation of how to conduct a product failure investigation, but rather will stimulate discussion about the best practices related to conducting quality investigations. Learn the tools and insights from an FDA expert with a wealth of inspectional experience and expertise to help you make the right decision.

This evening's program will be followed by an Ask the expert's session. The question and answer format following tonight's program will allow participants to get the information that they need about corporate compliance, the Food and Drug Administration (FDA) Inspectional process, how to prepare for a successful FDA inspection, and how to interact with the FDA investigator. If you had the opportunity to talk with the FDA Investigator of the Year, what would you want to ask? What would you want to know? Facing a FDA challenge? Get the FDA perspective. Bring all your FDA Inspection problems to February's ASQ meeting and get the advice and answers you need.

Lorelei Jarrell has been with the Chicago District FDA since the 1970's. For close to 20 years, she served as the lead investigator in charge of a suburban Chicago office, during which time she specialized in medical device and pharmaceutical inspections, and is currently recognized as a Regional Expert in both fields. In 1995, she became Chicago's first Pre-approval Manager. She currently focuses primarily on compliance activities. She has worn many hats throughout her dedicated FDA career. She has received several awards throughout her 30+ FDA years, the most notable of which is the first FDA Investigator of the Year Award. She has also received the distinguished Outstanding Service Award.

February 18th Pre-Meeting Clinic: Quality Career Fair - From 5:00pm to 7:00pm in the adjoining conference room.

Brought to you by Bill Stinchcomb, Placement Chair. Sponsored by ASQ Northeastern Illinois Section 1212 (see our flyer on page 9).

Career Fair Objectives:

- 📁 Meet participating company recruiters
- 📁 Networking opportunities
- 📁 Meet ASQ business leaders
- 📁 Provides a venue for marketing your resume

Some of the Participating Companies:

- 📁 Abbott
- 📁 Aerotek
- 📁 Baxter Healthcare Corporation
- 📁 ERA Industries, Inc.
- 📁 Validant Consulting

TO DO LIST:

- ✓ Join ASQ NEI LinkedIn group at: <http://www.linkedin.com/e/vgh/2236959/>
- ✓ Send email to asq1212jobs@yahoo.com
- ✓ Bring 10 copies of current resume
- ✓ Bring 50 copies of business cards

For further information, e-mail:

asq1212jobs@yahoo.com
Bill Stinchcomb, ASQ Fellow, Placement Chair, ASQ Section 1212

JOIN US FOR OUR NEXT SECTION MEETING!

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 100,000 members worldwide.

ASQ Section 1212 is dedicated to the promotion and advancement of quality tools, principles, and practices in the workplace and community. It is one of the top rated sections in the society and it meets on a regular basis to help their members become leaders of quality. We cordially invite you to join us on **Thursday February 18th** at the **Arboretum Club**, 401 W. Half Day Rd (Rt. 22 E. of Rt. 83), at Buffalo Grove Road (across from Dominick's), in Buffalo Grove. Members and non-members are always welcomed.

Pre-meeting clinic: Quality Career Fair - 5:00pm to 7:00pm in the adjoining conference room

Main Presentation: Understanding GMP/QSR as a Concept, by Lorelei Jarrell FDA Inspector- 7:30 – 8:30 pm

The meetings are always free, meals are \$25, please reserve in advance. E-mail: asq1212reservations@yahoo.com.

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Education Program Opportunities. *By David Taylor, Education Chair.*

I hope you all had a superior holiday! Mine was highlighted on December 16th by the addition of triplets; Samantha, Joe, and Jackson born to my daughter-in law Karen Taylor and her proud husband Mike. That was all the Christmas present I needed!

Why not make the spring come sooner by doing a little career improvement?

Our CMQ class with Marlyn Hyde kicked off successfully in January. Our remaining spring classes are shown below. Any suggestions would be appreciated.



Class	Duration	Trainer/ Coordinator	Contact	Start date	Sign up for exam (ASQ)	Exam
Certified Quality Engineer	30 Hours	David Taylor	kolimat@yahoo.com	3/20 (Wed Evening)	4/16	6/5
Green Belt Certification	40 Hours	David Taylor	kolimat@yahoo.com	3/20 (Tues. eve)	4/16	6/5
Certified Quality Auditor	Two Days	Bettina Karlove	vanguard@ameriteck.net	4/27 & 28 (16 hours)	4/16	6/5
Statistical Process Control	Two Days	Dave Ingram	ingramd@baxter.com	Not Scheduled	NA	NA
Statistics Workshop	Four days	Dave Ingram	ingramd@baxter.com	Not Scheduled	NA	NA

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 a most economical price to 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!

ISO Support Group Minutes for February 2010. *By David Taylor*

We continued our study of ISO/DIS 26000, Guidance on social responsibility. We began Section 6, "Guidance Principles on Social Responsibility". We covered sections 6.1 "General", Section 6.2 "Organizational Governance", and 6.3 "Human rights". Thankfully, this was not as dry as the precious section re: Stakeholders. We are not rating this document, but the discussions have been very lively! Six members attended the meeting on February 4, 2010 at the New China Buffet. In attendance were G. David Spengler, Peter Larson, Christine Rhodes, Jan Agostinelli, Bill Sherman and Dave Taylor. In the round robin review: Dave S is addressing Medical device product issues. He was happy to get a complement from a customer on the brazing standards he set for their product. He is currently auditing the powder coating operation. In addition, a black belt from Corporate is working with him on problem solving. Dave T continues with long-distance ISO 9001 customer in San Diego, CA. The new ISO 9001 was February first and the first Management Review Meeting on February 5th. The first internal audit is planned in late February. Also, Dave is working on a "Failure Mode Effects Analysis" at a company in Waukegan. Christine is planning on internal audits in Bowling Green about every other week. Jan gave a report on the status of Marlyn Hyde (she is still awaiting surgery and doctors are planning the next steps in her treatment. we all wish her well) Jan also gave an update on their "Certified Manager of Quality" class in Island Lake.

Our next two meetings will be held at 6:00 on Thursday, March 4 & April Fools Day! We will continue our review of ISO/DIS 26000, Guidance on social responsibility, I would encourage your attendance, as this new document has proved controversial and interesting to discuss.

An enjoyably 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 Dave Taylor at kolimat@yahoo.com if you have any questions or need directions.



January Section Review: Annual ASQ Section 1212 Business Meeting.

By David Norby

ASQ Section 1212 is dedicated to the promotion and advancement of quality tools, principles, and practices in the workplace and community. Benefits of membership: ASQ members help their employers remain cost-competitive by reducing cost, improving efficiency and assuring a high level of customer satisfaction from products and services. Your ASQ membership provides you with many learning resources, and many networking opportunities. Section members grow professionally at section meetings, and at section-sponsored activities. Members with ASQ certifications earn credits toward periodic renewals of certifications (RU's) through meeting attendance and through participation in a variety of section-sponsored activities. We are one of the top rated sections in the society. For the fifth year in a row, Section 1212 has been awarded the Gold-level section award by the ASQ national organization. This is the highest level awarded, and is given in recognition of the quality of section programs and activities. Sandra Storli, Section Chair, led each of our section leaders in presenting a quick summary and sharing what their committee has accomplished. She encouraged member participation and asked members give the SLC their needs and ideas for improvements:

ASQ1212 Chair Sandra Storli's 2009 Accomplishments: Developed the section's goals/metrics with SLC. Submitted Audit to ASQ Corporate before Aug 15. Developed Section 1212 Website. Plant tour of Colbert Packaging March 19th. *What We Need From Our Members:* Complete member surveys for the Section 1212 and Headquarters. Provide suggestions for speakers, programs and member leader. sandra.storli@abbott.com

Secretary David Norby's 2009 Accomplishments: Attends monthly SLC meetings, prepares & circulates minutes for review/approval at the next SLC meeting. Attends monthly Section workshops, meetings, prepares summaries of presentations for newsletters. Prepares communications on behalf of Section, at the direction of the SLC. Provides signature of record on behalf of Section for certain documents as required, such as bylaws. *What We Need From Our Members:* Provide feedback on our communications. david.norby@abbott.com

Treasurer G. David Spengler's 2009 Accomplishments: Successful financial audit to headquarters by July 15th. Provide monthly review of the Treasurers' Monthly report. gdspengler@yahoo.com

Arrangements Chair David Krasowski's 2009 Accomplishments: Meeting set up and timely reporting of attendance, door prize winners and any changes. Meeting Attendance has increased in each of the last four years. *What We Need From Our Members:* Please make reservations and LEGIBLE entries in the Attendance Log. djkrasowski@yahoo.com

Audit Chair Jim Sohn's 2009 Accomplishments: Successful monthly review to aid in the final yearly submission of ASQ NEI Section 1212 group account to ASQ Corporate Headquarters. Achieve Financial approval from ASQ Corporate for Corporate Dues. *What We Need From Our Members:* Support Treasurer and Auditor by providing timely bill submissions. Timely deposit of reimbursement funds from ASQ NEI Section 1212. james.sohn@yahoo.com

Education Chair David Taylor's 2009 Accomplishments: Monthly ongoing discussion/dissection of ISO standards. Refresher training courses held when requested by membership. kolimat@yahoo.com

What We Need From Our Members: Participation. Input on opportunities for in-house training (almost any quality related subject).

Membership Chair Maddy Bradford's 2009 Accomplishments: Contacted 80% of members. Distributed the electronic version of the section's newsletter. Encouraged the use of Twitter and LinkedIn groups. *What We Need From Our Members:* Participation! Join ASQ NEI Section 1212 group on LinkedIn.com and contribute to discussions. Keep your contact information with ASQ current. Maddy_Bradford@steris.com

What Can We Do For You In The Future: Improve communication to members who decline email from ASQ. Distribute surveys to gather feedback from members to guide programs for SLC. Look for opportunities to view or attend meetings offsite to members. Facebook.

Program Chair Marlyn Hyde's 2009 Accomplishments: Created a dynamic and repeatable process of programs (1 year of programs booked in advance). Provided great speakers /experts to share ideas, tools, processes that help our members, become more effective and efficient. Increased Member Skills satisfaction and attendance levels are high. Improved communications by publishing the program schedule for the upcoming year. *What We Need From Our Members:* Continue investigating and asking our members how we can do better. Fill out our Satisfaction Surveys. Get involved in the growth process in Section 1212. We need your input. *What Can We Do For You In The Future:* Broaden member knowledge of quality trends, tools, and topics. Provide programs on a variety of days, times, and locations, at no cost to the section. MarlynHyde@hotmail.com

Placement Chair Bill Stinchcomb's 2009 Accomplishments: Established active job postings in LinkedIn /ASQ NEI Section 1212 group. Established asq1212jobs Twitter account. Established asq1212jobs@yahoo.com email address. Arranged career fair. *What We Need From Our Members:* Join ASQ NEI Section 1212 group on LinkedIn.com. If you are in-between positions, let Bill know (all correspondence handled in confidence). Forward all job openings to bill.stinchcomb@abbott.com OR asq1212jobs@yahoo.com. bill.stinchcomb@abbott.com

SMP Chair Willie Carter's 2009 Accomplishments: Submitted section plan to ASQ headquarters as requirement for Total Quality Award. Established 2009/10 section management plan and submitted to ASQ. Our section was granted the Total Quality and Gold Excellence Award! *What We Need From Our Members:* Your input to the planning process. Your requirements or expectations of the section. wccarter@quantumassocinc.com

Publicity Chair Christine Rhodes's 2009 Accomplishments: Post meetings regularly in newspaper, calendars. Post meetings on Corporate bulletin boards. *What We Need From Our Members:* Information on how to post information on their internal company bulletin boards. Feedback on whether notices appear in your local paper. crhodes@fortdearborn.com

Newsletter Editor Frances Blosser's 2009 Accomplishments: Published monthly newsletter. Published electronic newsletters in Fall 2009.

What We Need From Our Members: Need quality articles to share with our members. fab8850@aol.com

Nominating Chair Sheldon Behensky's 2009 Accomplishments: Maintained contact data for all section leadership team members. Recommended new slate for section elected positions for 2009/2010. *What We Need From Our Members:* Suggestion for nomination from the membership for the elected positions. behensks@yahoo.com

Recertification Chair Merle Goddard's 2009 Accomplishments: Presented recertification information and tips, and answered questions at May's Recertification dinner meeting. *What We Need From Our Members:* Communicate with the chair in advance of the due date. *What Can We Do For You In The Future:* Have quarterly updates for those new to the process. Take questions and create FAQ for the section. Merle.Goddard@abbott.com

Lead Proctor Regina Fullin's 2009 Accomplishments: Completed 4 section exams for 2009. rmfullin@pharmtechinc.com

Historical Chair G. David Spengler's 2009 Accomplishments: Archives for permanent storage. Transferred copies of section documents to ASQ. gdspengler@yahoo.com

Awards Chair Virginia Gibbs' 2009 Accomplishments: Collected nominations for the current section term. *What We Need From Our Members:* Feedback on how the SLC team performance. *What Can We Do For You In The Future:* Create a new procedure for this process. Include awards on the survey questions. VirginiaG920@aol.com

Internet Liaison Donna Nash's 2009 Accomplishments: Maintained current data on ASQ mini-website. Completed section website development. Guided the approval and implementation of 3 new Section 1212 awards. *What We Need From Our Members:* Feedback on how we are performing. qlypest@gmail.com

By Laws Orville Krumdick's 2009 Accomplishments: A revision of the SOA was reviewed and adopted by the Section Leadership Committee. orvkrumdick@juno.com

Continued on page 4

January Section Review: Annual ASQ Section 1212 Business Meeting

Continued from page 3

Sandra Storli, Section Chair, discussed the direction of ASQ 1212 for 2010 and beyond. Our section continues to evolve and improve based upon member input, we need to know what you want us to do for you and we need to share what the SLC needs from you to make that happen and who to contact when you have something to share, or when you need information or resources. We are looking for volunteers that want to demonstrate their best by leading or assisting committees (the programs our section has identified as essential to promoting and supporting quality in our area). Come join us! Learn leadership skills, gain experience, and networks. Your ASQ SLC team is committed to helping you succeed!

The election of Officers was completed at this meeting as well. Election Results:
 1. Chair Elect: Maddy Bradford
 2. Treasurer: Jim Sohn
 3. Secretary: David Norby

<p style="text-align: center;">Are you signed up for facebook? ASQ is building a facebook page? Check out ASQ NEI Section 1212 And ASQ1212 Tell us what you like/dislike. We'll keep the best and delete the rest. Become a fan and you can write on the wall, post pics and more!</p>	<p>Quality Quote: "Asking questions and looking for answers without fear is how true solutions are found." ~ Lyell Jennings</p> <p>Have A Winning Day, Willie L. Carter</p>
<p style="text-align: center;">If you're job hunting. Please join us on our new LinkedIn discussion group. You can connect to the group through this link.</p> <p style="text-align: center;">ASQ NEI Section 1212</p> <p>Bill Stinchcomb our Placement Chair is posting jobs there regularly. Check out the jobs posted there!</p> <p style="text-align: center;">You can also follow us on our Twitter account:</p> <p style="text-align: center;">asq1212jobs</p>	<p>Let everyone know that the section's new website is up and available. You can navigate to the website using this link - www.asq1212.org.</p> <p>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. See you next week!</p> <p>Maddy Bradford, ASQ CQA, CMQ/OE, ASQ 1212 Section Membership Chair</p>

Section Chair's Message *By Sandra Storli*

February is a special month for us. We are getting the best bang for our buck. Our program includes a topic on cGMPs in the Medical Device Industry presented by the FDA, and for the first time a career fair for our members who are in transition between jobs. This links well to the career issue presented in the January issue of QP Live which featured articles not limited to:

- *Career climb* which offers the best next steps towards the right career move
- *Social graces* which take advantage of the expanding number of online options that are making it easier to establish a personal brand and lay the groundwork for the next stage of your career development.
- *Test run* which prepares you for ASQ Certification to help you advance in your next move, and
- *Acquiring assets* which are geared to bringing new employees to the work place.

With all that said, what is the likelihood you will change jobs in 2010? A recent survey conducted by linkedin medical device job poll, includes the results for a one day poll.

The total results for 1 day (675 votes) showed that:

- 27% - Unemployed or Actively Looking
- 31% - Strong possibility
- 21% - Keeping Options Open
- 10% - Happy where I am, but....
- 8% - No Way - Excited about 2010

The age distribution is intriguing as well... with the highest percentage of "actively looking" in the 55+ age group, followed by the 18-24 age group. The most content group by job function is in marketing (24%) and the group showing the highest interest in changing is Engineers (54%).

With an ever changing economy and a unusually high unemployment rate, there is a wave of change in the job market and that means that we must continue to keep our skills current and our networking updated.



Placement News. *By Bill Stinchcomb, Placement Chair*

As a service to our members, we offer this space to list any openings that benefit our membership.

How it works: To list openings in your organization simply e-mail a brief position description before the second Wednesday of the month. Include job requirements, company, location, and compensation, as appropriate. To inquire about any available positions, please e-mail me your resume or inquiry any time. We do get contacted by some placement services and will be happy to send your information to them. **Contact:** Bill Stinchcomb, Placement Chair: 847-938-1103 Bill.stinchcomb@abbott.com. ASQ Section 1212 provides advertising access to its newsletter as a service, but has no control over the operating policies or practices of those who provide the advertised services.

From ASQ Headquarters: ASQ's [Career Center \(http://www.asq.org/career/index.html\)](http://www.asq.org/career/index.html) is free to all job seekers and provides access to the best employers and jobs in the quality industry. It is powered by Boxwood Technology, an external vendor, 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 \(http://www.asq.org/members/leadership/mbrapp/index.html\)](http://www.asq.org/members/leadership/mbrapp/index.html) to those unable to pay membership dues due to being unemployed.

From ASQ 1212: If you have a job opening, need help with posting job, or have job support requests, please email to asq1212jobs@yahoo.com OR bill.stinchcomb@abbott.com.

Local Jobs - These are some of the many jobs found on our LinkedIn discussion group [ASQ NEI Section 1212](#):

Sr. Principle Engineer, Listening Systems, Round Lake, IL (84,000.00 - 126,000.00)

About the company: Baxter International Inc. develops, manufactures and markets products that save and sustain the lives of people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. As a global, diversified healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals and biotechnology to create products that advance patient care worldwide.

Job Description:

1. Analyzes data from various sources (including, but not limited to: Non-Conformances, FCA, MDR, Complaints, etc) to drive decision-making and effective corrective/preventive actions. a. Establish processes for analysis of quality data, and determination of alert and action levels. b. Design and execute protocols directed at compiling and analyzing quality data. c. Compile data and analyze to determine trends and systemic issues. d. Prepare and issue reports based on information analysis. e. Escalate issues detected to CAPA process.
2. Executes appropriate material control activities based on product monitoring a. Ensure holds initiated and processed as appropriate. b. Work with appropriate owners to ensure correct control and disposition of material.
3. Communicates significant issues or developments identified during quality assurance activities and provides recommended improvements.
4. Prepares and presents technical program information to team members and management.
5. Participates in corrective and preventive actions (CAPA)-related activities, including CAPA ownership if appropriate.
6. Recommends, leads, and/or supports projects for improvements to the quality system. Ensure implementation and optimization of quality metrics to drive improvement to products and systems.
7. Supports product evaluation activities associated with product complaints. a. Provides technical input and assist in gathering appropriate R&D and other functional inputs on issues b. Evaluates deliverables for compliance, completeness, and clarity, and provide feedback / disposition as appropriate.
8. Reviews and approves work for inclusion in Medical Device Reports (MDR's) and provides leadership in the management of investigations supporting an MDR.
9. May supervise one or more engineers or technicians.

Requirements:

1. B.S. degree in Engineering (minimum requirement) and 9-13 years of experience in Product Development, Manufacturing, or Quality.
2. ASQ Certified Quality Engineer or equivalent experience. Able to certify within one year.
3. Completely proficient in product & process development concepts, including change control and risk management.
4. Extensive cross-functional team experience, including technical and non-technical work.
5. Ability to organize and present technical and project management overviews without assistance.
6. Demonstrated ability to work independently.
7. Working knowledge of 21CFR820 (quality systems regulation/good manufacturing practices for medical devices) ISO 13485:2003, and ISO 14971 (risk management).
8. Problem Solving – Apply DMAIC and statistical techniques to address issues and investigations. Resourceful and independent. Applies organizational and technical knowledge to move teams through issues
9. Recognized for technical expertise by peers and or other personnel within the business unit.

For more information, go to: <http://careers.asq.org/jobdetail.cfm?job=3283537>

Quality Engineer

- 3 Years Minimum Manufacturing Experience
- Aerospace Experience Preferred
- Familiar With Process Improvement Tools
- Capable Of Producing Quality Control Plans
- Capable Of Producing FAls
- English Language Is A Must
- Reports To Quality Manager

Salary: \$55,000

Send Resumes To: Methode Electronics, Inc.
Power Solutions Group
Attn: John St. John
1700 Hicks Road
Rolling Meadows, IL 60008

email: jstjohn@methode.com

Mechanical Inspector

- 3 Years Minimum Mechanical Inspection Experience
- Aerospace Experience Preferred
- Capable Of Producing FAls
- English Language Is A Must
- Reports To Quality Manager

Salary: \$40,000

Send Resumes To: Methode Electronics, Inc.
Power Solutions Group
Attn: John St. John
1700 Hicks Road
Rolling Meadows, IL 60008

email: jstjohn@methode.com

Placement News - Local Jobs:

Continued from page 5

Black Belt, Ecolab, South Beloit, WI

The Black Belt will be a change agent and thrives on challenge as s/he assists the South Beloit plant with advancing the Lean Six Sigma initiative to improve profitability through supply & distribution strategies, continuous improvement in quality process control, material efficiency, & new product production. S/he will work in this highly visible role to execute projects, ranging in scope from \$100-600K e.g. material loss reduction/substitution, space lay out, cycle-time reduction, & process control/preventative maintenance projects. S/he will identify options & gain approval for best alternatives from the Plant Manager & support from managers who will be engaged in project implementation and provide leadership and coaching for green belts.

- Leads across organization & influences others. Trains & mentors in the Lean Six Sigma tools & methodology; coaches & develops the Green Belts assigned to projects. Models operational excellence by visibly demonstrating leadership.
- Continually seeks process improvement opportunities for the assigned function or business unit. Assesses & critiques resources required for Lean Six Sigma projects. Assesses & identifies risk in order to fulfill the defined objectives. --- Interprets both internal & external customer requirements. Facilitates the implementation & acceptance of change in the work place. Leverages best practices across the organization in tools & processes.
- Participates in the project identification & selection, determine benefits, recommend resources & team members. Uses data to guide the decision-making process. Identifies organizational barriers; recommends solutions
- Manages & supports projects, tracks improvement, ensure control & maintain accountability. Networks with both internal & external resources

Basic Qualifications:

- Bachelor's degree.
- 7+ years of experience in manufacturing, supply chain environment
- Green Belt training with project completion and 2+ years as a team member in a Toyota/Honda, TQM, Lean, or Six Sigma environment.

Preferred Qualifications: Bachelor's degree in Engineering, Logistics or Business. 2+ years supervisory experience and strong interpersonal skills with the ability to influence & persuade decision makers and motivate team members. Lean Six Sigma Black Belt certification & success in leading complex manufacturing black belt projects. Formal Project management training with strong analytical skills, high potential to assume management responsibilities. Verbal and written communication skills needed to train and coach.

For more information, go to: http://www.leansigmaedge.com/index.php?post_id=2905



World Conference on Quality and Improvement

May 24-26, 2010 · St. Louis, MO · America's Center

SAVE THE DATE

2010 ASQ World Conference
on Quality and Improvement

May 24-26 • St. Louis

Anything is possible if we expand the reach of quality.

Join us in St. Louis in 2010 to meet today's challenges and build tomorrow's confidence.

- Learn new and classic quality tools, methodologies, and techniques.
- Network with more than 1,500 attendees and exhibitors.
- Benchmark best practices in the International Team Excellence Award Process.

Think about it. Mandatory quality practices and methodologies could:

- Prevent food recalls by requiring HACCP certifications and ISO standards.
- Save lives by reducing patient errors.
- Save jobs by reducing waste and the costs associated with it.
- Increase student achievement by implementing continuous improvement tools.

Go to: <http://wcqi.asq.org>

Keynote Speakers:



Alan Mulally: President and CEO, Ford Motor Company- Monday, May 24 – from 8:00 a.m. – 9:00 a.m. **Alan Mulally** is president and CEO of Ford Motor Company. He also is a member of the company's board of directors. Prior to joining Ford in September 2006, Mulally served as executive vice president of The Boeing Company, and president and chief executive officer of Boeing Commercial Airplanes. Throughout his career, Mulally has been recognized for his contributions and industry leadership, including being named one of "The World's Most Influential People" by *TIME* magazine in its 2009 "TIME 100" issue, "Person of the Year" for 2006 by *Aviation Week* magazine, and one of "The Best Leaders of 2005" by *BusinessWeek* magazine. Mulally holds bachelor's and master's of science degrees in aeronautical and astronautical engineering from the University of Kansas, and earned a master's in management from the Massachusetts Institute of Technology as a 1982 Alfred P. Sloan fellow.



Robert Stephens: Founder and Chief Inspector, Geek Squad - Tuesday, May 25 – from 8:00 a.m. – 9:00 a.m. A native of Chicago, **Robert Stephens** left a scholarship at the Art Institute of Chicago in 1990 to pursue a degree in computer science at the University of Minnesota. While attending the university, he landed a job fixing computers for the Human Factors Research Laboratory. Over a three-year period, he rose to become head engineer of the lab. It was also during this time that he started a computer consulting business. In April of 1994, after three years at the university, he formed The Geek Squad with \$200. In 2002, Best Buy acquired The Geek Squad and opened Geek Squad precincts in all of its U.S. and Canadian stores. With more than 17,000 agents, The Geek Squad is now North America's largest technology support company offering phone, in-store, and in-home support. It also has operations in Shanghai and the UK.



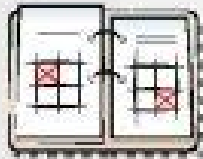
Terry Jones: Founder and Former CEO, Travelocity- Wednesday, May 26 –from 10:45 a.m. – Noon. **Terry Jones** founded Travelocity.com. He led the company as president and chief executive officer from its founding until May 2002. Previously, Jones served as chief information officer at Sabre Inc. In his 24 years at Sabre, Jones held various executive positions, including president of computer services, vice president of applications development, and vice president of product development. Jones is managing principal of Essential Ideas, a consultancy he co-founded to help companies in their transition to the digital economy. A graduate of Denison University in Granville, OH, Jones entered the travel industry in 1971 as a travel agent with Vega Travel in Chicago. He later served five years as a vice president at Travel Advisors, a company specializing in business travel to Eastern Europe and the USSR, with offices in Chicago and Moscow.



Quality Career Fair

Sponsored by ASQ Northeastern
Illinois Section 1212

Mark Your Calendar !



Thursday, February 18, 2010
5:00pm to 7:00pm

The Arboretum Club
401 Half Day Road, Buffalo Grove,
IL 60089

Phone: 847.913.9112

www.arboretumclub.com



Participating Companies

- Abbott
- Aerotek
- Baxter Healthcare Corporation
- ERA Industries, Inc.
- Validant Consulting

Career Fair Objectives



- Meet participating company recruiters
- Networking opportunities
- Meet ASQ business leaders
- Provides a venue for marketing your resume

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Dr. Margaret Hamburg, Commissioner of Food and Drugs - FDA and the American Public: The Safety of Foods and Medical Products in the Global Age

Remarks of Dr. Margaret Hamburg Commissioner of Food And Drugs, Center for Strategic and International Studies, February 4, 2010

The FDA is...a science based agency with mission to protect and promote the public...addressing threats to health, and as the gateway for products that people need. Our responsibility and reach is enormous. The products we oversee account for about 20 cents of every dollar of consumer spending in this country—food, drugs, medical devices, vaccines and biologics, cosmetics, dietary supplements, animal drugs and food, tobacco products, and certain products that emit radiation. Today the FDA faces a daunting set of tasks. **Globalization has multiplied the scale of our responsibility, and the challenges we face.** Consider that FDA-regulated products are currently imported from more than 150 countries, with more than 130,000 importers of record, and from more than 300,000 foreign facilities. This year, we expect that nearly 20 million shipments of food, devices, drugs, and cosmetics will arrive at U.S. ports of entry. Just a decade ago, that number was closer to 6 million, and a decade before only a fraction of that. It is estimated that somewhere around 15 to 20% of all food now consumed in the U.S. originates outside our borders. In fact, some 70 percent of seafood and about 35 percent of fresh produce consumed in the U.S., come from outside our borders. Strikingly those are some of the most vulnerable foodstuffs in terms of potential for contamination. Up to 40% of the drugs Americans take are imported, and up to 80% of the active pharmaceutical ingredients in those drugs come from foreign sources. So we are definitely talking about real numbers. Imported medical devices are another rapidly growing area. The rise of imports has brought clear benefits to the American people. We can eat a huge variety of delicious products from around the world and enjoy all kinds of fruits and vegetables way out of season. .. We can benefit from medical innovation across the globe and we can get certain products more cheaply than otherwise might otherwise have been possible.

Yet this tremendous shift in the global market for food and medical products also has brought important new challenges. In addition to this growth in the sheer volume of imports and foreign facilities, there has been an increase in the variety and complexity of imported products, and a large expansion in the number of countries involved in producing these products -- including many with less sophisticated regulatory systems than our own. Simultaneously, the supply chain from manufacturer to consumer has become more and more complex, involving a web of repackagers and redistributors, and making oversight significantly more difficult. This all adds up to an enormous task for the FDA, and we know that there are very real concerns.

A few examples: In early 2007, melamine-contaminated protein ingredients manufactured in China made their way into U.S. pet foods and animal feed, causing illness and death among household pets across the country. This incident also had major economic consequences, including the recall of hundreds of brands of pet food, and State quarantine or voluntary holds on livestock that had consumed suspect feed. Although these melamine-tainted ingredients were only found in animal products in the U.S., it is not difficult to imagine that they might just as easily have been used in the U.S. production of human food products. In fact, melamine did appear in Chinese infant formula, causing an estimated 300,000 illnesses and at least six deaths in China, and prompting worldwide recalls of milk-containing products. Unfortunately, melamine contamination appears to be a persistent problem, as only last week, Chinese authorities announced that they were pulling more milk products contaminated with the chemical from store shelves. Soon after the melamine incident, the highly poisonous industrial chemical diethylene glycol, or DEG, was found in toothpastes imported from China. Thankfully, FDA was able to issue import alerts, which led to the voluntary recall of the contaminated products before they brought harm to U.S. consumers. However, other countries have not been so lucky: DEG-contaminated products have led to scores of deaths elsewhere in the last several years. And the year before last, many of you may recall the tragedy that occurred when contaminated heparin (a blood thinning drug) came from China and caused deaths and hundreds of allergic reactions here at home. These episodes were particularly disturbing because they represented economically motivated adulteration: truly despicable acts of seeking profit by putting lives at risk. We see this also in the worldwide marketing of counterfeit medical products. Here in the U.S., federal and state authorities have done a lot to keep counterfeiting of drugs to a minimum because of our extensive system of laws, regulations and enforcement. But it requires constant vigilance, and the problem is growing. Counterfeit drugs represent a much greater threat in the developing world, where the system of laws and regulatory oversight do not afford so much protection. Numbers are hard to substantiate and estimates vary, but studies in some countries suggest that between 30 and 50 percent of certain available drugs are actually counterfeit. Needless to say, this is devastating to health and safety.

And in our modern world, profit isn't the only dark motive we must face. Sadly, we know that we are also vulnerable to potential attacks involving our food or drug supply by terrorists determined to do harm. While it is easy to focus on the most dramatic scenarios, there have also been many other significant, but less intentional, episodes associated with contaminated and adulterated products, both food and medical goods. Outbreaks associated with melons, peppers, raspberries, and seafood have all been in the headlines in recent years to name a few. In addition, every day, FDA rejects imports at the border for a range of problems including illegal drug residues, bacterial contamination, unapproved food additives, pesticides, heavy metals, and just plain filth. Each of these crises and near-misses is deeply troubling in and of itself. There are human costs, economic costs, and sometimes an undermining of confidence in government agencies, other critical institutions, and in the products themselves. Even more troubling is the fact that these events are more than isolated incidents. They are symptoms of a significant underlying problem: globalization has fundamentally altered our market landscape.

When the modern FDA was created in 1938, imports were a tiny part of the products used in our country. FDA's import inspection system reflected that fact -- and unfortunately it still does. Massive change will be required for FDA to be able to keep up with a globalized economy. It is easy to see that FDA faces a Sisyphean task if its employees are asked to inspect everything that enters our ports. The estimated 20 million shipments of FDA-regulated imports that will come into the country this year will be handled by fewer than 500 inspectors. Though these employees work tirelessly, they typically are able to examine less than one percent of these products before entry into the U.S. I'm going to talk briefly later about some improvements in this area. But it is simply not possible to count on interdicting everything harmful at our borders.

Similarly, FDA cannot alone conduct a sufficient number of inspections at foreign manufacturing facilities to help ensure product safety. Current estimates are that FDA inspects only about 8% of foreign drug manufacturing establishments each year. At this rate, it would take us more than 13 years to inspect all registered foreign drug facilities. We are taking important steps to increase the number of inspections, as well as follow up inspections of establishments that previously had violations or deficiencies. But it is simply not possible for FDA to inspect our way to safety. **Clearly our nations' traditional approach – relying on FDA inspections to catch problems at the border or in foreign facilities – needs significant overhaul. We need to recognize that addressing the challenge must be a collective and collaborative effort on an international scale...and it will require fundamental and systemic change in the way we, and all of our trading partners, think about import safety.**

To assure the safety of imported products and fulfill our public health mission in a global age, **the FDA must adopt a new approach an approach that takes into account the entire supply chain and its complexity; and an approach that will address product safety by preventing problems at every point along the global supply chain... from the raw ingredients... through production... and distribution... all the way to U.S. consumers. We must move from an approach based on reacting to problems... to one that proactively prevents such problems from ever occurring.** This is a simple, yet profound paradigm shift. This idea is embodied in the food safety legislation now moving through Congress, which would for the first time **allow FDA to establish basic preventive controls throughout the food production process.** This modernizing of our basic authorities is critical to our success as a public health agency in the 21st century. And we must apply this basic principle of prevention to all imports. We are starting now to make this shift.

So let me now share a few elements of our overall strategy:

First, we are seeking better controls at the point of production. This is a shared responsibility among manufacturers, who have the primary responsibility for the quality and safety of their products ... national regulatory agencies, which we are supporting through collaboration and with technical assistance, and the global regulatory community, which must come together as never before. **We're moving into a phase where FDA works with regulators, manufacturers and suppliers wherever they are. We now have permanent FDA offices in Beijing, Shanghai and Guangzhou, China, in New Delhi and Mumbai, India, in San Jose, Costa Rica, Mexico City, Santiago, Chile, and—soon—Amman, Jordan. These offices enable us to have a regional presence around the world; a home base from which to undertake a range of important activities.** We are working with these countries and others to help assure oversight and regulatory capacity. By helping more countries build their regulatory capacity, we build confidence in the safety and quality of the goods they send us. But we are doing much more....we're helping them establish the regulatory powers necessary to support safe products for their own domestic use and a strong, reliable export market. It will benefit their health and development in very fundamental, long-lasting ways.

In addition, there is also much important collaborative work to be done with allies who already have well-developed regulatory systems. In fact, we now have more than 30 agreements with foreign counterparts to share inspection reports and other non-public information that can help us make better decisions about the safety of foreign products. So if a shipment of fish contaminated with a banned fungicide shows up in a port in Italy, we'll hear about it swiftly and be on the lookout for products from the same shipper. Or if our British counterparts share with us critical information about their inspections of certain factories in China, or Egypt or Thailand, we can use that information and not re-inspect those same facilities behind them, but rather use our resources to inspect elsewhere .. places that otherwise none of us would have seen. For example, FDA and our partners in the European Union and Australia are jointly planning and conducting inspections of facilities in countries that manufacture the starting materials for many of our drugs. And we also now have FDA staff working in the offices of key regulatory agencies overseas to build on these relationships, and we have EU representatives working with us. These programs are promising, and all of them make one thing clear: to address import safety, we will not be able to go it alone.

A second key element of our strategy is to hold importing companies responsible for their supply chain. In this day and age, companies must be able to effectively demonstrate that safety, quality and compliance with international and U.S. standards are built into every component of every product and every step of the production process. Some companies already do a terrific job at this, tracking where and how their products are made and the path taken to reach our shores. Obviously they have a vital interest in assuring confidence in the safety and quality of their products and their brand. These best practices need to become standard practice throughout industry. And FDA will work with industry to set standards for technologies and other approaches that can help them strengthen the safety of their supply chains.

On the other hand, companies that sell contaminated products because of loose supply chain oversight need to face serious penalties ... and cannot excuse themselves by blaming their suppliers, blaming FDA or blaming anyone else. Only when we have a sense of shared responsibility – and accountability – will we have a truly safe global supply chain.

Third, we at FDA have a responsibility to deploy our agency's resources as strategically as possible. This is more critical than ever, as our mandate keeps expanding, despite these economically challenging times. In this regard, I want to take this opportunity today to formally announce a new FDA program that will enable us to more effectively and efficiently do import inspections. I have already discussed how in today's world, we can't simply be "guardians at the gate" attempting to detect and weed out dangerous and contaminated products at our ports and borders. But as part of a comprehensive program we still need to screen at the borders....and we can and must do it in a much more meaningful way. The system we are now deploying is called **PREDICT**–the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting. It is a sophisticated information technology system developed for use by our border inspection operations, that will allow us to monitor products at the port of entry more reliably and to target shipments for inspection that pose the greatest risk. The system was piloted in Los Angeles and we are currently bringing it on line in New York. Hopefully we will have it up and running around the country by the end of the Spring. With PREDICT, investigators will still be checking only a small percentage of all import shipments. But they'll be using better intelligence to decide which shipments to check. PREDICT uses a variety of assessments to rank import shipments according to risk. It considers everything from whether a product is intrinsically risky–raw seafood falls into this category– to information we've acquired from previous examinations of shippers or producers. We can even add information on things like floods, hot weather or market conditions that suggest whether a particular shipment is at risk of being spoiled or shoddy. These and other factors

are added up to give a risk score—and the riskiest items are the ones that our investigators will check first. We expect PREDICT to offer two major benefits to FDA import inspectors, to importers, and to the public. First, the system will automatically flag potentially risky shipments. Second, the system will give lower risk scores to more innocuous materials, which can then be cleared through FDA inspection rapidly. This allows FDA inspectors to spend their time looking at the highest-risk items. It also means that carefully labeled products with good histories will be held up for shorter periods, which is better for everyone. I brought a short video demonstrating the PREDICT system in action which I think we may show when I am done speaking. It's only about four minutes I'm told...PREDICT is an exciting innovation, that harnesses advances in information science to enable us to do our job better and to improve our service to the nation. But it is just one step.

More broadly, we are moving from a system that places most of the regulatory burden on the FDA's modest inspection force, to one that creates greater oversight at points further back along the production chain. We need to know who is making our foods and drugs, where they are located, and we need to be sure that these facilities are being inspected and are accountable for what goes into their products as well as the products they produce. We need to create a global safety net. I can assure you that addressing the problem of global supply chain safety, and shifting the existing paradigm from reaction to prevention, is one of my highest priorities for FDA. Refining our understanding of the problem and exploring and assessing possible solutions will be a major focus of our work over this next year and well beyond.

Ironically, seventy years ago, DEG – the same poisonous chemical found just a few years ago in tainted Chinese toothpaste – precipitated another similarly significant shift in the FDA's approach to product safety. In 1937, 105 people in the U.S. died after ingesting Elixir Sulfanilamide, an antimicrobial medication that included DEG as an ingredient. In response to this tragedy, Congress passed the 1938 Federal Food, Drug, and Cosmetic Act. As a result, **FDA moved beyond simply responding to problems and intercepting adulterated drugs on the market: we began to conduct pre-market evaluations to prevent unsafe drugs from entering the market in the first place. The most recent DEG episodes show that we need another fundamental change in the way we do business... this time on a global scale.** This will require new ways of thinking and new partnerships, in addition to new resources and new authorities.

Now is the time for FDA to fully engage –bilaterally, multilaterally and through international and regional organizations—to work with countries

**And going forward, I firmly believe that we need to marshal the talents and engage the creative thinking of determined citizens, scientists, government officials, business and political leaders, thought leaders....in short, all of you...because this is a universal vulnerability and a universal responsibility. ~ Dr. Margaret Hamburg
Commissioner of Food and Drugs**

*Remarks of Dr. Margaret Hamburg
Commissioner of Food and Drugs at
Protecting Health: FDA's Global Challenge,
January 28, 2010*

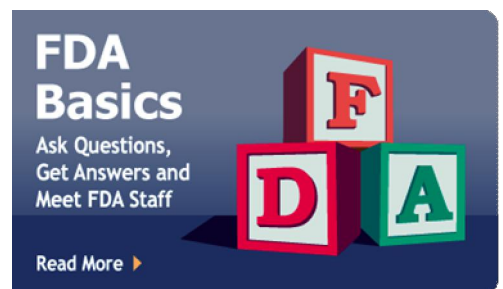
throughout the world to share scientific and technical expertise; to harmonize international standards for safe food, drugs and medical products; to work with industry to enhance compliance with standards; and, very importantly, to help countries with less mature economies and regulatory systems build capacity so that they can produce food and commodities that are safe, wholesome and meet international safety standards, for both their own consumption and for export. Such an approach represents a shift to a new paradigm for the safety of U.S. food and drug imports, and it will not be easy to accomplish. We will need to marshal the support of our stakeholders, our international partners, and the Congress.

However, the benefits of this new paradigm for global product safety go well beyond our borders, and in fact, they go beyond health. When governments collaborate to invest in the capacity of countries to produce food, drugs, medical devices, and cosmetics for export in accordance with strong safety standards, there are multiple and mutual benefits.

Although my duty as FDA commissioner is to protect the health of the American people-- and importantly the safety of our nation's supply of food and medical products--my experience throughout my career has shown me, time and again, that public health protection is a global endeavor. All people in the world deserve safe food and access to quality medical care. All nations deserve the opportunity to participate and prosper in the global economy. We as an agency have difficult work ahead of us ... but this is a challenge that we are eager to meet. I look forward to hearing your ideas about how we can move toward a global vision for import safety...and how we can do it together.

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From The Nor'easter Editor - Call for Articles

By Adela Crandell, Editor, The Nor'easter

Many thanks to those who have contributed articles and we wish to emphasize that we need articles. Please submit all information for the **March 2010 Nor'easter** by **Thursday, February 18, 2010. We need a bank of outstanding Quality Articles. RU Ready to Submit your Article?** If your technical, quality related article of one page or less (approximately 500 to 1000 words) is published, you can receive 1 RU credit, as long as you keep a copy of the newsletter as proof. You then submit that to ASQ with your re-certification journal packet. Text can be sent to adelacrandell@mac.com. If you have graphics, logos, photos, etc., please call or e-mail. Please e-mail me your questions. The editor reserves the right to edit material, and items received after the deadline may be dropped or inserted in a future issue.

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By Adela Crandell, Editor, The Nor'easter

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✓ Planning Ahead - Mark Your Calendars:

February 2010

ISO Support Group Date: Thurs. Feb. 04, 2010 Location: The New China Buffet. 1161 S Milwaukee Ave.; Libertyville Time: 6:00 pm <i>The Meal is \$5</i>	Leadership Committee Meeting Date: Thurs. Feb. 11, 2010 Location: Dover Straits, 890 E Rt 45, Mundelein. Time: 6:00 pm <i>The Meal is Free</i>	Section Meeting Date: Thurs. February 18, 2010 Location: Arboretum Club 401 W. Half Day Rd, Buffalo Grove Pre-meeting clinic: 5:00 – 7:00 pm Career Fair Networking: 6:00 – 6:30 pm Dinner: 6:30 pm <i>the Meal is \$25</i> Main Presentation: 7:30 – 8:30 pm Main Presentation: FDA Guidance: Understanding GMP/QSR as a Concept By Lorelei Jarrell, FDA Chicago Branch
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March 2010

ISO Support Group Date: Thurs. March 04, 2010 Location: The New China Buffet. 1161 S Milwaukee Ave.; Libertyville Time: 6:00 pm <i>the Meal is \$5</i>	Leadership Committee Meeting Date: Thurs. March 11, 2010 Location: Dover Straits, 890 E Rt 45, Mundelein. (847) 949-1550 Time: 6:00 pm- <i>Meals Free</i>	Section Meeting Date: Thurs. March 18, 2010 Location: Colbert Packaging Corporation, 28355 North Bradley Road Lake Forest, Illinois 60045 http://www.colbertpkg.com/ Lambs Farm Country Inn Restaurant, 14245 W Rockland Rd, Libertyville, IL 60048 Plant Tours / Buffet Dinner 5:30 – 8:00 pm Meal is \$25 Main Presentation: Lean Process by Gary King (8:00 – 9:00 pm)
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April 2010

ISO Support Group Date: Thurs. April 01, 2010 Location: The New China Buffet. 1161 S Milwaukee Ave.; Libertyville Time: 6:00 pm <i>the Meal is \$5</i>	Leadership Committee Meeting Date: Thurs. April 08, 2010 Location: Dover Straits, 890 E Rt 45, Mundelein. (847) 949-1550 Time: 6:00 pm- <i>Meals Free</i>	Section Meeting Date: Thurs. April 15, 2010 Location: Arboretum Club 401 W. Half Day Rd (Rt. 22 E. of Rt. 83), Buffalo Grove Pre-meeting clinic: Process Improvements for Admin Departments By Willie Carter (5:30 – 6:00 pm) Networking: 6:00 – 6:30 pm Dinner: 6:30 pm <i>the Meal is \$25</i> Main Presentation: FDA By Hugh Grimes (7:30 – 8:30 pm)
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The Nor'easter is published monthly for the Northeastern Illinois Section 1212 of the American Society for Quality.



The Nor'easter

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SECTION 1212 GENERAL MEETING INFORMATION

**Meets on the 3rd Thursday of the month - Pre-Meeting Clinic begins promptly at 5:30;
 Networking / Social from 6:00, Dinner is served 6:30; Main Presentation from 7:30-8:30**

For reservations, contact asq1212reservations@yahoo.com

If you wish to attend without the meal, there may be a section reserved for non-dining guests.

DATE	PRE-MEETING CLINIC	MAIN PRESENTATION
February 18, 2010	Career Fair Brought to you by Bill Stinchcomb, Placement Chair. Featuring recruiters from companies such as: Abbott, Aerotek, Baxter, ERA Industries Inc. 5:00-7:00pm in the adjoining conference room	FDA Guidance: Understanding GMP/QSR as a Concept By Lorelei Jarrell, FDA Chicago Branch 7:30 – 8:30 pm
March 18, 2010	Plant Tour: Colbert Packaging Corporation 28355 North Bradley Road, Lake Forest http://www.colbertpkg.com/	Lean Process By Gary King Lambs Farm Country Inn Restaurant, 14245 W Rockland Rd, Libertyville www.lambsfarm.org
April 15, 2010	Process Improvements for Admin Departments By Willie Carter	FDA By Hugh Grimes
May 20, 2010	Getting Your Certification – How to Take the Exam By Dave Taylor and Dave Spengler	Recert & Packet Info By Merle Goddard
June 17, 2010	Putting Contest and Statistics By Dave Taylor	Quality Tools By Wayne Taylor

Feel free to contact any of the committee chairs or officers, if you have any questions or if you would like to help us provide quality meetings, programs and activities. We welcome your participation.