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Thursday April 15th's Main Presentation: Deming's System of Profound Knowledge (SoPK) – The Key to Success in Change Management

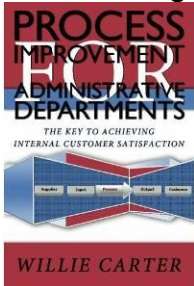
By Marlyn Hyde Program Chair

We hoped to inspire you to become change agents with our March programs. Today's World is changing at a rapid rate - the organizations that thrive are agile, adaptive, and understand the magnitude of change management. Darwin said "It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is the most adaptable to change." Recent economic challenges have made successful change management (the management your organization's most complex change challenges) an essential skill for all leaders and managers. This April, one of our favorite speakers, Wes Bucey, returns to share with us an inspirational methodology for successful Change Management based on the theory of Dr W. Edwards Deming. Be inspired by Wes Bucey's insights. Whether you are within the pharmaceutical, service, or manufacturing industries - don't miss this perfect chance to learn how to become a better change leader: to inspire, engage, empower, and energize your organization to take advantage of the window of opportunity before it closes.

Continued on page 3

Pre-Meeting Clinic: Willie Carter's Process Improvement for Administrative Departments -The Key to Achieving Internal Customer Satisfaction

By Marlyn Hyde Program Chair



In today's economy, traditional methods like restructuring and reorganizing are stop gap and fleeting solutions. Methods that were popular in the early 1980s (downsizing and mergers) no longer ensure long-term competitiveness, nor do they remedy the inconsistencies caused by knee-jerk reactions. A more focused approach for improving quality and productivity has to be found. Sandra Storli and David Norby present key elements from Willie Carter's book, "Process Improvement for Administrative Departments: The Key to Achieving Internal Customer Satisfaction", including simple steps to help you improve collaboration and communication between your administrative departments. This presentation will provide real world tools and techniques to improve departmental processes by focusing on the customers of those processes. Companies that manage their operations by focusing on customer-oriented processes do a much better job of putting customer needs first because process performance is measured in ways that support customer expectations.

Imagine how much more efficient your administrative or office processes would be if they treated downstream departments as customers!

This presentation will show you how to get focused by using an eleven step proven approach for improving administrative/office processes. The focus is on administrative departments and their internal customers because many times organizations lose sight of how important it is to satisfy the internal user of departmental output. Sandra and David will be joined by Kevin Cloonan for the question and answer session, after the presentation.

Continued on page 4

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 April 15th** 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: Willie Carter's Process Improvement for Administrative Departments: The Key to Achieving Internal Customer Satisfaction by Sandra Storli and David Norby - 5:30-6:00 pm

Networking/Dinner: 6:30 pm

Main Presentation: Deming's System of Profound Knowledge: The Key to Success in Change Management by Wes Bucey - 7:30- 8:30 pm

The meetings are always free, meals are \$25, please reserve in advance.

E-mail Dave Krasowski, Your Arrangements Chair: asq1212reservations@yahoo.com.



Inside This Issue

April Section Meeting	1&3	April Pre-Meeting Clinic	1 & 4
Education	2	ISO Group Minutes	2
March Reviews	5 & 6	Message From the Chair	6
Supplier Selection Assessment/Audit	7	Planning Ahead	8
World Conference on Quality and Improvement	8	FDA Task Force	9



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

Except for the Certified Quality Auditor class (see below), all our scheduled classes are underway or finished for this semester.

Class	Duration	Trainer/ Coordinator	Contact	Start date	Sign up for exam (ASQ)	Exam
Certified Quality Auditor	Two Days	Bettina Karlove	vanguard0@comcast.net	4/27 & 28 (16 hours)	4/16	6/5

Once again, thank you to all who supported our section by training or attending classes this year.

June training meeting in July! On July 15, 2010, we ask all who are interested in becoming involved in training for the section attend a meeting to discuss our training programs and what would be the best ways to proceed in the future. See the May newsletter for details or contact Dave Taylor at kolimat@yahoo.com.

Look for fall training information in the August edition of this newsletter.

ON-SITE COURSES OFFERED ALL SUMMER. And 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 - including these offerings and many others:

CRE Review
 Engineer Review MSA/Gage R&R
 Six Thinking Hats (Team Building)
 Improving Team Performance With Quality Tools
 Short Run SPC
 The Illinois Lincoln Award

Review Certified Reliability Engineer Review
 8D Problem Solving Methods
 Successful Acceptance Sampling
 QS-9000 Continuous Improvement Tools
 Upgrading to ISO 9000 to QS-9000
 Lean Office Simulation

Certified Software Quality
 Quality Function Deployment
 Lateral Thinking
 Robust Tolerance Analysis
 Statistical Thinking
 Lean Office Training

If your company has specific training requirements or you want information about any of our courses, please contact Dave Taylor at kolimat@yahoo.com.

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

Nine members attended the meeting on April Fools Day (really) April 1, 2010 at the New China Buffet. In attendance were G. David Spengler, Jan Agostinelli, Bill Sherman, Peter Larson, Christine Rhodes, Maya Wolf, Dylan McDaniel, Luke Nedza and Dave Taylor. The group continued our study of ISO/DIS 26000, Guidance on social responsibility. We reviewed Section 6.3.7 Human rights issue 5: Discrimination and Vulnerable Groups, Section 6.3.8, Human rights issue 6: Civil and Political rights, Section 6.3.9, Human rights issue 7: Economic, Social and Political Rights and 6.3.10 Human rights issue 8 Fundamental; Principles and Rights at Work. We are not rating this document, but the discussions are most enlightening and entertaining!

In the round robin review: Dave S is working with company manager on several projects, which is a good thing, is developing helpful documents for the customers, highlighting where specifications can be located. Also, Machinists are developing best practices and writing specs on powder coating. Dave T continues with long-distance ISO 9001 customer in San Diego, CA. The Stage I audit was held in March and a registration audit in late April. Also, Dave completed a project on a "Failure Mode Effects Analysis" project at a company in Waukegan. Jan had 100% success rate with her students in the CQM/OE course in Island Lake. All who took the exam passed. Bill got an opportunity for a FDA opening from networking at an ASQ meeting. Peters company has a successful ISO 9001 surveillance audit. Some minor findings were easily fixed. Christine will be busy in April and May with several internal audits.

Our next two meetings will be held at 6:00 on Thursday, May 6 and June 3. We will continue our review of ISO/DIS 26000, "Guidance on Social Responsibility", I would encourage your attendance, as this Guideline has shown to be very interesting to discuss.

A gratifyingly succulent 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.



Main Meeting: Deming's SoPK – The Key to Success in Change Management

Continued from page 1

Change Management is one of those topics which raise fears of layoffs and downsizing. Deming frequently said - "Remove FEAR!" Wes Bucey's presentation will help you have the confidence to be a change agent and to embrace change with enthusiasm and hope. As Wes says "In all change, there are folks who resist it, those who go along reluctantly, those who embrace it, those who manage it, but, most importantly, there are a few folks who see the need for change and make it happen! Those of us in the Quality profession usually find ourselves in the role of 'followers.' On some occasions (rare ones), we are allowed the opportunity to 'manage' change". Wes's contention is that more of us in the Quality profession should be the ones who "make" change. He'll offer tips on how to do that based on his forty plus years of experience as a "suit" in the executive suite. Wes Bucey, will help us understand how adopting and implementing Deming's System of Profound Knowledge will help any organization achieve breakthrough success in process improvement, regardless of where an individual stands on the corporate ladder. For organizations engaged in Change Management or contemplating Change Management, SoPK is probably the single most important factor in implementing a successful change.



As always, Wes Bucey will present a MAGICAL EXPERIENCE, audience interaction, and lots of fun! Wes specializes in making a fun presentation with lots of audience participation. This will NOT be a snoring session with Wes reading his PowerPoint slides in a dull monotone. Wes is semi-retired; his most recent full time posting was Quality Manager for an

aerospace firm with facilities in the USA and France. Previously, he was Chief Operating Officer for a high tech contract machining company serving the aerospace and medical device industry. He is currently writing a book based on case studies of firms he is advising which have reached a crisis point and need help and advice to achieve the next plateau in their development.

Understanding of the system of profound knowledge – by


Deming. "The individual, transformed, will perceive new meaning to his life, to events, to numbers, to interactions between people. Once the individual understands the system of profound knowledge, he will apply its principles in every kind of relationship with other people. He will have a basis for judgment of his own decisions and for transformation of the organizations that he belongs to. The individual, once transformed, will: set an example, be a good listener, continually teach other people, and help people to pull away from their current practices and beliefs and move into the new philosophy without a feeling of guilt about the past."


Deming advocated that all managers need to have what he called a System of Profound Knowledge, consisting of four parts:

- **Appreciation of a system:** understanding the overall processes involving suppliers, producers, and customers (or recipients) of goods and services
- **Knowledge of variation:** the range and causes of variation in quality, and use of statistical sampling in measurements
- **Theory of knowledge:** the concepts explaining knowledge and the limits of what can be known
- **Knowledge of psychology:** concepts of human nature.


..."The various segments of the system of profound knowledge proposed here cannot be separated. They interact with each other. Thus, knowledge of psychology is incomplete without knowledge of variation".

To view the writings by Dr. Deming – you can go to: *The W. Edwards Deming Institute* at <http://deming.org>

<p align="center">Are you signed up for facebook?</p> <p align="center">ASQ Section 1212 is building a facebook page... Check it out out ASQ NEI Section 1212</p> <p>*Become a fan and you can write on the wall, post pics and more!</p>	<p>Quality Quote:</p> <p>"The biggest mistake organizations make is failing to focus on the high leverage actions that really make a difference in the organization's long-term competitiveness." ~ Michael Cowley</p> <p>Have A Winning Day! Submitted by - Willie L. Carter</p>
<p>If you're job hunting, please join us on our new LinkedIn discussion group ASQ NEI Section 1212 http://www.linkedin.com/groups?home=&gid=2236959</p>  <p>Bill Stinchcomb our Placement Chair is posting jobs there regularly. Check out the jobs posted there!</p> <p>You can also follow us on our Twitter account: asq1212jobs</p>	<p>Let everyone know that the section's website is up and available. You can use 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>



Door Prize Winners from our last 1212 Section Meeting.
 Congratulations to our lucky winners: "Jimmy" Jun Nie and Nick Lyons!



Pre-Meeting Clinic: Process Improvement for Administrative Departments: The Key to Achieving Internal Customer Satisfaction

Continued from page 1

At this presentation, you will learn that in order to improve collaboration in the workplace you must improve your processes by:

- Establishing a department mission
- Identifying your customers (internal and external)
- Identifying and defining customer requirements
- Planning to meet customer requirements
- Delivering on the promise
- Tracking and analyzing process performance

Key Benefits:

- Enables your organization to focus on the internal customer
- Learn some simple techniques to improve your work processes
- Learn how to translate customer needs into a language your department can understand and measure their performance against.



Sandra Storli, Senior Quality Project Manager/Division Auditor for Abbott Diagnostics Division, has over 25 year's quality assurance expertise within the Diagnostic, Medical Device, and the Food industry. Sandra has held various managerial, supervisory, project management and individual contributor positions with Abbott and the Kellogg Company. Sandy holds a BS from the University of Wisconsin, MBA Degree from Franklin University, MS

from the University of Wisconsin and currently working on a Graduate Degree in Regulatory and Compliance. Sandy also holds several certifications including: CMQOE, CQA, CBA, RABQSA-LA and Certified Trainer for the CQA refresher course. Sandy is working with several of ASQ's Divisions in promoting Quality as a regional councilor for Region 12 for the Audit and Food, Drug and Cosmetic Divisions (FD&C). Sandy is also a member of the Technical Program Committee (TPC) for the World Conference in St. Louis. She will work with several of the speakers of the conference in assisting them with their presentation material.

David Norby is a Principal Technical Support Scientist in the On-Market Statistical Support Group (D-04Z7) of the Diagnostics Division at Abbott Laboratories. He has a PhD in Biochemistry, is an ASQ Certified Quality Engineer, and is certified to the Corporate CAPA Rubric Investigator and Resolution Planner roles. He provides consultation and statistical analysis for customer complaint and other product or process performance investigations, CAPA improvement projects, and other issues. In nearly 20 years with ADD, Dr. Norby has held both managerial and individual roles in product and process technical support, product and process development, process and test method validation, statistical process control and other statistical support. Before he joined Abbott, he held managerial roles in Plant Quality for a commercial cell culture facility, Process Development for a company producing sterile cell culture nutrients and media, and Production and Purification Process Development for a company producing industrial-scale enzymes by fermentation. His academic experience included faculty positions of medical or dental schools at Case Western Reserve University, State University of New York at Stony Brook, and University of Alabama in Birmingham, where his research included studies of proteins and protein-polysaccharides related to development and diseases of the musculoskeletal, cardiovascular and dental systems.

Kevin Cloonan is the Metrics Manager for the Medication Delivery Division of Baxter Healthcare. He is an ASQ Certified Manager of Quality/Organizational Excellence. His current responsibilities include the development, implementation, analysis and reporting of a wide variety of Quality System and Operations process metrics for the Medication Delivery Division. His focus is using process metrics and appropriate statistical analyses to drive continual process improvements. Prior to joining Baxter in November 2008, Kevin worked for 27 years at Abbott Laboratories in a variety of Quality Management, Project/Program Management, and Product/Process development roles.



Willie L. Carter is the author of the book "Process Improvement for Administrative Departments: The Key to Achieving Internal Customer Satisfaction", at Amazon.com.

He is the president and principal of Quantum Associates, Inc. – an independent consulting firm specializing in providing solutions for creating customer value. Northbrook, Illinois. Willie Carter has over 30 years experience as a professional quality and operations manager with the following companies: Dexter Corporation/Reliance Universal (AKZO NOBEL), Reichhold Chemicals and International Jensen. Since 1986, Willie has generated millions of dollars of bottom line savings for companies by maximizing value and minimizing waste in manufacturing, management and administrative processes. He has put together a specialized team of consultants with various skill sets (ISO 9000, Lean Manufacturing, Lean, Six Sigma, Process Performance Improvement, Team building, team problem solving/root cause analysis, organization development and project management) dedicated to helping industrial and service organizations become more efficient and cost competitive. For more information on how they help companies create customer value, visit their website at <http://www.quantumassocinc.com>. Prior to starting Quantum Associates, Carter was Vice President of Quality and Operations Support Services for International Jensen. He is an adjunct faculty member of the Walter E. Heller College of Business Administration at Roosevelt University (Chicago) teaching BA/MBA courses in Operations Management, Statistics and Executive Leadership. Willie Carter, Senior Member American Society for Quality (ASQ), is a Certified Lean Sensei, Certified Manager of Quality/Organizational Excellence, and a Certified ISO 9000 Lead Assessor, an ASQ certificate in Customer Satisfaction Measurement, Team Facilitation and Quality Management certificates from the Joseph Juran Institute, ISO 9000 documentation certificate from Michigan State University, Process Mapping Training from Motorola University, and Just -in-Time Manufacturing certificate from Ken Wantuck and Associates. Certifications and degrees include: MBA (Honors), Roosevelt University, BA Chemistry, Southern Illinois University. He serves on the boards of the Institute of Management Consultants-Chicago Chapter and the Northeastern Illinois Section of ASQ. He is a member of the following organizations: Association for Manufacturing Excellence, American Society for Quality, Institute of Management Consultants, Society of Manufacturing Engineers, Society of American Military Engineers, Beta Gamma Sigma Honorary Business Society, Delta Mu Delta International Honor Society in Business Administration, and Kappa Alpha Psi Fraternity Inc.

Contact Willie at: wcarter@quantumassocinc.com



Section Events

Come join us! Share the passion for excellence with talented top speakers, authors, quality experts, and active quality professionals. ASQ Section 1212 provides a wide range of quality related topics, events, and resources to meet your needs.



David Norby
Section Secretary

We were proud to offer you three programs at [Colbert Packaging](#) and at [Lambs Farm Country Inn Restaurant](#)

March 18th Review - Pre-Meeting Clinic: Plant Tour at Colbert Packaging *By David Norby*

Our plant visit to Colbert Packaging's site on Bradley Road in Libertyville was another great learning opportunity. Our hosts gave us a warm welcome, and the pride they took in their plant and work was evident from beginning to end of the tour. For those of us with little prior exposure to this business area, this was an eye-opening learning experience. We began with a brief orientation, where we were shown some of the range of types of packaging produced at the plant. Much of the production at this plant is for packaging that is used in the food, pharmaceutical and medical device markets, so very exacting standards are applied to each lot to assure that each lot will fulfill customers' needs for clarity, consistency, traceability, durability and security. Our hosts described the technologies associated with completing the different stages of processing. Some of the steps include cutting large rolls of stock into uniform sheets, printing in up to 6 colors, application of waterproof overcoat layer, cutting and scoring, removal of scrap paperboard stock, accumulating and packing the product for shipment to customers. Much of this takes place within machinery with metal panels that shield the processing activity from view, so the initial orientation helped us a lot in understanding different areas of the plant. During the actual tour, we visited the design area, where computers are used to design outer packaging and protective inserts, as well as the cutting/scoring dies and the printing masks for customers' artwork. We then were led around the manufacturing floor and saw in progress each of the steps that had been described earlier. We saw a plant well-arranged to support efficient work flow, and there was much evidence of care being taken to assure segregation of work while still maintaining efficient use of floor space. All in all, it was an enlightening experience.

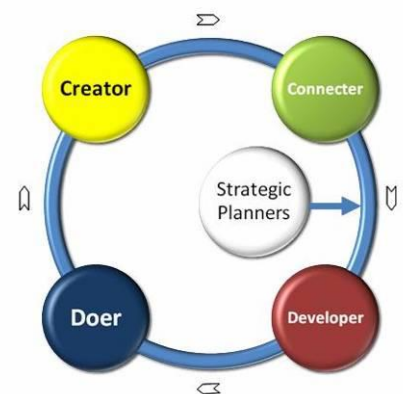
March Review - First Presentation: Innovation. Driver of Value Creation *By David Norby*

First Speaker: Willibert (Willy) Fabritius of the third-party inspection/audit company BSI spoke on "Innovation. Driver of Value Creation." Willy opened his presentation by addressing the notion of "Innovation" itself, in order to set a framework of thought. Showing a number of quotations on the topic, he was able to show that there is a wide range of perceptions as to what it is, what it should be and what it needs to deliver. Ultimately, he reverted to a dictionary-like definition: "The successful conversion of new concepts and knowledge into products and processes that deliver new customer value in the market place." Innovation is widely recognized as a key to success for both manufacturing and service sector companies. It drives the creation of new businesses, which are the principle source of new job creation in our country. It is also the key to new value creation within existing companies. On both accounts, it is clear that innovation is a key to growth/success of our national economy. This makes it essential for management to understand the elements of the innovation process and to identify the best management practices that create, promote, and sustain an environment that stimulates innovation in a way that results in new profits. One of the key elements in management of the innovation process is recognition of the rapid changes occurring in many markets. Things like emerging markets, demographics, and fundamental technology changes can profoundly impact the success of a new product in the market place. Willy cited several changes, including the change in the photographic market: the shift from film to digital cameras. At this point, even the most creative and imaginative new product is unlikely to have a broad market if it depends on the use of film photography.

Willy described the concept of an "Innovation Cycle", consisting of five phases:

1. Find the opportunity
2. Connect to the Solution
3. Select the Solution and Set Strategy
4. Make it User Friendly
5. Get it to Market

It needs to be understood that the different phases need to be managed in different ways to obtain optimal performance. In the first phase, a looser management style is needed, and proceeding forward to the fifth phase, a progressively tighter management style is needed to assure timeline fulfillment, achievement of financial objectives, and delivery of a product that delights the customer. Willy described four different categories of personality traits important to innovation, which he called "Creators," "Connectors," "Developers," and "Doers," and then addressed how they fit into different phases of the Innovation Cycle. It is important to recognize that innovative ideas can come from many directions, so it is critical to generate an environment that welcomes ideas from all directions.



He discussed the importance of forming a Strategic Plan, particularly in the definition of Tipping Points, where the project is reviewed and assessed for continuing support. People involved in this process need to continually manage external risk – at key points, it's essential to assess market changes and determine whether the market envisioned at the start still exists and is likely to remain when the product launches, and to assess the emergence of potentially competing technology. This difficult decision-making process is essential to assure that further resources are not wasted.

In conclusion, Willy addressed the path forward – he encouraged us all to Start a Project – Get an Early Win. Nothing succeeds like success.

March Review - Main Presentation: The Safety of Foods and Medical Products in the Global Age: Strengthening the Safety of Supply Chains *By David Norby*

[Disclaimer: the following notes are intended to be a faithful summary of our speaker's remarks. However, the reviewer does not represent or otherwise speak on behalf the FDA. No reader should imply or assume any exact or literal use of these notes as "FDA guidance." For specific questions affecting your business, please consult FDA publications and/or contact the FDA directly.] Second Speaker: Nick Lyons, Drug Team Supervisor, Foreign Cadre Coordinator, Food And Drug Administration, Chicago Office, spoke on "The Safety of Foods and Medical Products in the Global Age: Strengthening the Safety of Supply Chains."

Brief summary: Mr. Lyons spoke with a sense of urgency about an important message that needs to be received, understood and acted upon by responsible leaders and staff of companies manufacturing and distributing products regulated by the FDA, namely food, drugs, medical devices and cosmetics. I understood that message to be that recent well-known incidents of product contamination highlight the need for companies in these businesses to assume a more active/aggressive role in managing their total supply chains. Companies must be more active in all areas of identification, qualification, selection, monitoring and management of their supply chains. Extra steps must be taken to go beyond simply checking to see if a supplier has a paper quality system. Supplier auditors need to insist that suppliers demonstrate that their quality systems are suitable and are actively used. Suppliers must show that they are willing and able to identify problem areas, and that issues potentially affecting the integrity of the product are actively sought out, and resolved when found. FDA will be increasingly holding manufacturers responsible for due diligence in this area.

Mr. Lyons began his presentation by framing the scale of the issue currently facing FDA in its inspection programs: Approximately 1/4 of United States Gross Domestic Product falls under regulation by FDA. Over 20,000,000 shipments of FDA-regulated items per year arrive at US ports from over 300,000 foreign sources, including 15-20% of all food consumed in US. FDA has established offices in a number of foreign countries, but current staffing only supports inspection of about 8% of foreign plants per year. Only 500 inspectors are assigned to port inspections, paperwork for all shipments is reviewed, but less than 1% of shipments are physically inspected by FDA.

He then went on to describe a number of relatively recent product recalls that resulted from raw material contamination. One American manufacturer voluntarily recalled several lots of Over-The-Counter (OTC) medicine due to potential contamination with a fumigant used on wood pallets. A different American manufacturer recalled all material produced for a year due to salmonella in hydrolyzed vegetable protein, causing over 30 customer companies to also issue recalls. Another American manufacturer recalled soy grits due to salmonella contamination. A major processor of raw peanuts had to recall everything produced at its Texas and Georgia plants due to bacterial contamination, causing many of its customers to issue recalls. A pistachio processor issued a recall for salmonella contamination. An American manufacturer recalled nine lots of heparin due to contamination with over-sulfated chondroitin sulfate (not normally part of a heparin preparation). Protein raw material used in manufacture of pet foods was found to contain toxic compound melamine, causing widespread recalls of pet foods. Diethylene glycol was found in toothpastes imported from China, causing a recall. Counterfeit drugs are an additional complex issue. All of the issues cited and reviewed were already of public record.

The primary responsibility for the recall issues lies with the manufacturing supplier. But many of these issues could have been identified through more in-depth evaluation by manufacturers' supply chain auditors, enabling both the supplier and the manufacturer to avoid costly recalls. Things that could enhance effectiveness of supply chain audit reviews include walk-around inspections, watching a process flow and verifying it against the written documentation, reviewing microbial test results and follow-up actions. Other things that could help include establishment of a system for component supplier to notify manufacturer of a product problem.

Mr Lyons went on to list a number of initiatives that the FDA is pursuing: Emergency Response Coordinators, Reportable Food Registry, Prior Import Notice, Complaint Investigations, MedWatch Reporting System, and the new PREDICT reporting system.

Message from the Chair *By Sandra Storti*

Spring into Action! Spring is upon us and there are many opportunities for learning, change, and growth. With change comes transformation!



We are continually striving to provide our members with the tools, principles, practices, topics and resources to:

- ☀️ Help you grow personally and professionally.
- ☀️ Help you, and your company, keep pace with the velocity of change and blossom.
- ☀️ Help you become a leader of quality.
- ☀️ Inspire and empower each of you to reach out to our members and cultivate a Quality culture (expanding the Reach of Quality is the theme of the World Quality Conference <http://wcqi.asq.org>).

We were very happy with the Career Fair turn out and hoped it helped our members who are between jobs, or are in transition within the job market. If you're job hunting join us on our new LinkedIn discussion group at [ASQ NEI Section 1212!](#)

We will have a new newsletter editor and Nor'easter format. Our website is up and live - please check out the website at www.asq1212.org.

Section1212 is committed to helping you succeed! By supporting each other, we can all stay positive, work together and help each other during these challenging times. We are dedicated to being a primary source for your individual and organizational excellence. Your active on-going membership is very important to collectively making our section one of the top rated sections in the society. So, if there is anything that we can do to help you achieve your goals - please let us know.

Supplier Selection- Assessment / Audit *By Marion Menze*

In March's issue of the Nor'easter, the Supplier Selection process was described. A supplier or two have been selected that appear to be prime candidates to produce the piece parts required for that new product.

As most experienced auditors know, there are varying degrees of supplier certification to ISO 9001. The question is to what degree of certification is the candidate supplier. The only way to find out is to visit the supplier and either make a basic assessment of their Quality Management System (QMS) or perform a full audit. In general, a basic assessment can take, depending on the size of the company, a few hours or most of a day, while an audit, since it is more detailed can take 2 to 4 days depending on the size of the company.

An assessment or an audit cannot be performed by just anyone. The Lead Auditor should have audit training and credentials such as being an ASQ Certified Quality Auditor (CQA) as well as adequate experience as an assistant to the Lead auditor and individual Lead Auditor experience or a RABSQA Certified Lead Auditor.

In general, the assessment consists of basically two groups of information. The first is Business related with basic questions on how the supplier conducts their business. The second group is Quality related. Basic questions regarding their Quality Manual, Quality Assurance Planning are asked. Are there periodic meetings where their Quality and Continuous Improvement Plan (CIP) is discussed? How is the quality of the incoming material/piece parts verified and what happens if there is non-conforming material? In their manufacturing process, how is the quality of the process verified? Are 100% testing, statistical process control or sampling used and by what method? To insure quality, measuring devices have to be calibrated periodically, where are the calibration records kept for these instruments? Are Gage Repeatability and Reproducibility studies performed? What is the maintenance schedule for the manufacturing tooling used? Where are the training records for the quality assurance personnel?

When the assessment is completed, the score is calculated and shared with the supplier. If the score is high, like in the 80's or 90's, you have a potentially excellent supplier. If the score is below 50, you may want to rethink doing business with this supplier.

From questions like the above, a fairly accurate assessment can be made of the prospective supplier's QMS. Simple observations can also be indicative such as the cleanliness of the facility. Does the supplier subscribe to the 5 S's? Are the work and inspection areas reasonably clean?

Should a full audit be desired, a CQA or similarly certified Lead Auditor is required. The steps in performing a full audit are similar to the assessment but are more formal, detailed and very business like.

The first step is to schedule the audit to make sure necessary supplier personnel are available. If you are auditing offshore, you may want to consider hiring an interpreter. The second step is to request a copy of their Quality Manual to review and get a flavor of their QMS. The 3rd step is to conduct the audit, calculate the audit score and inform the supplier of their score, any nonconformance and/or corrective actions. The next step is to complete and submit the Final Report to the supplier. Similar to the assessment discussed above, the final score needs to be carefully evaluated. The next article in the Nor'easter will discuss the ongoing evaluation of Supplier's performance.

Just what can purchasers reasonably expect from suppliers who put forward their company's ISO 9001 certification as an argument in favor of their products or services? ISO provides answers to this and related questions in an updated edition of... [ISO 9001 – What does it mean in the supply chain?](#)

The document is particularly aimed at purchasing managers of business enterprises and public sector officials responsible for procurement, but it will also be useful for organizations representing consumer interests – as well as for consumers themselves. ISO 9001 is implemented by organizations in 176 countries and has become the global benchmark for quality management systems (QMS). The standard is used as a framework for providing assurance about the supplier's ability to satisfy quality requirements and ISO 9001 certification is often a market requirement for suppliers to participate in supply chains or to bid for procurement contracts. It is also widely used as a marketing argument by companies selling goods or services to consumers.

For these reasons, the update of ISO 9001 – What does it mean in the supply chain? is timely. It provides concise answers to common questions such as:

- What does "conformity to ISO 9001" mean?
- How does ISO 9001 help you in selecting a supplier?
- How can purchasers be sure that the products they receive will meet their requirements?
- How can you have confidence that your supplier meets ISO 9001?
- Can suppliers claim that their goods or services meet ISO 9001?
- What can a customer do if things go wrong?

In addition, the document serves as a "mini-primer" to ISO 9001 because it includes brief, but essential, explanations of the standard, quality management systems and the options for claiming conformity with ISO 9001. The online brochure has been updated by Dr. Nigel H. Croft, the founding Co-chair of the ISO 9000 Advisory Group, which developed the original version of the document, and who was been appointed to chair subcommittee SC 2, which responsible for developing the ISO 9001 and ISO 9004 standards, of ISO technical committee ISO/TC 176, Quality management and quality assurance. Dr. Croft comments: "The brochure provides purchasers with the information needed to ensure that the ISO 9001 standard is used to its full potential in the business-to-business supply chain."

ISO 9001 – What does it mean in the supply chain? is available as an online, electronic document only. It can be accessed free of charge on the [Management standards section](#) of the ISO Website. Read more – go to <http://www.iso.org>

The latest issue of the Supply Chain Strategy newsletter from Harvard and MIT offers a simple but effective model for keeping track of the outside forces that an have a big impact on supply chain performance. The template is offered by professors Stanley Fawcett of Brigham Young University and Greg Morgan of Seattle University, who promote the idea of "supply chain scanning." This means consistently analyzing your supply chain through the lens of a set of key macro-forces. The template suggests the following 10 vectors of analysis:

1. Competition: especially focused on aggressive new competitors.
2. Globalization: how is the "flattening" of the world impacting sourcing and marketing opportunities and threats?
3. Customer Expectations: What do they want, really? Often unarticulated.
4. Global Capacity: what's really happening in terms of supply and demands?
5. Mergers: What is happening within your industry, and is it giving competitors scale advantages?
6. Role Shifting: How are outsourcing, virtualization and other role shifts impacting performance, and what are your core competencies?
7. Technology: You need a strategy and to keep up to speed on developments .
8. Time compression: what can you do to reduce cycle times across key processes?
9. Virtual Integration: Where are you at with integration and collaboration?
10. Wall Street: How is the supply chain contributing to financial performance? [Read more...http://www.scdigest.com](http://www.scdigest.com)

✓ Planning Ahead - Mark Your Calendars:

April 2010

<p>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></p>	<p>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 are Free</i></p>	<p>Section Meeting Date: Thurs. April 15, 2010 Location: Arboretum Club 401 W. Half Day Rd, Buffalo Grove Pre-meeting clinic: Willie Carter's Process Improvements for Admin Departments By Sandra Storli and David Norby (5:30 – 6:00 pm) Networking: 6:00 – 6:30 pm Dinner: 6:30 pm <i>the Meal is \$25</i> Main Presentation: Deming's System of Profound Knowledge – The Key to Success in Change Management By Wes Bucey (7:30 – 8:30 pm)</p>
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May 2010

<p>ISO Support Group Date: Thurs. May 06, 2010 Location: The New China Buffet. 1161 S Milwaukee Ave.; Libertyville Time: 6:00 pm <i>the Meal is \$5</i></p>	<p>Leadership Committee Meeting Date: Thurs. May 13, 2010 Location: Dover Straits, 890 E Rt 45, Mundelein. (847) 949-1550 Time: 6:00 pm-<i>Meals are Free</i></p>	<p>Section Meeting Date: Thurs. May 20, 2010 Location: Arboretum Club 401 W. Half Day Rd, Buffalo Grove Pre-meeting clinic's Featured Presenter: Get Ahead - Get Certified By Dave Taylor & Dave Spengler (5:30 – 6:00 pm) Networking: 6:00 – 6:30 pm Dinner: 6:30 pm <i>the Meal is \$25</i> Main Presentation's Featured Presenter: Recertification Process Improvement and On-site Recertification Reviews By Merle Goddard, Dee Miranda, and Stefanie Koenig (7:30 – 8:30 pm)</p>
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June 2010

<p>ISO Support Group Date: Thurs. June 03, 2010 Location: The New China Buffet. 1161 S Milwaukee Ave.; Libertyville Time: 6:00 pm <i>the Meal is \$5</i></p>	<p>Leadership Committee Meeting Date: Thurs. June 10, 2010 Location: Dover Straits, 890 E Rt 45, Mundelein. (847) 949-1550 Time: 6:00 pm-<i>Meals are Free</i></p>	<p>Section Meeting Date: Thurs. June 17, 2010 Location: Arboretum Club 401 W. Half Day Rd, Buffalo Grove Pre-meeting clinic: Putting Contest and Statistics - By Dave Taylor (5:30 – 6:00 pm). Networking: 6:00 – 6:30 pm Dinner: 6:30 pm <i>the Meal is \$25</i> Main Presentation: Quality Tools: Finding Root Cause for CAPAs – By Wayne Taylor (7:30 – 8:30 pm)</p>
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Keynote Speakers:



Monday, May 24, from 8– 9 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.



Tuesday, May 25, from 8– 9 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.



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.



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 May 2010 Nor'easter by Friday, April 9th, 2010. We need a bank of outstanding Quality Articles. 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, graphics, logos, photos, etc., can be sent to adelacrandell@mac.com. Please e-mail me with questions. The editor reserves the right to edit material, and items received after the deadline may be dropped or inserted in a future issue.



Plan Now to Advertise in The Nor'easter

By Adela Crandell, Editor, The Nor'easter

Plan now to advertise in *The Nor'easter*. We have approximately 800 ASQ members on our mailing list for the northeastern area of Illinois...one of the most active growth areas in the country! Our readers will be interested in your company's products or services. Deadline for prepaid advertising is the 1st of the preceding month. Your check for the correct amount (payable to ASQ, NEI Section 1212) must be received at the following address prior to issue in *The Nor'easter*.

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FDA Task Force Seeks Public Comments on Increasing Transparency With Regulated Industry

As part of the final phase of its transparency initiative, the U.S. Food and Drug Administration is seeking comment from the public and other interested stakeholders on how the agency can increase transparency in its interactions with regulated industry.

The FDA regulates products responsible for about 25 percent of the gross national product of the United States and the industries responsible for these products. Products regulated by the agency – biologics and blood products, human drugs, foods, medical devices, radiation-emitting devices, and veterinary medicines – are integral to public health and to the U.S. economy.

The agency formed an internal Transparency Task Force in response to the Obama Administration's commitment to achieve "an unprecedented level of openness in Government." The Task Force is developing recommendations for making information about FDA activities and decisions more useful, understandable, and readily available, while appropriately protecting confidential information.

The Task Force held public meetings in June 2009 and November 2009. Based upon input received thus far, the Transparency Initiative has been divided into three phases. The first phase, creating a Web-based resource called "FDA Basics" to provide information on commonly misunderstood aspects of the agency, has been completed. The second phase, improving FDA's disclosure of information to the public, is underway and the agency intends to issue draft proposals for public comment soon. The request for comment for the third phase follows a series of listening sessions with members of regulated industry in January 2010. Transcripts and summaries of those listening sessions are available at <http://www.fda.gov/transparency> and at <http://www.regulations.gov>.

For this final phase, the FDA is particularly interested in comments from all interested parties on how the agency can make improvements in the following areas:

- Training and education for regulated industry about the FDA regulatory process in general and/or about specific new requirements
- The guidance development process
- Maintaining open channels of communication with industry routinely and during crises

Providing useful and timely answers to industry questions about specific regulatory issues Electronic comments may be submitted to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, Md., 20852. All comments should be identified with docket number FDA-2009-N-0247.

For more information:

March 12, 2010 Federal Register Notice: <http://edocket.access.gpo.gov/2010/2010-5377.htm>

FDA Transparency Task Force Web Page: <http://www.fda.gov/AboutFDA/WhatWeDo/FDATransparencyTaskForce/>

FDA Basics Web Page: <http://www.fda.gov/AboutFDA/Basics/default.htm>



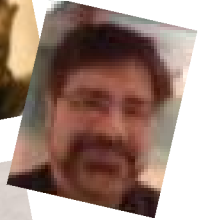
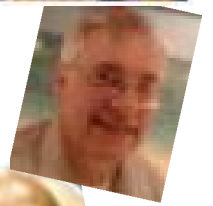
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Our Section is renowned for serving our members, industry, and the community through our leading edge events, programs, and services. We care. You want to develop superior skill we'll assist you with the knowledge, education and skills you need to succeed.



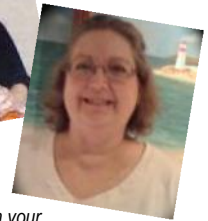
Success

The American Society for Quality is the world's leading authority on quality and our section is one of its top rated sections. We assist companies to improve their systems, processes, organization, and profits. You'll get the resources to succeed today, and to compete in the future.



Your SLC

The Section Leadership Committee welcomes your participation! We want to give you every opportunity to expand your leadership and quality skills, both personally and professionally, through volunteer positions on the Section Leadership Committee, serve as back up support, or on a subcommittee.



Achieve Greatness with ASQ Membership

Select 1212 as your section! Our section is one of the top rated sections in the society! We are here to help you find solutions, achieve credibility, be inspired, build strong networks, and reach greatness. We are dedicated to providing you with the Quality technologies, concepts, and tools to improve yourself, your company, and your world.



Some familiar faces from your Section 1212 leadership. Look for more colleagues in upcoming issues.

We want to hear from you

Extraordinary! There is no other way to describe the past 30 years. We continue to set our sights high and are looking for ways to reach an even larger audience. We are constantly looking for ways to serve our members. Your opinion counts! Make your opinions known.



Past Chairs at the 30th Anniversary party!

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

DATE	PRE-MEETING CLINIC	MAIN PRESENTATION
April 15, 2010	Willie Carter's Process Improvements for Admin Departments By Sandra Storli and David Norby	Deming's System of Profound Knowledge (SoPK) – the Key to Success in Change Management By Wes Bucey
May 20, 2010	Getting Your Certification/How to Take the Exam: Get Ahead - Get Certified By Dave Taylor and Dave Spengler	Recert & Packet Info: Recertification Process Improvement and On-site Recertification Reviews By Merle Goddard, Dee Miranda, and Stefanie Koenig
June 17, 2010	Putting Contest and Statistics By Dave Taylor	Quality Tools: Finding Root Cause for CAPAs 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.

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