

**MAY
2008**

What's Inside

May Meeting

Start of Summer



**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 **Newsletter**

Next ASQ 0905 Dinner Meeting - May 8th

Interactive Root Cause Analysis

by Nancy Berger and Jim Lee

EAGLE Registrations will present an interactive Root Cause Analysis program. We explain how to use several tools, 5 Why, Fishbone and the 8 D. We then break everyone into groups and have them work on a finding. We bring everyone back together to share their thoughts and provide feedback on the analysis. One comment back from a San Jose section member, "Best ASQ presentation they had ever been to".

Nancy Berger. Sales Manager, EAGLE Registrations Inc.

As Sales Manager for EAGLE Registrations, Nancy is involved with helping companies achieve registration to ISO 9001:2000, AS9100:2004, ISO/TS 16949:2002, ISO 14001:2004, ISO 13485, and TL9000. Nancy is a IRCA certified Lead Auditor for ISO 9001:2000 and has 9 year's experience as an internal auditor. Nancy was a lead internal auditor for the first meat manufacturer to become ISO certified back in the mid-90s.

Jim Lee. President and Owner, Simple QuE Inc.

Jim has 23 years of experience in quality and manufacturing and is a certified quality manager and quality auditor with ASQ. He holds a bachelor's degree in electrical engineering from Ohio University and is also a six sigma quality black belt leader and champion. He served on various ASTM subcommittees developing standards for juvenile products. He was awarded "Friend for Life" by Colorado Advocates for Child Transportation Safety.

Where?

Hall's Guesthouse
1313 W Washington Center Road
Fort Wayne, IN

Social at 5:30, Dinner at 6:00, Presentation approx 6:30

Please RSVP by Monday, February 8th to Jim Smith at 260-434-5464 or james.e.smith@baesystems.com

Dinner \$19.00

If you can't make the meeting, please have the courtesy to notify Jim of the cancellation. We are charged for all reservations whether or not you show up.

BEAT OFFSHORING-ADD 10X VALUE

Manual Inspection and Gauge Block Style Quality Control are becoming standardized processes... easily offshorable.

Analysis adds value.



Don Wheeler came to Fort Wayne.

People who came to the day-long conference on the 24th or the monthly section meeting that same evening were treated to polished and authoritative presentations on analyzing quality data. Analyzing data is the quality profession's strength and true growth area. We are professional problem solvers and problem preventers. ASQ 0905 and Ivy Tech support increasing quality's professionalism in Northeast Indiana. Ivy Tech has made no secret of trying to develop an Associate's degree in quality. Obviously, ASQ heartily endorses that effort.

Does anyone expect that lot inspection and gauge block measurements are the future of the quality profession? Look around. Inspection and measurements are a cost. How do you reduce cost without decreasing information? The answer's automation. Within five years automated collection of inspection information will be dominant. Process records will be carried on individual products and components readable by remote sensors. Statistical analysis of the data can be handled by software, for example, MINITAB. Once you automate and standardize, the next step is very easily offshoring the work.

They haven't automated Lean Sigma!

What can't be offshored is the constantly improving knowledge base; the familiarity with history of the product or service, the ability to understand the complexity that arises in the product system, or the continual improvement. They haven't automated Lean Sigma!

Our profession has to be adding value at a rate almost 10 times the rate that offshore

professionals can add value. How is this done? NOT WITH BABY STEPS; NOT "MORE OF THE SAME ONLY BETTER." Try continual sharpening of your saws to borrow Steven Covey's words.

How can you continually sharpen when the corporate budget is so tight in this down economy? In talking with other section leaders, everybody is suffering. ASQ World Conference attendance is down. Midwest Conference attendance is down. People can't afford travel or the time.

Control this: YOUR CAREER. Dr Wheeler's presentations were a solution. We plan on doing this again: an inexpensive local conference with a world-class teacher:

May marks the end of the 2007-2008 ASQ Year., I want to thank evryone who has participated in the section. Certainly the Leadership Team deserves praise: Meeting attendance is up significantly, Ivy Tech has stepped up its steadfast partnership another notch, we have several new members coming to the Leadership team, and we met at least 80% of our goals for the Section Management Program.

Where do we need work? (1) We need to get back to our superb communiocations with the section. (2) We need to develop a pipeline of leaders. (3) We need to continue to prepare for future quality everything from broadcasting new technologies to preventing breaches of our duty to protect product quality.

These have already started: John Chalmers has agreed to become internet liaison. We have gotten some strong interest in committee membership. And, new quality concepts for a broader array of industries are coming to the fore.

Further, we have begun exploring having simultaneous section meetings in several localities to allow members to attend and network without excessive driving or use of time. An experiment later this year is likely. Stand by.

Start of Summer

It's that time of year again when everyone wants to be outside to soak up some much needed sunshine. I don't know about everyone else but I am just happy to see the snow disappear.

But with the beginning of summer, it means the end of the year for the 'Histogram'. It has been a very trying year with getting the issues out. I have had multiple problems with my computer and it has been getting harder to get articles. I am sorry for any inconveniences these delays may have caused but I have all summer to try and straighten them out.

If you have something that you would like to see printed in the 'Histogram', please send it to me at lzody@indianadata.com and if it is appropriate, I will be happy to add it.

Have a good summer and look for the next issue of the histogram in September.

Thanks

Call for Instructors

I'm currently in-process of updating our database for individuals who may be interested in instructing the Refresher courses which review the ASQ Body of Knowledge for each of the applicable certification exams. Refresher courses are intended to help exam applicants prepare for taking an ASQ certification exam. These courses are delivered in a traditional classroom setting with a great amount of interaction between instructors and participants while reviewing the BOK, primer materials, and sample exam questions. Each course is designed with 24 contact hours and sessions may be scheduled to accommodate an instructor's availability (including evenings).

If you are interested in being an instructor and have successfully passed an ASQ certification exam, or if you consider yourself a topic matter expert in a related field, contact me to be put on our list for consideration. Instructors are compensated at a competitive local higher learning institution hourly rate and can gain RUs for maintaining their own certifications!

James Teeple
ASQ 0905 Education Chair

Phone: (260) 480-4165
Email: jteeple@ivytech.edu

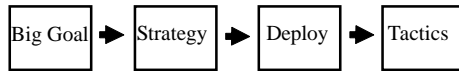
Information Needed

Our section is trying to gather information for the History of Section 0905. Very little information has been found concerning the years 1995 thru 2005. If you have any old newsletters or other information from this time, please contact an officer of board member listed on the last page of this newsletter.

QUALITY PROCESS UPDATE

MAY 2008

QUALITY POLICY DEPLOYMENT PROCESS



STRATEGY

COMPANIES ARE UNPREPARED FOR RECALLS

Analysts attribute the increasing number of recalls to tougher regulations or heightened consumer awareness rather than poorer quality products. But, despite this change in the attitudes and political environment, many large companies remain unprepared according to a new study by Freshfields Bruckhaus Deringer, a law firm.

Of 100 multinational companies surveyed, 60% attributed the recall increase to tighter regulations over the last five years, and 27% to consumer activism. About 6% blamed poor quality products and 9% pointed to outsourcing that made monitoring quality more complex.

The survey also found that 40% of the companies had no contact with regulators and 10% had no contingency plan or specialist team ready to deal with any recall crisis. Despite this lack of preparation, over 60% had had to deal with recalled products since 2004 (about a 20% chance each year). A third of those found a significant negative financial impact on the business.

The first reaction of half of the companies was to conduct an immediate recall. The second most likely option was to stop supplies while the company dealt with the situation or changed manufacturing. Over a third of the companies could not trace faulty batches to the customer level.

Preventing failures in the process, failures which may lead to recalls, is a primary role of quality assurance in the 21st century. The customer and the customer's customer

traditionally are at one end of the supply chain, while the vendor and the vendor's vendor comprise the other end. In some industries, for example, pharmaceuticals, there is also the return or reverse distribution from the customer's customer.

TACTICS

To meet these challenges, let's examine some the current practices. Despite the advancement of quality systems, increasingly it is buyer beware and seller beware world! Pharmaceutical firms are focusing on counterfeit product being shipped into the legitimate manufacturing supply chain. Further, the pharmaceutical firms are being pummeled by counterfeit products being slipped into the reverse distribution network. This network returns expired to pharmaceuticals back to the manufacturer. Some have begun using high-volume, non-destructive testing such as energy dispersive x-ray diffraction to do attribute testing of returned product.

Adding to the intentional subversion of the supply chain quality is the inadvertent loss of traceability when lots are combined in larger batches by customers. Examples are the humungous lots of ground beef recently recalled because several smaller daily batches possibly contaminated with E.coli were blended with clearly fine-quality beef. Lot and sub-lot size control (a two-year size set of correlated lots) had been lacking in this example. Negative impact: it bankrupted the company.

An emerging risk for quality professionals are recalls needed because of post-hoc analyses such as by the FDA in the case of newly approved pharmaceuticals. Classic examples may be Vioxx and Fenphen drugs pulled from the market when follow-on studies revealed possible side effects not recognized during the drug approval process. The leader of the Center for Drug Evaluation and Research says that the size and length of clinical trials has grown substantially in recent years. But she argued that this was a result of

a better understanding by regulators of how best to identify risks. "We're smarter now, but still humbled by what we don't know," she said. She also warned that FDA staffing and funding for the inspection of foreign manufacturing sites for medicines remains "thin." There has been and is unlikely to be any increase in inspectors. Inspection is being replaced by a risk-based approach where regulators share information and rely on the FDA's gold standard of placebo-controlled trials.

In particular, the FDA Center leader has concerns that the risk-based approach may not be a complete substitute for inspections. She pointed to the recent incident of Chinese-sourced ingredients for the anti-clotting agent Heparin. Study of the Heparin case is an excellent contrast in quality systems. This kind of direct oversight can be important in China, where enforcement is often lax even in a tightly controlled industry like pharmaceuticals. Vendors from other nations and cultures may have different views about responsibility for quality. A senior Chinese minister declared, "companies receiving product from China have the responsibility for the quality." No other senior officials stepped-up to refute this claim.

Like the case during 2007 of phenolics in toothpaste, dog food, and other Chinese imports, intentional subversion of quality standards is likely to remain an issue. In the Heparin case, Shenzhen Hepalink company has a high-tech factory in Southern China where workers wear protective surgical gear during making the active pharmaceutical ingredient for heparin. The plant has been inspected and approved nine times in recent years by Chinese health authorities, German regulators, and the US FDA. Buyers have done an additional 25 products. The company's chairman claims the Company keeps more than 300 pages of data for each batch to ensure traceability of each lot. Shenzhen Hepalink controls its supply chain closely. They receive supplies of pig intestines only from government-certified slaughterhouses. Shenzhen stations their employees in all suppliers' quality assurance labs to make sure that the company's rules are followed.

Changzhou Qianhong Biopharma and Yantai Dongcheng Biopharmaceuticals have had heparin product recalled in Germany. The process of heparin production starts with extraction of crude heparin from slaughtered pigs. Essentially, there is no oversight by Chinese health authorities of this operation often carried out in small shops in agricultural communities. Trading companies buy up this crude heparin to sell to bulk drug manufacturers. The lots may be traded by the trading companies several times before they reach the manufacturers. Traceability, forget it. One of the suppliers admitted they had been forced to use sheep intestines in addition to pig intestines because of shortage of pigs. It is suspected that other crude heparin suppliers cut costs by using pigs contaminated with blue-ear disease. One American importer says that it tests all crude heparin to make sure that its only from healthy pigs.

When FDA officials toured the Changzhou plant in February they found flaws in record keeping as well as a lack of validation of the effectiveness of their process for removing impurities. Changzhou's US customer had toured the plant in September of last year and observed some similar issues.

One approach to detecting, predicting, and preventing these system failures is to use classic risk analysis of a process map looking at potential failure modes and effects as well as fault tree analysis associated with the process steps. The key improvement in developing the quality system is asking the question, "How do I make these failure modes have been 100% at the time?" Once that has been figured out, find a way to subvert one of the steps in that guaranteed failure process so that the probability of being able to actually have the process work is zero. This is the approach of Anticipatory Failure Determination and Prediction, effectively FMEA on steroids.

Quality Assurance leaders, you are the ones who must plan for recalls, plan for control of outsourced vendors' processes, and enforce the discipline. You are the ones who must make the business case for these protocols to the business leaders.

Recertification Contact Person

Mr. Chuck Bandelier
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Columbia City, IN 46725
260-244-5429
cbandelier@embarqmail.com

The importance of maintaining the currency of your hard-earned certifications by using continuing education credits or other acceptable credits can not be over stated. Do not send recertification paperwork to the Section's mailing address, as the timeliness of your recertification may be lost. Paperwork should be sent directly to Chuck. If you have any questions about the material required to verify your recertification, call Chuck. remember the other way to retain your certification is to simply retest. I don't know anyone who wants that option.

Interested in advertising in the Histogram? The Histogram is published from September thru May. The charge is as follows:

1/4 page advertisement \$25.00/each month

1/2 page advertisement \$50.00/each month

Whole page advertisement \$100.00/each month

Contact Leslie Zody at 260-244-2114 or leslie.zody@autoliv.com for more details.



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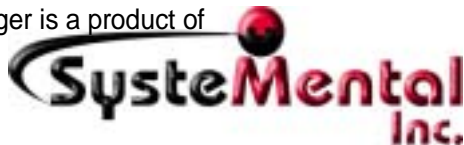
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