
**APRIL
2009**

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**Be sure to visit our section
website:**

<http://www.asq0905.org>

Section 0905 Mission Statement

The mission of Section 0905 is to develop and provide a strong organization for exchanging knowledge and ideas necessary for the growth and development of quality professionals in a manner that benefits the membership, business, and the Northeast Indiana Community.

Mailing Address:

**American Society for Quality
Northeastern Indiana Section 0905
P.O. Box 11887
Fort Wayne, Indiana 46861-1887**

The Histogram

N e w s l e t t e r

April Meeting

April 9, 2009 (Thursday)

Arrival: 5:30 - 6:00 PM

Dinner: 6:00 PM

Presentation: ~6:30 PM

Don Hall's Guest House

1313 West Washington Center Road

Fort Wayne, IN 46825

For reservations contact James Smith :

james.e.smith@baesystems.com

Telephone: 260-434-5464

Dinner Meeting at Warsaw, Indiana

Ramada Inn

2519 East Center Street

Warsaw IN 46580

Same times as above and same dinner price

Webcast of the Fort Wayne Presentation

For reservations contact Nathan Prieshoff:

nathan.prieshoff@mchsi.com

Telephone: 574-267-6826, ext 7863

Topic: Critical Feature Traceability in the Medical Device Industry

The medical device industry provides highly effective therapies for orthopaedic problems that can radically improve a patient's quality of life. There are a myriad of features that define a device, but just a relative few that are critical to its success in service. Failure to adequately control this set of features can undermine device performance and cause harm to recipients and even medical practitioners.

This presentation, in an entertaining way, discusses Critical Features, traceability to initial design requirements, and associated manufacturing controls.

Bio

Thomas Slagle serves as Vice President of Quality and Facilities, as well as Compliance Officer for **OrthoPediatics**. Mr. Slagle is a seasoned industry veteran with nearly 30 years of experience in medical device design, engineering and manufacturing.

Before joining **OrthoPediatics**, Mr. Slagle served as the Senior Manager for Quality Engineering at Medtronic Spinal and Biologics, where he helped lead a major modernization of the design quality systems, resulting in the company's first FDA approval of a cervical disc. Prior to Medtronic, Mr. Slagle spent nearly two decades at DePuy Orthopaedics in senior management capacities overseeing manufacturing engineering, plant management, manufacturing systems deployment, tooling services, distribution management, custom and special products, NDT, metrology, calibration and receiving inspection.

Mr. Slagle earned a bachelor's degree in metallurgy and materials science and an MBA, both from Case Western Reserve University. He holds a certification for quality engineering from the American Society for Quality. Mr. Slagle also is a lead ISO 13485 auditor, a six-sigma black belt candidate, and an expert in lean manufacturing.



ADVANCING THE QUALITY PROFESSION

FROM WHERE DO QUALITY ENGINEERS COME?

In reviewing our Section's strengths, weaknesses, opportunities, and threats (SWOT), a number of answers pointed towards K-12, the "school years."

There is little that is new about this idea. ASQ has had Koalty Kids as a program since the 80's. It is not a big deal in Indiana, but that appears to be untrue elsewhere, including Baldrige-award winning districts.

As part of the Strategic Skills Initiative, which is designed to improve the skills of the general workforce, introducing Koalty Kids to the local schools was at least considered. But, K-12 was later ruled out-of-scope for the Strategic Skills Initiative.

Until we can try to break into the K-12 curriculum at some future date, it is important to note a study showing the many engineers get their interest from their parents.

In studies of engineering, math, and science students, parents were most often mentioned as the most important influence in a young person's decisions to go into science or engineering. Encouragement doesn't have to be financial or informational (they do help though). You don't have to be a scientist or an engineer to give a kid confidence. Today, whether it's staying in science, working with computers, or doing a science fair project, having a parent say "give it a try" can make a difference.

Turning to how our Section can make a difference:

- Sponsoring the robotics group
- Providing scholarships

But, in new efforts, we can try to do some of the following:

- Providing afternoon or evening session focused on quality profession activities, possibly through established organizations like Science Central;
- Sponsoring summer camps focused on quality, or ones that include quality profession topics in their curriculum, like a section on software QA at computer camp;
- Intervening at school, especially at the 8th and 10th grade levels, which have been identified as key turning points in deciding to go into science and engineering;

Intervene in 8th grade

In 8th grade, most students decide if they will take algebra in 9th grade, an important first step to continued math involvement, the root of science and engineering. The experience has to be fun, though

Intervene in 10th grade

Sophomore year is another key decision-making time. While girls and boys are equally apt to take math until math requirements for college admission are fulfilled, girls are more likely than boys to stop here and take no more math. The key is small-group work and support, such as group reunions.

Lilly just gave the Community Development Foundation a grant to improve K-12 education. Can this section advocate for increased Quality Profession education and support of students?

Join the Leadership Meetings at Ivy Tech's Carroll Hall or on-line

Next one: Thursday, April 23rd at 5 p.m.

Access Numbers: 1.866.409.4300

Participant Entry Code: 4070204

QUALITY PROCESS UPDATE

APRIL 2009

QUALITY POLICY DEPLOYMENT PROCESS



This month, QPU looks at challenges that are beyond current capabilities of the Quality Profession, and suitable for setting the sights of the next generation's

STRATEGY

How do we protect a long supply chain from a quality standpoint? Complicate the question further, protect that chain when lots are co-mingled, detection methods are slow and expensive (more than pennies a test), and the chain spans a plethora of sources in multiple countries.

The most current example and one that is highly relevant to us is the food supply chain.

Problem Definition

How do you know that the food you eat today is safe? Passing recognition of the question typically elicits a few grimaced smiles.

The first answer is that the grocery store or the restaurant has a solid reputation. The second answer is these establishments are routinely inspected by governmental inspectors. We see the reports in the newspaper each Sunday. If you want, you can dodge the suspect eateries.

The answers to a third level of "whys" include that the components of dinner were generally safe. Safe components prepared or sold in a safe facility should be soothing. Further, the safe facility arises from adopting the best hygiene practices in facility design and construction to food handling practices. Every practice has a history of failures writ deep that best practices overcame and permanently fixed.

Less than 100 years ago, that wasn't true. Everyone has heard stories of Teddy Roosevelt getting sick at breakfast while reading Upton Sinclair's book, *The Jungle*, about the meatpacking houses' practices. Other stories describe candy adulterated with nuts and bolts. The result was the Pure Food and Drug Act of 1906.

The Act led to inspection of the whole supply chain to a set of best hygiene practices.

So back to the question: why do you have that uneasiness when asked whether the food you eat is safe?

The counterstories include that Ft. Wayne's restaurant inspectors were fired over failure to inspect or

The *E. Coli* detection method's sensitivity, sampling strategy efficiency, and speed needed for food safety are beyond current capabilities.

inspect properly. Outbreaks have occurred with moderate frequency. Examine Exhibit A: Peanut Corporation of America. Supplier Quality Assurance plans, like the one you routinely answer, missed the problems. Federal and Texas officials didn't even know that the Plainfield, TX facility existed. It was unlicensed and uninspected for four years. A private firm's purchasing agent failed the company three times in the 1980's. He would not buy from them. But, the word never got out beyond the firm.

Case two involves an *E. Coli* outbreak. A nurse in an isolated Indian reservation spotted the outbreak very early. The Centers for Disease Control (CDC) jumped right on the case. A classic opportunity for

successfully controlling an outbreak were in place. As the outbreak unfolded the mixing of ingredients in the salsa, combined with loss of lot traceability at blending vats, and weeks to culture bacteria resulted in implicating 500 Mexican producers, another 300 importers, and 25,000 shipments spread over several days.

In short, the system of inspectors and quality assurance was overwhelmed. What was needed was an *E. Coli* detection method that was sensitive, had sampling strategy efficiency, and was speedy. This is beyond current capabilities.

World-class quality assurance systems failed. Inspection schemes failed. Over 40% of firms that a reporter called have had no contact with regulators. World-class monitoring systems failed. And, recalls have failed. While 60% of 100 multinational companies have had to deal with recalls, the average recovery rate is only 28% of defective products. For Chinese products laced with melamine or adulterated heparin, only 4% of the products were recovered, even with global TV coverage and pundits' outrage.

In short, world-class QA systems may be necessary, but they are not sufficient!

World-class QA systems may be necessary, but they are not sufficient!

For a solution strategy while we develop the roadmap for tomorrow's QA systems to meet this challenge, QA systems need to focus on

- detecting to prevent
- detecting to protect
- detecting to recover or minimize regret.

Detecting to prevent

This is the classical confirming no contamination at the farm or the processor's facility. But, the point of testing to prevent is economically crucial. If a test costs \$5 (a six-minute job), in the US dairy system, testing at the farm means \$150 Billion each year for one contaminant! At the processor's plant, it is *only*

\$21 Billion dollars per contaminant. Plus, we are dealing with false positives. At 5-6 sigma, a 10 ppm false positive rate, a milk tanker is rejected weekly and a follow-on investigation consumes many hours of many inspectors. Likely a business takes a substantial hit, or its insurance company does, thus leading to higher insurance rates.

So at present, economically acceptable food-safety and food-defense requires the following:

- preventing high levels of contamination
- preventing high mortality events
- rapid confirmatory tests

Are you squeamish about dinner yet?

The food QA future may rest with these new fields of development:

New testing methods

Advanced sensor development, such as microarray chips, may solve the need for inexpensive, high-throughput, and speedy testing. But, even these require development of quality assurance standards for microarray chips. Further, there needs to be quality assurance standards for reading or imaging the chips.

There have been 10 patent applications for microarrays for food pathogens, toxins, and adulterants since 2002. One from ANP Tech has come to the market, illustrating the long development time for this new quality testing method.

The EU has started EMERALD, an initiative for microarray quality metrics. As reported previously in QPU, the FDA has been driven MAQC, the microarray quality control project. A technical committee of another professional organization is developing the imaging standards.

Quality Assurance developments

As previously reported in QPU, several academic groups are pursuing methodologies to measure and lower false positive rates.

A new Nobel-prize winning arena emerges in "Mechanism Design." The assurance system designer needs to craft a solution so that each party: producer, processor, and consumer gets the benefits and costs of actions they choose in response to carrots and sticks of the assurance system. **A Good Job and the Golden Rule are NOT separable,**

ASQ Certification Refresher Courses

These courses are being offered as a cooperative between Workforce & Economic Development of Ivy Tech Community College NE and ASQ Northeast Indiana Section 0905.

These courses are designed to prepare you for taking the ASQ Certification exams. Each course entails 24 hours of class time (2.4 CEUs) and utilizes the Quality Council of Indiana primer/solution text materials - which can be obtained by contacting them at (812-533-4215) or via the web at (www.qualitycouncil.com). These courses are conveniently scheduled in the preceding weeks running up to the applicable scheduled ASQ exam dates.

Refreshers Course Schedule for "Summer 2009"

Workforce & Economic Development of Ivy Tech Community College Northeast will be offering certification refresher classes on the following dates:

The CQE, CQA, CQIA and SSGB refresher classes will meet on Saturdays, **April 18th through May 23rd** (*should minimum enrollment be met*).

NEW LOCATION: Classes will meet from 8:00 a.m. to 12:00 p.m. in Carroll Hall at the Ivy Tech Community College "North Campus" (Stellhorn & St. Joe)

Cost is \$279

For directions and to register, call Ann Travis at (260) 480-4118

For more information, contact ASQ 0905 Education Chair, James Teeple at (260) 480-4165 or jteeple@ivytech.edu

NOTE: The ASQ exam registration deadline is April 16th and the exam June 6th

Please note that the certification exams are proctored at Ivy Tech Community College 3800 N. Anthony Blvd. Fort Wayne, IN 46805

NOTE: Cost does not include primer/solution texts or ASQ exam fees. Participants will be responsible for applying with the ASQ as there are prerequisites for taking the certification exams. More information on the exams and the application process is available from the national ASQ headquarters toll free at (800-248-1946) or via the web at (www.asq.org).

Congratulations to the following ASQ 0905 members who passed certification exams in March 2009!

Certified Quality Technician

Rhonda Ware

Ricky Jefferson

Claire Wagner

Certified Quality Inspector

Scarlet Montague

Certified Reliability Engineer

Robert Payonk

Certified Manager of Quality / Organizational Excellence

Bruce Merritt

Ian Hickman

Matt Kramer

Cynthia Maxwell

Note: The next round of exams is June 6th and the application deadline is April 17th at Ivy Tech Community College

This April, ASQ has a special offer for our members!

Recruit a member and get double the ASQ Bucks and be entered to win a GPS navigation device. This gives you the opportunity to guide someone to the same great networking opportunities, solutions, access to information, and professional development benefits you get with your ASQ membership—while you get rewarded. For every member you recruit in April* through the Each One Reach One (EORO) recruitment program, you'll earn double the ASQ Bucks and be entered in a drawing to win a TomTom XL 330 GPS navigation device. This GPS device features a 4.3" touch screen, preloaded maps**, spoken instructions, points-of-interest, and traffic information.

Visit www.asq.org/eoro-april for more details about this offer.

**All online or faxed new member applications must be sent by midnight on April 30, 2009. Applications that are mailed must be postmarked by April 30, 2009.*

***TomTom XL 330 maps include only the United States and Canada. If the winner is a member outside of these areas, they will be rewarded 250 ASQ Bucks in lieu of the GPS navigation device.*

Opportunity Knocks for Midwest's Unemployed

ASQ World Conference Includes Free Career Fair

Milwaukee, Wis., February 26, 2009 – With the Midwest unemployment rate at 7.5%, and more than 200,000 people unemployed in Minnesota alone, now is the perfect time for job seekers to attend ASQ's (American Society for Quality) **FREE** Career Fair, held in conjunction with the ASQ World Conference on Quality and Improvement, May 18–20, 2009, at the Minneapolis Convention Center, Minneapolis, Minn.

The Career Fair, sponsored by Microsoft, is open to the public and will focus on quality professions, from top organizations such as Johnson & Johnson and Stryker Orthopaedics.

The event begins Monday, May 18, 2009, with free Career Development Workshops for both professionals and students. The workshops will include interview tips and tools, how to position your quality certification, résumé help and much more. The Career Fair will continue Tuesday, May 19, 2009, with opportunities to network and talk to employers looking for quality employees in a variety of industries.

Space for the workshop attendees is limited. To register, or for more information, visit <http://wcqi.asq.org/career-fair>. Registration will also be available on-site.

ASQ, www.asq.org, has been the world's leading authority on quality for more than 60 years. With more than 90,000 individual and organizational members, the professional association advances learning, quality improvement and knowledge exchange to improve business results and to create better workplaces and communities worldwide. As a champion of the quality movement, ASQ offers technologies, concepts, tools and training to quality professionals, quality practitioners and everyday consumers, encouraging all to Make Good Great®. ASQ has been the sole administrator of the prestigious Malcolm Baldrige National Quality Award since 1991. Headquartered in Milwaukee, Wis., ASQ is a founding partner of the American Customer Satisfaction Index (ACSI), a prominent quarterly economic indicator, and also produces the Quarterly Quality Report.

Advanced ASQ Membership

Leadership and professional achievement do not go unnoticed by ASQ. The Society offers advanced levels of membership—Senior and Fellow—for individual members who represent the upper echelon of the quality profession and serve as the backbone of the Society. ASQ Senior and Fellow membership rewards members with enhanced benefit selections.

Senior membership status may be awarded to those individuals who have been ASQ members in good standing and meet the following criteria:

Have been an individual member for one year

Have 10 years of professional experience. Up to 4 years may be satisfied by graduation from an accredited university.

Have qualified in one of the following ways:

1. Conducting quality-related engineering, inspection, or statistical work, or applying quality on the job for at least 2 years.
2. Teaching quality or related arts or sciences at an accredited institution for at least 2 years.
3. Being a Senior Member or comparable grade in an American Society for Association Executives' list of recognized organizations.
4. Currently holding an ASQ certification that requires recertification.

To apply for Senior membership status log-in with your membership number and password at <http://www.asq.org>, click on the Membership tab, scroll down to Senior, click on UPGRADE, and download the application.

World Conference on Quality and Improvement

(Formerly the Annual Quality Congress)

Minneapolis, MN - May 18-20, 2009

Visit <http://wcqi.asq.org/> for more information.

SPECIAL BOOK DISCOUNT

Forrest Breyfogle's "Going Beyond Lean Six Sigma and the Balanced Scorecard", presentation was given here in Fort Wayne November, 2008, sponsored by ASQ0905 and Ivy Tech Community College. During the presentation, Forrest mentioned his new books on Integrated Enterprise Excellence (IEE). You can learn more about these books, on his website: <http://www.smartersolutions.com/integrated-enterprise-excellence.htm>

Forrest Breyfogle is extending an offer to ASQ0905 to save up to 40% off list price on books in his webstore. Webstore: <http://www.smartersolutions.com/store/home.php?cat=2>

Coupon Code: s083n67

ASQ Career Center

www.asq.org/career

Are you looking for a job? ASQ's Career Center is here to help. Post your resume, search job postings, get career advice, and explore career development opportunities.

Do you need to hire a quality professional? Post jobs and search resumes from the largest, most qualified audience of quality professionals—ASQ members.

Job Seekers

ASQ's Career Center (powered by Boxwood Technology) is FREE to all job seekers and provides you with access to the best employers and jobs in the quality industry:

Employers

The ASQ Career Center is the premier electronic recruitment resource for the industry. Here, employers and recruiters can access the most qualified talent pool with relevant work experience to fulfill staffing needs.

Future ASQ Dinner Meetings 2008/2009

(All at Don Hall's unless otherwise specified)

May 14, 2009

Dana Haenner (ISO Laboratory Accreditation)



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