

Gabriel's Horn

February, 2008

The official newsletter of the San Gabriel Valley section
of the American Society for Quality
www.asq702.org

Our Mission

To further the Knowledge and Professional Accomplishments of our Members
and Quality Professionals in our Community Dedicated to Performance
Excellence and Quality Improvement.

ASQ SURVEY

ASQ Headquarters is conducting a survey on how well your section or division is serving you. The survey is being conducted via the web. So if you receive an eMail requesting your participation, it is in your best interest to seize the opportunity and get your feedback heard.

Message from the Chairman

Dear members,

The time flies by and leaves memories to chew upon. Our section is indeed getting a good boost from efforts of all members. We are having exciting events planned for the year.

My sincere wish is that all members expand their knowledge of quality and learn a lot and spread the knowledge of quality among our peers at our places of work or business. There is so much that quality professionals have to offer to the society.

The ASQ 702 website is getting updated and soon all program information and quality activities will be posted on the site. Please visit the site and provide your feedback. All new ideas and comments are warmly welcome.

The board is also looking for volunteers to fill important positions in the board. I am looking forward for young people to come forward and provide the support to the section. Please contact any board member to participate in the board. All you need is to give a few hours of you time per month towards your profession for a noble cause.

Sincerely Yours,
C.G.Mistry,
Chair Section 702

Announcements of Coming Programs and Activities

Please join us for a presentation on **COST of Quality** by Joe DeSimone

Meeting Date: Feb 20, 2008

“Joe will explore new ideas on how to effectively categorize your company’s Quality Cost’s, with additional fundamental concepts of Activity Based Costing. He will also present ideas on the implementation in your company and a Six Sigma approach to COQ/COPQ statistical analysis. Joe will also introduce a new Control Chart he has developed based on Taguchi’s Loss Function. Participants will engage in a team activity that will illustrate first-hand, the importance of understanding, analyzing and reducing the Costs of Quality”.

ABOUT THE SPEAKER

Joe DeSimone is the owner and president of DeSimone Engineering, a consulting firm specializing in quality and productivity improvements. Joe has more than 18 years of experience in training, consulting, and implementing SPC, DOE, FMEA, GD&T and Lean Six Sigma in various industries, from aerospace to food and drug.

Additionally, Joe has been preparing examinees for the ASQ’s CQE, CQM, CRE, SSBB and auditor exams for the past 10 years. Joe is also a degreed QE, and is certified as a Quality Engineer and CQM, CRE, CSQE, and SSBB. He is actively involved with the Project Management Institute and is a certified Project Management Professional (PMP). Joe is the LA Sections certification chairman and currently the vice chairman of DeSimone Engineering, Inc.'s offices of DeSimone Engineering, Inc. in San Pedro, Calif. and Beijing, China.

January’s Presentation

The members that attended the January meeting were treated to an excellent presentation on LEAN and a workshop using some of the tools that had just been introduced. The presenter was Larry Bartkus. He is the Master Black Belt for business excellence for Biosense Webster, a Johnson and Johnson company.

In the first part of his program, Larry spoke on LEAN and the 8 wastes, yes he has more than just the classical 7 wastes. He introduced four of the tools in detail, Value Stream Mapping, Poka Yoka, Kaisen, and 5s. During the second part of the program, Larry had the attendees break up into four groups, with each group applying one of the tools. The group with the Kaisen tool applied it to the U.S. presidential election process. I am sure that by November, all of us will be supporting their proposal to overhaul a process that was developed for an era when all information could only be transmitted at the speed of a messenger on a horse.

All participants appreciated the opportunity to use the tools and discuss real applications of the tools with members that had experience with their application.

Chapter 702 * 2008 Meeting Calendar *****

February 20 meeting
Cost of Quality speaker: Joe DeSimone

March 3 executive board meeting

March 19 meeting
Statistics – Sampling speaker: Linda HowieGarriz

April 16 meeting Joint meeting with Biomedical Discussion Group
Managing Risk using ICH Q9 & ISO 14971 speaker: Mike Wakshull

May 5 executive board meeting

May 21 Full day Seminar
Subject to be announced

June 18 meeting
Subject not yet finalized speaker: Chris Christensen

July 7 executive board meeting

July 16 meeting Joint meeting with Biomedical Discussion Group
Program to be announced

August 20 meeting
ASQ's International Team Excellence Awards
speaker: Kandy Senthilmaran

September 1 executive board meeting

September 17 meeting
Program to be announced

October 17 meeting
Joint meeting of Section and Biomedical Discussion Group
Program to be announced

October 18 Quality Day joint effort with L.A. Chapter
Cal State Dominguez Hills
Organizational Excellence

November 3 executive board meeting

November 19 meeting
Program to be announced

December no meeting

2009

January 21 meeting
Joint meeting of Section and Biomedical Discussion Group
Program to be announced

Supplier Auditing and Supplier Certification

The ASQ Customer-Supplier Division announces the first of their one-day seminars for 2008. The very popular Supplier Auditing and Supplier Certification courses will be offered in the southwest: Torrance, Ontario, and Las Vegas. The Torrance classes will be April 7 (Auditing) and April 8 (Certification). Ontario will be April 8 and 9. Las Vegas will be April 9 and 10.

For detailed information, including registration fees and site locations, please visit the Customer-Supplier Division's web site at <http://www.asq.org/cs/courses/>. Or contact Dick (DickGouldCSP@aol.com) or Dennis (dennis@auditguy.net). Classes are limited to 30 participants and pre-registration is required.

**Looking for a few good members
to be editors of features of this section's newsletter.**

Industry News

Service Industry

Looking for an editor for this feature.

Food Industry

Looking for an editor for this feature.

The FDA is so understaffed that, at its current pace, the agency would need at least 27 years to inspect every foreign medical device plant that exports to the United States, 13 years to check every foreign drug plant and 1,900 years to examine every foreign food plant, according to government investigators. [These are the findings from a series of reports by the Government Accountability Office to the House Energy and Commerce Committee.]

“Our investigation has found ample evidence that FDA inspections across the board are sorely lacking,” said Representative John D. Dingell.

The FDA is considering posting staff overseas to perform inspections and foster relationships with for foreign government counterparts and industry.

IT/Software Industry a coming attraction

Editor: Kandy Senthilmaran

Pharmaceutical Industry

Looking for an editor for this feature.

Canada has issued a guidance document – Cleaning Validation Guidelines – GUIDE-0028. This document is intended to address special considerations and issues pertaining to validation of cleaning procedures for equipment used in the manufacture of pharmaceutical products, radiopharmaceuticals, and biological drugs.

http://www.hc-sc.gc.ca/dhp-mps/compi-conform/gmp-bpf/validation/gui_0028_tc-tm_e.html

This is just one of several Guidelines that Canada released in January; all are available at their website.

Medical Device Industry

It appears that people at the agency were busy getting their 2007 work objectives completed. A number of new guidelines were issued at the end of the year.

- The Review of Inspection of Premarket Approval Application Manufacturing Information and Operations www.fda.gov/cdrh/comp/guidance/1566.pdf
- The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program www.fda.gov/cdrh/comp/guidance/1602.pdf
- Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices www.fda.gov/cdrh/oivd/guidance/1171.pdf

Quality Topics

Looking for contributing editors for this feature.

LEAN

The Shingo Prize is an annual award to recognize organizations with lean-thinking maturity.

The process requires the organization to conduct a self evaluation and submit an Achievement Report following the Shingo Prize Model. If the organization scores high enough, then a site visit by an audit team is arranged. By this process winners are selected.

Steelcase in the City of Industry won the 2006 award.

If your company is implementing LEAN, you might want to review the content of the Shingo Prize Model for some very good information.

www.shingoprize.org

Networking for Quality Professionals

Attending ASQ meeting is most likely your only opportunity to network with other quality professionals outside of your place of business. So attend your section's functions and meet other professionals.

ASQ Orange Section www.asqorangeempire.org

ASQ Los Angeles Section www.asqla.org

ASQ Inland Empire Section www.asq711.org

ASQ Temecula Valley Section www.asqtemecula.org

ASQ San Fernando Valley Section www.asqsfv.org

Educational and Professional Developments

Does your Personal Improvement Plan for 2008 include going back to school? Then why not obtain some of the free money that is available.

Rules for Scholarship Application – 2008

Richard A. Freund International Scholarship

Graduate students are invited to apply for the American Society for Quality's Richard A. Freund International Scholarship. This \$5,000 scholarship is for students pursuing a master's degree or higher with concentration in quality control, quality assurance, quality improvement, total quality management, applied science, or a similar quality emphasis. An application and more information are available on the [ASQ Web site](http://www.asq.org). The deadline to apply is April 1, 2008. Contact Trish Borzon at tborzon@asq.org or 1-800-248-1946 x7580 with questions.

The application is on the site – you will need an acceptance letter from the university you plan on attending as well as transcripts for your BA degree (s). All the details are outlined on the applications. The **Freund scholarship is the only scholarship that ASQ headquarters oversees**, however **there are several available through sections and divisions**. Each member unit has their own criteria and guidelines for nominations. Unfortunately you'll have to do a little searching on the various sites for more detailed information.

Here's a list of all the Member Unit (Section/Division) scholarships that have been approved through our Awards Board

<http://www.asq.org/about-asq/awards/docs/scholarship-list-200607.pdf> -

Usually for a Section (local area) scholarship you have to reside in the area - <http://www.asq.org/sections/sect.html>

Division or Forum scholarship criteria you'll have visit their sites <http://www.asq.org/forums-divisions/index.html>

I know that the Statistics division does have a scholarship for Masters level - <http://www.asqstatdiv.org/awards.html>

Trish Borzon, CQIA

Program Administrator Membership & Community Development & Value

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Thank you to everyone who contributed to this newsletter.

To all 702 MEMBERS, tells us what you liked and didn't like about this newsletter. The goal is to make a newsletter that has value to YOU.

Send your feedback or material for inclusion in the newsletter to:
chair@asq702.org