



# The Nor'easter

News from the Northeastern Illinois Section  
American Society for Quality [www.asq1212.org](http://www.asq1212.org)



*Sailing into the Future*



March 2010

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**March 18th - We are proud to offer you three programs: Colbert Plant Tour, Willibert Fabritius' Innovation-Driver for Creation, FDA Supervisory Investigator Nicholas Lyons' Strengthening the Safety of Supply Chains.** *By Marlyn Hyde Program Chair, James Sohn, and Sandra Storli Chair*

**5:30-7:00; Program 1, Pre - Meeting: Tour of Colbert Packaging, Corp. The Plant Tour's 10 minute tour sessions: At [Colbert Packaging Corporation Corporate Headquarters](#) at 28355 North Bradley Road Lake Forest, Illinois 60045. (See pages 2 - 3)**

Colbert Packaging Corp. is a \$45 million, independent, privately-held company with customers located throughout the U.S. and parts of Europe that include Abbott Labs, Anderson Packaging, Wrigley Co., Novartis, and Blistex. Agility and the Ability to Deliver Leading-Edge Products and Services, Effectiveness and Efficiency, Continuous Excellence and Continuous Commitment to: Quality, Delivery Performance, Service, Cost Effectiveness, Process Improvement, Innovation and Sustainability, as well as Disaster Recovery and Business Continuity Plans. Supplier partnerships are a key factor in a company's competitiveness, and leading edge organizations are studying other organizations' best practices to better understand how to measure performance, close gaps and select productivity initiatives to maximize effectiveness and improve the corporate bottom line.

**7:00-7:45; Program 2, Presentation 1: Innovation - driver for value creation. At the [Lambs Farm Country Inn Restaurant](#) at 14245 W Rockland Rd, Libertyville. (See page 3)**

Making business innovation a priority: Innovation is one of the key drivers of economic growth and is critical to our prosperity, our economic strength, and our ability to compete in the global economy. As Darwin said, "It is not the biggest or strongest that survive, but the one that can adapt to its (changing) environment." Innovation enables you to be adaptive, agile, and have fast response capabilities. Our speaker, member of the Innovation and Value Creation Technical Committee and BSI third Party Registrar Willibert Fabritius, will help you and your organization promote and enhance innovation to succeed in this rapidly changing competitive environment. This presentation will inspire you to accelerate innovation, create and sustain competitive advantage

**8:00-9:00; Program 3, Main Presentation: Strengthening the safety of supply chains - *Strengthening the shared responsibility – and accountability – of safe global supply chains between industry and FDA* At the [Lambs Farm Country Inn Restaurant](#) at 14245 W Rockland Rd, Libertyville. (See page 4)**

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. Supervisory Investigator in the FDA Chicago District, Nicholas Lyons' presentation will detail some of the expectations that affect the supply chain, and inspire you to proactively stimulate implementation of improvements in your supply chain integrity. This presentation will focus on the FDA's strategic plans to protect the consumer and provide guidance to industry which may help drive supply chain transformation, the latest updates on FDA's supply-chain issues across the industry, and the new emphasis on quick, effective enforcement as a path to compliance and increased public confidence in safety.

### **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. This is a must attend meeting for ASQ 1212 members. There will be something for everyone to adapt for use in your business. We would like to see us break attendance records for this event. We cordially invite you to join us on **Thursday March 18<sup>th</sup>** - The **Plant Tour's** 10 minute tour sessions run from 5:30 – 7 pm at Colbert Packaging Corporation Corporate Headquarters at 28355 North Bradley Road Lake Forest, Illinois 60045. The buffet dinner (6-7PM) and both presentations will be at the [Lambs Farm Country Inn Restaurant](#) at 14245 W Rockland Rd (Route 176), Libertyville. Members and non-members are always welcomed.

**Pre-meeting clinic: Colbert Plant Tour - 5:30pm to 7:00pm at 28355 North Bradley Road Lake Forest ([Directions](#)).**

**Presentation 1: Innovation – Driver for Value Creation by BSI Lead Auditor Willibert Fabritius 7:00pm to 7:45pm at Lambs Farm Country Inn Restaurant at 14245 W Rockland Rd, Libertyville ([Directions: located at the intersection of I-94 and Route 176](#)).**

**Main Presentation: FDA: Strengthening the safety of supply chains by FDA Supervisory Investigator, Chicago District, Nicholas Lyons (8:00 – 9:00 pm).at Lambs Farm Country Inn Restaurant at 14245 W Rockland Rd (Route 176), Libertyville ([Directions](#)).**

The tours and both presentations are free, the buffet is \$25. If you want dinner, please E-mail: [asq1212reservations@yahoo.com](mailto:asq1212reservations@yahoo.com).

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### March 18<sup>th</sup> Program 1, Colbert Plant Tour (5:30-7:00 pm)

**Agility and the Ability to Deliver Leading-Edge Products and Services, Effectiveness and Efficiency, Continuous Excellence and Continuous Commitment to: Quality, Delivery Performance, Service, Cost Effectiveness, Process Improvement, Innovation and Sustainability, as well as Disaster Recovery and Business Continuity Plans.** Supplier partnerships are a key factor in a company's competitiveness, and leading edge organizations are studying other organizations' best practices to better understand how to measure performance, close gaps and select productivity initiatives to maximize effectiveness and improve the corporate bottom line.

Founded in 1959, Colbert Packaging Corp. is a \$45 million, independent, privately-held company with customers located throughout the U.S. and parts of Europe that include Abbott Labs, Anderson Packaging, Wrigley Co., Novartis, and Blistex. Producing approximately 272 million boxes, 350 million cartons, and 15,000 tons of board each year, the company is also environmentally conscientious, recycling 5,000 tons of material annually. The production of folding cartons and rigid setup boxes still lies at the very heart of Colbert's 50-year history. Through innovation and expansion, Colbert's diversified portfolio now also includes paperboard specialty products, flexographic printed packaging, tamper-proof patented blister packaging, sustainable packaging, security solutions, pressure-sensitive roll labels, and a growing line of market-specific packaging products. Colbert offers the full breadth of their expertise, and the quality and service commitments of their entire team.

Some of Colbert Packaging Corporation's many awards are:

- **Multi-Year Winner of Supplier Excellence Award for Outstanding Performance.** *Presented by Abbott Laboratories.* The Abbott Supplier Excellence Award program began in 1991 and utilizes an assessment process that combines performance data along with feedback from internal stakeholders, including manufacturing, material control, quality, engineering, administrative services and select others. The program identifies Abbott's highest performing suppliers by assessing performance in the categories of quality, delivery performance, service, cost effectiveness, process improvement and innovation. Winners were recognized for exceptional contributions to Abbott in 2008, and were chosen from more than 15,000 worldwide suppliers because of outstanding performance and continuous improvement in supplying materials, equipment and services to Abbott. "Abbott's performance excellence is possible through partnerships with suppliers that share our commitment to the highest measures of quality," said Sarah Catterson, divisional vice president, corporate purchasing, Abbott. "These awards recognize companies that have consistently delivered in an outstanding manner."
- **Illinois Sustainable Technology Award for BlisterGuard and EnviroGuard (2007).** *Presented by the Illinois Department of Natural Resources.* The Illinois Sustainable Technology Award recognizes a novel technology or process that leads to significant waste reduction, waste elimination, or environmental impact. Colbert's BlisterGuard® and EnviroGuard™ packaging solutions were recognized for their role in protecting the environment, helping sustain the future, and improving the economy. The Sustainable Technology Award recognizes novel technologies and processes that lead to significant waste reduction, waste elimination or environmental impact. Colbert's BlisterGuard and EnviroGuard packaging solutions meet these requirements in several ways. They are a greener safer replacement to the plastic clamshell and they reduce or eliminate the use of petroleum-based plastics. BlisterGuard is made using 76 percent paperboard material and 24 percent thermoformed plastic, while EnviroGuard is made entirely of paperboard containing recycled and post-consumer content fibers. The products continue to be recognized for their ability to meet, and oftentimes to exceed, expectations for environmentally friendly packaging – enabling waste reduction and resource sustainability at a national level).
- **PACK EXPO Selects Award for a Shure Product Packaged in BlisterGuard (2007).** *Presented to Combined Technologies by PMMI; Awarded by Attendees' Majority Vote.* The Blisterguard was chosen for exceptional use of a new type of tear-resistant board to create a pilfer-proof, carded package. Colbert used the Everest® Safe-Pak bleached board from International Paper, a heat-sealable, tear-resistant paperboard made with multilayer Valéron® Strength Film, and a clear plastic blister. The foldover board encapsulates the plastic blister, then the board is printed on a four-color standard offset press and die-without additional equipment for conversion. Sensomatic and Checkpoint security tags are applied to cards, and as the packs are filled, the back of the card is folded over for the sealing process. The inside of the board is bonded to itself by applying heat. This new package is an alternative to clamshells, which Colbert-customer The Topps Co., Inc., thought was "too expensive and not aesthetically pleasing." The Blisterguard was created to effectively display Topps' Major League Baseball cards while counteracting theft with an enclosed security tag. The strength of the material also prevents the packages from being ripped off of display pegs. It has up to five times the tear resistance of current foldover boards and is easier to recycle than polyvinyl chloride clamshells. The winners of the National Paperboard Packaging Competition are the best the industry has to offer—shining examples of its commitment to quality, service and innovation.



BlisterGuard and EnviroGuard, alternatives to clamshell packaging, are two of the innovative products that Colbert Packaging has introduced in the past several years. In its launch, the company and its licensees have sold more than 100 million units of BlisterGuard.

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## Other highlights:

- 99.9 percent inventory. These certifications were awarded for our ability to track certified paperboard used in our customers' packaging from a responsible forest all the way to the retail shelf, and in this way, they are also a win for our customers, retailers, consumers and the environment, "accuracy and improved visibility. The company is running a tighter business with reduced costs, improved customer service levels, and it has achieved compliance with tri-weekly audits. For more information about Colbert Packaging visit [www.colbertpkg.com](http://www.colbertpkg.com).
- Disaster recovery and business continuity is a far more complicated and involved process than simply making sure your servers are backed up on a regular basis. Inventory Resources — Hardware and Software: Understand the organization's business needs and the systems that map to those needs. Key hardware, configurations and passwords should be included in inventory. Establish Recovery Objectives: Specific RTO objectives ensure Colbert Packaging remains a top vendor with its customers - to have reliable systems to provide uninterrupted service. Understanding recovery time objectives (RTO) and recovery point objectives (RPO) becomes the foundation on which an effective business continuity solution is built - to match hardware and software with business processes and data recovery needs. In some cases, it's important to have systems back online within minutes; in other cases, hours or days will suffice. Budget Adequately: Quantify risks and understand the costs of redundant systems, backup power, redundant Web connections, spare servers and offsite storage. Develop a Response Plan: An effective plan spells out tasks, responsibilities and roles — and it covers an array of situations that could demand entirely different responses. Designate a Recovery Team: to lead employees through the recovery process. Armed with phone trees, mobile technology and a clear response plan, these individuals are able to make quick decisions and change course on the fly. Revisit Business Continuity Often: Because business conditions, processes and technology constantly change, it's vital to re-examine business continuity and update a plan on a regular basis. An organization must also test systems periodically — every quarter or at least once a year — to ensure that it hasn't overlooked anything and that the plan works. Finally, it's crucial to update and upgrade systems periodically to fit changing requirements.
- Colbert Packaging received Sustainable Forestry Initiative® (SFI®) Chain of Custody Certification (NSF-SFICOC-C0038447) from NSF-ISR and Forest Stewardship Council® (FSC®) Chain of Custody Certification (SCS-COC-003001) from Scientific Certification Systems (SCS). Meeting international standards and strict tracking requirements to ensure that certified paperboard comes from a well-managed forest. The certifications are a key component of Colbert's sustainability goals. Chain of Custody is the process of tracking certified paperboard and its wood fiber back to the sourcing forest - through all processing, manufacturing and distribution stages - to verify that the sourcing forest is responsibly managed through harvesting and replanting efforts. Colbert Packaging typically uses virgin solid bleached sulfate paperboard derived from these responsibly managed forests to manufacture paperboard-based packaging products for its customers. "Our sustainability initiatives are rooted in our timeless commitment to social, environmental and fiscal responsibility, and provide a solid framework for employing good business practices in the quest for a greener world," said Nancy Colbert MacDougall, chairman of Colbert Packaging. "These certifications are a natural extension of our company-wide sustainability initiatives." Jim Hamilton, president of Colbert Packaging, added, "The SFI and FSC Chain of Custody Certifications further our commitment to meeting manufacturers' and retailers' demand for sustainability, while ensuring the reduction of nonrenewable resources in our manufacturing operations.

## March 18<sup>th</sup> Program 2, Presentation 1: Innovation – Driver for Value Creation. (7:00 – 7:45 pm)



Willibert Fabritius of the Innovation and Value Creation Technical Committee <http://www.asq-qm.org/innovation-and-value-creation> will present: Innovation - driver for value creation. He will help you and your organization promote innovation: learn the elements of the innovation cycle, learn the five discovery skills, and identify and manage the four different innovation personalities (creator, connector, developer, and doer).

Willibert (Willy) Fabritius, CQA, CQM, CSSBB, Senior Member ASQ, BSI lead auditor, has 15 years of 3rd Party Auditing experience of Management Systems to various standards (e.g. Quality management: ISO 9001, ISO/TS 16949, Information Security Management: ISO 27001, IT Service Management: ISO 20000).

International experience: work experience in three continents: Europe (Germany), South Africa and Northern America. Willy published several articles and presentations concerning information Security and Quality management systems.

**The Innovation and Value Creation Technical Committee** Mission: Turning Good Ideas into Great Results - To extend strategic development and problem-solving methodologies into creative design practices to satisfy increasingly sophisticated customers and marketplace environments with innovative solutions; to promote an environment where innovative ideas are actively planned, executed, and rewarded, and teach others to do the same.

Charter: The Innovation and Value Creation (IVC) Technical Committee of the American Society for Quality, Quality Management Division (QMD) is responsible for developing high-level content, in the form of articles, books, conference publications, courses, web-based media, and other products, that:

- Educate executive, business, and quality professionals in the development of business strategies that include innovation, as well as the technologies, methodologies and tools needed for effective innovation management.
- Provide business leaders with necessary perspective to support innovation and value creation as part of quality management.
- Maintain relevant content for the CQM/QE certification and other Bodies of Knowledge.

The Innovation and Value Creation Technical Committee was newly formed in late 2008 as part of the realignment of the QMD Technical Committees. This realignment was designed to expand the influence of the quality management domain into new industries and government services and was driven by the 2005 ASQ Future Study, In the Chase. This study identified 'value creation' as a force of change in the future of quality professionals. The IVC Technical Committee takes as a given that organizations must innovate to survive. Their activities have focused on how to take a systematic approach to innovation to help ensure successful innovations in the most timely and valuable way. Specifically, the quality management tools and technologies can be leveraged for innovation management and they seek to provide insights into these methods for others to use.

**March 18<sup>th</sup> Program 3, Main Presentation: Strengthening the safety of supply chains: Strengthening the shared responsibility – and accountability – of safe global supply chains between industry and FDA - from 8:00-9:00PM.**

The FDA's oversight approach takes into account the entire supply chain and its complexity (a web of re-packagers and redistributors) and is focusing its efforts on protecting consumers by strengthening oversight on the global supply chain (from the raw ingredients through production and distribution, all the way to U.S. consumers). **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.** This presentation will be an awakening – a call to action! It will focus on the FDA's strategic plans to protect the consumer and provide guidance to industry which may help drive supply chain transformation, the latest updates on FDA's supply-chain issues across the industry, and the new emphasis on quick, effective enforcement as a path to compliance and increased public confidence in safety (the FDA takes this responsibility seriously and will be quick to act to protect the public-to improve trust and confidence in both the FDA and the industry). Supervisory Investigator in the FDA Chicago District, Nicholas Lyons' presentation will detail some of the expectations that affect the supply chain, and inspire you to proactively stimulate implementation of improvements in your supply chain integrity:

- Case study presentations on where the supply chain played a critical role in protecting public health.
- Accountability. Make the right decision for your bottom line, for your reputation, and above all, for your consumers: *industry bears responsibility for the safety of the products in their supply chain and take a proactive role (locally and globally) to anticipate problems before even one human being is needlessly harmed. Companies are responsible for their supply chain. Companies are accountable for what goes into their products as well as the products they produce –they must 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 - they cannot excuse themselves by blaming their suppliers.*
- Supply Chain Management: *enhance supplier quality management (selection, qualification -ongoing monitoring and management). Design and development, risk management and process controls are intricately linked to strong supplier controls. Address value chains in their entirety. Overcome supplier risk management issues (and the importance of improving design communication and transparency).*
- Supply Chain Security - Create a global safety net: *The tremendous shift - Global Supply Chain and its Supervision - more countries are part of the global supply chain (factors barriers include language, geography, time, culture, facility information, and product history).*
- Prevention - Global Supply Chain Safety. The strategy, a simple, yet profound paradigm shift from reaction to prevention, is a high priority for the FDA (moving from an approach process that reacts to problems to one that proactively prevents them from ever occurring): *Identify and prevent problems to ensure quality before problems occur. Build quality into each stage of process. As the industry becomes more global and supply chains more complex, the FDA's reorienting inspectors to focus on key measures for prevention not just evidence of current problems.*

Become a change agent – inspire a paradigm shift. Gain real-world advice from an FDA expert with a wealth of inspectional experience and expertise to help you gain the inspiration and strategies to make the right choices now and in the future. This evening's program will be followed by a short "Ask the expert's" session. If you had the opportunity to talk with a Supervisory Investigator, what would you want to ask? What would you want to know? Facing a FDA challenge? Get the FDA perspective. No matter your company's area of expertise, help your company thrive. Everyone in your organization with a role in strategic planning and the end to end supply chain deserves to take part in this event. Whether you are from the food, biologics or pharmaceutical industries, this presentation is for you!

Nicholas Lyons is a Supervisory Investigator in Chicago District for the United States Food & Drug Administration and has served in that capacity for approximately nine years. He oversees a dozen Consumer Safety Officers that conduct inspections domestically & internationally primarily in the drug program area. Prior to his current position, he was a Consumer Safety Officer in the Chicago District Office for approximately five years and conducted inspections in the regulated industry with a focus on pharmaceutical inspections. Mr. Lyons also spent six years working in industry prior to joining the agency, working on screening and developing new drug products against several pathogenic forms of viruses that included HIV-1, HIV-2, CMV, HSV, Influenza and HPV. Mr. Lyons' greatest medical research accomplishment was to be part of the Norvir Team that has extended the lives of many patients throughout the world.

Mr. Lyons educational background consists of a Masters in Science with a concentration in Microbiology from Illinois Institute of Technology and a Bachelors of Science with a concentration in Biology from Saint Xavier University. Mr. Lyons also has held the position of Drug Chairman for the North Central Association of Food & Drug Officials in 2002 & 2003 and helped to organize several drug educational workshops during that period of time.

➤ **✓Regular Monthly Meeting Schedule (see back panel for highlights):**

ISO Support group	Leadership Committee Meeting	Section Meeting
<b>Date:</b> 1 <sup>st</sup> Thurs. each month <b>Location:</b> The New China Buffet, 1161 S Milwaukee Ave., Libertyville <b>Time:</b> 6:00 pm	<b>Date:</b> 2 <sup>nd</sup> Thurs. each month <b>Location:</b> Dover Straits, 890 E Rt 45, Mundelein. (847) 949-1550 <b>Time:</b> 6:00 pm	<b>Date:</b> 3 <sup>rd</sup> Thurs. each month – <b>Location:</b> Arboretum Club 401 W. Half Day Rd (Rt. 22 E. off Rt. 83), Buffalo Grove <b>Pre-meeting clinic:</b> 5:30 pm <b>Networking:</b> 6:00 – 6:30 pm <b>Dinner:</b> 6:30 pm <b>Presentation:</b> 7:15 – 8:00 pm

## **February Review - Pre-Meeting Clinic: Quality Career Fair** *By David Norby*

To all Section 1212 members who contributed to the success of our first Career Fair, and especially to our section Placement Chair, Bill Stinchcomb, thank you one and all. Bill originally proposed the Career Fair, and he carried the largest share of the workload in organizing the event. Thank you also to the employers, recruiters, ASQ representatives and Career Corner participants who staffed tables to meet with our candidates, and thank you to all job-seekers for your participation. The Section Leadership Council extends our thanks, best wishes and encouragement to all candidates who attended. Our original hope was to draw about 100 applicants, but we actually drew over 200. Participating interviewers included local employers Abbott Laboratories, Baxter Healthcare, ERA Industries Inc and Supply Chain Services Inc, as well as recruiting agencies Validant Consulting and Aerotek, all seeking candidates. These companies had the chance to meet many candidates with excellent credentials. We hope some of you will have made contacts leading to new career opportunities. Remember: the object is not so much to beat the other applicants applying for a job as it is to find a good match. Each of you brings a unique set of skills and experience to your personal search. It takes persistence to find that match, but when you get the offer, you'll know that it was worth the effort.

## **February Review - Main Presentation: Understanding GMP/QSR as a Concept** *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."]

This month we were fortunate to have another presentation by Lorelei Jarrell, Compliance Officer for the FDA at its Chicago Office. Ms Jarrell has worked at the "Chicago" office for a many years, and has inspected essentially all the regulated manufacturers in the area. Our members look forward to her presentations, as our attendance consistently reflects.

This presentation was a thought provoking discussion on best practices related to conducting quality investigations. In her opening remarks, Ms Jarrell commented that even if it were to grow 10-fold, the FDA does not have the personnel or resources to act as the final inspector for each lot/batch of all products that are under the authority of the FDA. As a result, the FDA cannot be in the business of Quality Control. Rather, the agency is in the business of Quality Assurance. In this role, manufacturers are held accountable to implement their own Quality Systems and then to follow the Quality Systems they have implemented.

The key areas of the federal regulations enforced by the FDA for Good Manufacturing Practices (GMP) are 21 CFR 211 (drugs and biologics) and 21 CFR 820 (medical devices). The current drug regulations (which superseded 21 CFR 133), were written in 1978 and have remained essentially unchanged since then. It has been the FDA's responsibility to interpret and apply the '211' regulations through all the technological developments, political changes, and shifts in ways of doing business – including internationalization. From the start, '211' has emphasized a comprehensive approach covering both design of a product and its manufacture, from raw materials to finished product. Medical device regulations were first published in 1978. Although medical devices typically consist of many more components than drugs, the original '820' device GMP regulations did not cover design issues. The '820' regulations have evolved to the current state where design issues occupy a central role in inspection and regulatory activity. For both '211' and '820' regulations, we are urged not to think of the Quality System regulations as a collection of forms to be completed. Instead, we are urged to think of our Quality Systems in terms of the concept of what are we trying to accomplish in providing this product. Our Quality Systems need to cover all areas necessary to assure that products consistently deliver needed performance where and as they are used. Furthermore, manufacturers are increasingly being held accountable to anticipate potential modes of misuse/abuse/misapplication of their products, and to implement measures to prevent or minimize associated risks. A common sense approach is to consider the question: do you want to have this product available in the market when you, a family member or someone else dear to you needs it? If not, work is needed.

Corrective and Preventive Action (CAPA) is the true center of the regulation. It says that we need to have a system to identify all real or potential issues that could affect product safety and effectiveness. Then we need to respond to those issues, taking corrective or preventive actions. Then, if a new problem is found, we need to return to the original evaluations, re-analyze the system to find out what was missed, and find a solution so that it is not a recurring problem.

Some general cautions: In general, it's a problem to have a set of specifications, have a batch/lot that fails the specifications, and then release the product on a deviation acceptance. FDA no longer accepts simple acceptance by attributes inspection. They expect the manufacturer to design the process for success, then track the process and show by historical performance that predicted performance is confirmed. Ms Jarrell reserved much her presentation time for a question and answer period. Space limitations do not allow for detailed recounting of each, but there were several consistent threads of thought, both in the questions and in her replies. Central Role of Manufacturer in Design Quality Assurance – It is not FDA's role to be the manufacturer's design consultant. It is the responsibility of the organization that "owns" a product (the manufacturer) to take the steps needed for the design to meet the quality, safety, utility and effectiveness needs of the product. The manufacturer must understand the range of conditions under which a product will be used, and design the product to be consistently safe, effective and useful under those conditions, including risks of misuse and abuse of the manufacturer's product.

Companies that focus on improvement often see that reflected in lower incidence of complaints. It's important though, to recognize all of the issues that need improvement. Some companies comment in the review process that they "...get lots of complaints like that – it's normal..." Well, why is it ok to have all of those complaints and simply accept it as normal? For example, many issues are categorized as "User Error," and then ignore the issue simply because the user "...did not follow the package insert instructions..." There is no review of the instructions to assure that they are accurate and clear and appropriately targeted to the user audience. The regulations require consideration of human factor issues as a design element. You are expected to know the environment in which your product will be used, and to design it so that it can be used successfully and safely.

In general, manufacturers are required to manufacture under a design history that satisfies current design history requirements. The manufacturer is responsible for setting up its change management system. When a change occurs that can potentially affect product design, the design history file must be brought to current standards. You don't need to make a more complicated process out of an effective simple process. The process does need to be thorough enough to be effective, and needs to be planned ahead, documented and monitored for effectiveness.

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## February Review - Understanding GMP/QSR as a Concept

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External Vendors of Materials and Services – Quality cannot be inspected into products, including raw materials for a manufacturing process. The definition of requirements for externally-supplied materials and services, and the selection, qualification and monitoring of vendors is the manufacturer's responsibility. This includes not only raw material vendors, but also suppliers of contract R&D services, suppliers of contract manufacturing services, and suppliers of any other services that could affect product quality. Vendors may need to establish relevant quality system elements to assure that they consistently fulfill the manufacturer's requirements. The FDA may elect to audit a vendor, but the manufacturer remains responsible for its own supplier quality management system. More complex products may involve integration of components and services from multiple suppliers. This complexity places increased emphasis "on the role of the manufacturer in management of supplier quality assurance issues".

Role of Corrective And Preventive Action (CAPA) – Side-by-side with Management Responsibility, CAPA plays a central role with respect to all other elements of a compliant quality system. Whether the CAPA system consists of manual or electronic records, FDA holds the manufacturer responsible for having a system that is effective. FDA does not approach inspections as themselves being subject matter experts. FDA inspectors look carefully at CAPA records near the start of inspections. This information is a key starting point for further review. They look for problems as indicators of issues or defects, and look for indications of hidden issues. If needed, they call on other resources to take a closer look. FDA does not apply a formulaic standard to evaluate whether a manufacturer has identified "root cause." When a manufacturer investigates an issue, implements a "fix," and the problem returns, it's obvious the root cause of the problem has not been fixed. FDA does not gather or monitor information regarding use or impact of Six Sigma programs at manufacturers.

Recent developments and trends in the agency – The agency has reduced the number of layers of review to improve the efficiency and timeliness of issuing Warning Letters. But they are still being reviewed at several layers, and the "Washington" office still participates. They are working to assure consistency of the process across all district offices. Since the start of the new administration, a lot of new (and hence inexperienced) people have been hired to become inspectors. Early on, they may miss some issues, but they will generally start doing inspections with participation of more experienced inspectors, both to facilitate the learning process and to maintain inspection standards. FDA has three certification levels for inspectors. New inspectors are expected to reach Level 2 Certification, and Level 1 is expected in the first year. The QSIT exam must be passed before applying for Level 2 certification. Those with Level 3 certification will be drug-level inspectors. The current system provides little incentive for inspectors to seek Level 3 certification, so it's unclear how many new inspectors will seek the certification.

In recent years, frequent citation issues in inspections to the "211" (drug) standard are: failure to do a complete CAPA investigation, process validation issues, and microbial contamination issues. Common citations to the "820" (device) standard are CAPA, complaints, and design issues. This does not necessarily mean that these are the most important issues at the facilities involved. Some investigators may tend to inspect repeatedly for the same issues. International inspections present many challenges. For example, when the recent heparin contamination issue occurred, FDA inspectors encountered multiple delays in getting visas and related documents. By the time the inspection team arrived, the manufacturing plant associated with the issue was gone – it had been demolished. Some people have recently been trying to push the agency in the direction of becoming the quality control group evaluating each lot/batch of material before it is distributed domestically. Considering the scale of what would be required, that is not likely to happen. We will probably continue to have on-site inspections domestically and internationally, but even a doubling of the inspection force would not provide enough inspectors to conduct meaningful inspections at all domestic and international plants even once a year.

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### **Supplier Selection** *By Marion Menze*

Your company's upper management has determined that in order to be more competitive in the market, a new highly automated manufacturing process was required to reduce cost in the existing successful product line. However, your current suppliers do not have the manufacturing technology required. How do you find that new supplier and make sure that they will produce a quality product at an economical price? The challenge for your company's Procurement and Supplier Quality Departments working together as a team is to find that special supplier that can produce the unique part(s) to the Design Engineering specifications with Zero Defects, targeted cost and delivered on time. This article is the first in a series to appear in the Section 1212 Nor'easter newsletter of how to find, evaluate and select that new supplier with the criteria stated above.

In order to find a number of candidate suppliers, some supplier company names are required as well as other considerations such as a domestic or offshore locations factoring in the shipping charges. In this modern age you can always "Google" for the supplier. Other, more traditional methods are someone internally having previous experience with a supplier. There is always the "Yellow Pages" and most Business Representatives are pretty knowledgeable regarding suppliers and the processes they use.

Once a number of supplier names have been established, the Procurement Commodity Manager makes initial contact with the suppliers, introduces them and submits the engineering specifications for quotes. Since the cost per unit is a critically important prime factor, this is typically the first step in the selection process. Those suppliers with the lowest prices are rank ordered on a spreadsheet for evaluation purposes.

Once we have an understanding of the potential cost, we need to know more about these suppliers, especially regarding their Quality Management System (QMS). The Commodity Manager in most companies sends a form to the supplier for them to fill out and return. The form requests a variety of information typically including a question whether the supplier is ISO 9001 (And/or TS 16949) as well as ISO 14001 certified. If they are, a copy of their ISO certification is requested when the form is returned. This is basically the second screening. If a supplier is not ISO 9001 or TS 16949 certified or their certification has lapsed as viewed in the returned copy of their ISO certification form, that is an indication that their QMS may not be acceptable. However, if they are both ISO 9001 and ISO 14001 certified as copies of their certification indicates, there is a high probability that their QMS is acceptable.

Typically, also requested is their DUNS (Data Universal Numbering System) number. Once the DUNS number is received, a DUNS Report can be requested from Dun & Bradstreet in order to assess the financial health of the company, a very important 3<sup>rd</sup> screening of a new supplier. Should the financial health of the potential supplier be judged excellent, discussions can continue. Should the supplier's financial health be waning, caution is advised for potential selection.

Continued on page 7

In reviewing and evaluating the spreadsheet matrix created after the individual forms are returned from the suppliers, an analysis is typically performed regarding the overall cost per unit including shipping charges, the quality capability of the suppliers as well as their financial health. A picture should be emerging as to which suppliers are viable candidates and which suppliers can be dropped from future consideration.

The next step of the new supplier evaluation process is for the Procurement Commodity Manager and the Supplier Quality Engineer to visit the supplier and make a "Hands On" assessment of their manufacturing capability as well as their Quality Management System. The Procurement Commodity Manager and the Supplier Quality Engineer Team visit to the supplier will be covered in the next issue of the Nor'easter.

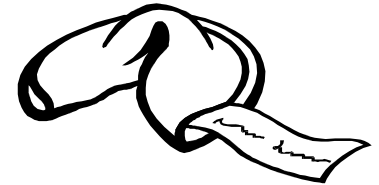
**ISO Support Group Minutes for March 2010.** *By David Taylor*

Six members attended the meeting on March 4, 2010 at the New China Buffet. In attendance were G. David Spengler, Jan Agostinelli, Bill Sherman, Karen Perkins, Regina Fullen and Dave Taylor. The group continued our study of ISO/DIS 26000, Guidance on social responsibility We reviewed Section 6.3.4 Human rights issue 2: Human rights risk situations, Section 6.3.5, Human rights issue3: Avoidance of complicity, and 6.3.6 Human rights issue 4 Resolving grievances. We are not rating this document, but the discussions are enlightening and entertaining!

In the round robin review: Dave S is addressed an issue with bus bars for powder coating a medical imaging machine and how "tribal knowledge" can cause problems when a supervisor moves on. Thankfully the non-conformities were resolved to the satisfaction of all. Dave T continues with long-distance ISO 9001 customer in San Diego, CA. The internal audit for the new ISO 9001 program was held on February 26, 27 & 28. The company is now preparing for a registration audit in late April. Also, Dave is working on a "Failure Mode Effects Analysis" project at a company in Waukegan. Jan finished the CQM/OE course in Island Lake. Bill is volunteering for Habitat for Humanity in Schaumburg and reported their warehouse has great bargains for do-it-yourselfers. Karen is seeking Mil. Spec. C documentation and is working as a sales associate for Sears. Regina's position with GE healthcare gained more responsibility. In addition, she has been appointed as a Quality Liaison with a new acquisition and the Barrington location... And she is doing training on the investigative problem solving software now in use.

Our next two meetings will be held at 6:00 on Thursday, April Fools Day and May 6. 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 pleasingly tasty 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](mailto:kolimat@yahoo.com) if you have any questions or need directions.



**6:00 PM; Every 1st Thursday of the month all year long at the New China Buffet at 1161 S Milwaukee Ave Libertyville IL,**

<p><b>Are you signed up for facebook? ASQ is building a facebook page? Check them out out <a href="#">ASQ NEI Section 1212</a> and <a href="#">ASQ1212</a> – any fan* can post! Suggest something! 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!</b></p>	<p><b>Quality Quote:</b>  "Objectivity comes with not placing the blame for problems on individuals. Aim the questions and probing at the job. The job is what failed, not the individual." ~ Phillip Crosby</p> <p><b>Have A Winning Day,</b> Willie L. Carter</p>
<p><b>If you're job hunting. Please join us on our new LinkedIn discussion group. You can connect to the group through this link.</b></p> <p><b><a href="#">ASQ NEI Section 1212</a></b></p> <p><b>Bill Stinchcomb our Placement Chair is posting jobs there regularly. Check out the jobs posted there!</b></p> <p><b>You can also follow us on our Twitter account:</b></p> <p><b><a href="#">asq1212jobs</a></b></p>	<p><b>Let everyone know that the section's new website is up and available. You can navigate to the website using this link - <a href="http://www.asq1212.org">www.asq1212.org</a>.</b></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>

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

Our Oldest certification class, the CQE review is currently underway at Baxter Healthcare. The only scheduled class left this year is Bettina's Quality Auditing class. This will help you prepare for the CQA exam or Qualify you as an internal auditor for your company.

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 Auditor	Two Days	Bettina Karlove	<a href="mailto:vanguard@ameriteck.net">vanguard@ameriteck.net</a>	4/27 & 28 (16 hours)	4/16	6/5
Statistical Process Control	Two Days	Dave Ingram	<a href="mailto:ingramd@baxter.com">ingramd@baxter.com</a>	Not Scheduled	NA	NA
Statistics Workshop	Four days	Dave Ingram	<a href="mailto:ingramd@baxter.com">ingramd@baxter.com</a>	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 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 Engineer

Quality Function Deployment

Lateral Thinking

Robust Tolerance Analysis

Statistical Thinking

Lean Office Training



Contact Dave Taylor at: [kolimat@yahoo.com](mailto:kolimat@yahoo.com) for details!



## 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](mailto: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](mailto:asq1212jobs@yahoo.com) OR [bill.stinchcomb@abbott.com](mailto:bill.stinchcomb@abbott.com). **Are you job hunting please join us on our new LinkedIn discussion group through this link. [ASQ NEI Section 1212](#).** Bill Stinchcomb, our Placement Chair, is posting jobs there regularly. Check out the jobs posted there! *Here is one of them...*

### Senior Quality Engineer

Salary: Open. Employer: [SRAM, LLC](http://www.sram.com). Categories: Operations, Six Sigma. Location: [Chicago, Illinois](http://www.sram.com) Type: Full Time – Experienced. Required Education: 4 Year Degree

**Employer Information:** About [SRAM, LLC](http://www.sram.com) - SRAM Corporation is one of the world's largest suppliers of components to the bike industry. Established in Chicago in 1987, SRAM continues to promote cycling through its products, its advocacy, and its employees who are dedicated to improving the cycling experience. Today, SRAM employs more than 2,800 people in 13 offices across 7 countries. SRAM is proud to be an equal opportunity employer.

**Job Description:** Do you have exceptional process control and SPC expertise with job experience in quality, process, manufacturing and/or product design engineering? Can you work closely and accurately to ensure that details are handled quickly, correctly and efficiently? At the same time, do you have a persuasive communication style that can adjust to different audiences and situations easily? If you are a combination of the above you might be our new Senior Quality Engineer. SRAM is a bicycle component design and manufacturing company that promotes a healthy lifestyle and work life balance. We are in a growth mode and as a result we have a newly created opportunity for an experienced Senior Quality Engineer to join our family oriented team. SRAM was recognized by Outside Magazine as one of the best places to work in 2009!!

The Senior Quality Engineer is responsible for implementing quality tools, process definition guidelines, process control tools, and process improvements over cross-functional and cross-location teams including factories, engineering, and customer service ensuring the SRAM continuously improves reputation as an innovator and manufacturer of the highest quality and reliable product. If this opportunity sounds right for you please submit your resume in confidence to [SrQualityEng@advisahiring.com](mailto:SrQualityEng@advisahiring.com) - SRAM has engaged ADVISA Hiring to identify the top candidates for this position. Per their request, please direct all communications about this position to the address above. As we will be communicating with you through this and other [advisausa.com](http://www.advisausa.com) and [advisahiring.com](http://www.advisahiring.com) e-mail addresses, please be sure to take the necessary steps, such as adding this address to your address book, to avoid having correspondence caught in your e-mail filters.

**Requirements:** The ideal candidate will have a Bachelors Degree in a technical field and be an expert in business application of statistical process control. In addition, Black Belt Six Sigma experience in a manufacturing discipline and experience in providing leadership in dynamic global situations with significant Asia experience are preferred.

## ✓ Planning Ahead - Mark Your Calendars:

April 2010

<p><b>ISO Support Group</b>  <b>Date:</b> Thurs. April 01, 2010  <b>Location:</b> The New China Buffet. 1161 S Milwaukee Ave.; Libertyville  <b>Time:</b> 6:00 pm <i>the Meal is \$5</i></p>	<p><b>Leadership Committee Meeting</b>  <b>Date:</b> Thurs. April 08, 2010  <b>Location:</b> Dover Straits, 890 E Rt 45, Mundelein. (847) 949-1550  <b>Time:</b> 6:00 pm-<i>Meals are Free</i></p>	<p><b>Section Meeting</b>  <b>Date:</b> Thurs. April 15, 2010  <b>Location:</b> Arboretum Club 401 W. Half Day Rd, Buffalo Grove  <b>Pre-meeting clinic: Process Improvements for Admin Departments By Willie Carter (5:30 – 6:00 pm)</b>            Networking: 6:00 – 6:30 pm Dinner: 6:30 pm <i>the Meal is \$25</i>  <b>Main Presentation: FDA By Hugh Grimes (7:30 – 8:30 pm)</b></p>
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May 2010

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

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

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### Keynote Speakers:



**Alan Mulally:** President and CEO, Ford Motor Company- Monday, May 24 – from 8– 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– 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.



**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.

## 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 April 2010 Nor'easter by Friday, March 26th, 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, graphics, logos, photos, etc., can be sent to [adelacrandell@mac.com](mailto: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.

Posted in the March 12, 2010, Federal Register, the request for electronic or written comments has a deadline of April 12, 2010.

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.



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## SECTION 1212 GENERAL MEETING INFORMATION

**Meets on the 3<sup>rd</sup> 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](mailto: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
March 18, 2010	<b>Plant Tour:</b> Colbert Packaging Corporation (5:30-7pm) at 28355 North Bradley Road, Lake Forest <a href="http://www.colbertpkg.com/">http://www.colbertpkg.com/</a>	<b>Presentation 1: Innovation – Driver for Value Creation</b> by BSI Lead Auditor Willibert Fabritius 7- 7:45pm at Lambs Farm Country Inn Restaurant at 14245 W Rockland Rd, (Route 176) Libertyville <b>Main Presentation: FDA: Strengthening the safety of supply chains</b> by FDA Supervisory Investigator, Chicago District, Nicholas Lyons (8 – 9pm).at Lambs Farm Country Inn Restaurant at 14245 W Rockland Rd, Libertyville <a href="http://www.lambsfarm.org">www.lambsfarm.org</a>
<ul style="list-style-type: none"> <li>✓ 2 Different Locations! 1 minute away from each other in Libertyville/Lake Forest</li> <li>✓ (A)Lambs Farm: 176/94</li> <li>✓ (B)Colbert: Bradley/176</li> </ul>		
April 15, 2010	<b>Process Improvements for Admin Departments</b> By Willie Carter	<b>FDA</b> By Hugh Grimes
May 20, 2010	<b>Getting Your Certification – How to Take the Exam</b> By Dave Taylor and Dave Spengler	<b>Recert &amp; Packet Info</b> By Merle Goddard
June 17, 2010	<b>Putting Contest and Statistics</b> By Dave Taylor	<b>Quality Tools</b> 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.