

Gabriel's Horn

March , 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.

Message from the Chairman

Dear members,

I am very excited to inform you that the section is poised for a growth that will surely take it to the glorious days of 1990s. The attendance at the section meetings is on the rise. The interest for participation in board membership is increasing.

A new development is the organization for quality day in October 2008. Our section is taking part in the event in collaboration with LA section 700. The exact details will be announced soon.

The board is also actively looking for volunteers to fill important positions in the board. I am requesting and challenging young people to come forward and provide the much-needed boost 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. You will have rewards of earning points towards recertification and feeling of self respect of helping an organization that helps quality professionals like all of us stay together and work towards common goals of self improvements and bettering the organization.

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

Breaking News -----Workshop – MiniTab ----- Breaking News

Section 702 is putting together a workshop on the use of MiniTab. The tentative date is April 27th a Saturday. The workshop will be 3 to 4 hours in duration. The exact time and location is to be announced.

Announcements of Coming Programs and Activities

March Program

Please join us for a presentation on **Sample Size Selection** by Linda Howe Garriz
Meeting Date: March 19, 2008 at 6:00pm

This session will examine how to select the appropriate statistical samples to meet your objectives. Both attribute and variable samples size determination will be covered during this session. The session will focus on real-life situations you face in selecting samples.

ABOUT THE SPEAKER

Linda Howe Garriz is Associate Director, Quality Assurance Operations at the Irvine Technology Center of Alcon Manufacturing, Ltd. in Irvine. She received her B.S. in Mathematics/Economics from Allegheny College and her M.S. in Industrial Administration from Carnegie-Mellon University. She currently is an instructor for the Certified Engineer, Certified Biomedical Auditor, and Certified Six Sigma Black Belt Refresher Courses for the Orange Empire of the ASQ.

February's Program

The speaker, Joe DeSimone, drew in members from near and far to hear what he had to say about the Cost of Quality and the Taguchi Loss Function. It was a record turn out. And everyone that attended learned something.

Joe reported to the audience that he has a control charting method using the Taguchi Loss Function currently being reviewed by Dr. Taguchi. I think that I can speak for all of us, that when Joe is ready to bring this new tool out to the world we would like to have him back to share it with us.

In the first part of his program, Joe spoke on the traditional Cost of Quality, but then he presented it using "hard" COQ and "Soft" COQ concepts. For anyone that has tried to use the COS, his warning about trying to quantify exact numbers on the COS is a sure way to lose focus on the real goal. His council was to use the data you have and start making improvements. With the improvements, the COS goes down, everyone becomes a believer, your credibility goes up and you get to keep doing it.

The second part of his program was a hands-on exercise using catapults to demonstrate the Taguchi Loss Function. Each team's results were based on the repeatability of the projectile landing on the same target. The rewards/loses were proportional to the lack of repeatability. The loses got rather large in a very short time for some teams, just like what happens in the real world as the Taguchi Loss Function predicts.

If this was the first time you had ever been to a Joe DeSimone presentation I am sure that his enthusiasm and humor made a dry topic a heck of a lot of fun. For everyone that had been entertained by Joe before it was great to see he has still got the magic.

News -- News

Randall Wong has accepted the position of editor for the Pharmaceutical column of the newsletter. His first article is in the Industry section of this newsletter. Please extend a warm welcome to Randall for stepping up and taking on this role.

If you would like to be an editor of one of the sections, or if you have an article even for just one newsletter, please contact us directly or through the section's eMail, chair@asq702.org.

Also, if there is something you would like to see included in the newsletter or any suggestions for the newsletter, please contact us directly or through the section's eMail, chair@asq702.org.

The section is looking for some one to be the web master. If you have any interest, please contact a member of the board, or send an eMail to chair@asq702.org .

New Members

Section 702 would like to welcome the new members

Donald Thomas
Marquis Chambers
Thomas Lebs
Hong Leong
Bill Stick

Chapter 702 * 2008 Meeting Calendar *****

- 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 14971:2007 speaker: Mike
 Wakshull
May 5 executive board meeting
May 21 Full day Seminar
 Subject – Food and Drug
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
 How to setup a Center of Excellence
 speaker: Sara J. Mayo
October 15 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

Section meetings start at 6:00 pm and are held at Biosense Webster, 15715
Arrow Hwy, Irwindale
Executive Board meetings start at 6:00 and are held at Marie Calendars,
3117 E. Garvey Ave., West Covina

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 Food and Drug Administration announced March 14th plans to place eight full-time, permanent FDA positions at U.S. diplomatic posts in China, pending approval by the Chinese government. FDA deputy commissioner Murray Lumpkin stated, "Our efforts to file permanent FDA positions in China are a significant step towards ensuring access to safe food, drugs and medical devices in the global market."

IT/Software Industry a coming attraction

Editor: Kandy Senthilmaran

Pharmaceutical Industry

Editor: Randall Wong

By way of introduction to the topic of Quality as it relates to the Pharmaceutical Industry, the U.S. FDA has an agency initiative titled "**FDA's Pharmaceutical Quality for the 21st Century A Risked Based Approach**". This is an effort by the FDA to update the current Good Manufacturing Practice regulations to be more aligned with the Quality concepts from the Medical Device Industry, International Standards Organization (ISO), and harmonization with other Regulatory Bodies through the International Conference on Harmonization (ICH). The Quality concepts put forward in this 21st Century directive

includes Quality System Approach, Risk Assessment, CAPA, Process Analytical Technologies (PAT), Drug Development Life Cycle, and guidance documents for specific aspects related to Pharmaceutical Manufacturing ranging from Sterile Drug Manufacturing to Investigating Out-of-Specification Results.

This month's column provides links to the FDA website for

FDA Pharmaceutical Quality for the 21st Century

www.fda.gov/oc/cgmp/

FDA Guidance for Industry - Quality Systems Approach to Pharmaceutical CGMP Regulations

www.fda.gov/cder/guidance/index.htm#CGMPS-Eff

ICH Q10 Pharmaceutical Quality System

www.fda.gov/cder/guidance/index.htm#International%20Conference%20on%20Harmonisation-Quality

These latter two guidance documents emphasize a systems based approach to Quality as opposed to the prescriptive Quality Control requirements of the GMP's specified in 21CFR 210 and 211.

Medical Device Industry

February 20th, the United States Supreme Court precluded imposition of any additional requirements under state product-liability law on medical devices.

The ruling generally says that patients can not sue medical device manufactures over products cleared for sale under the more intensive federal review process.

This will not stop suits on products produced by device manufactures with U.S. FDA warning letters or worse issued against them. Warning letters, etc. establish that the manufacture was not operating within the regulations and as such they have an open exposure for some one to use when suing a medical device manufacture.

The message to management of medical device companies, operating within the regulations has large financial benefits.

Quality Topics

Looking for contributing editors for this feature.

Joseph M. Juran, 1904-2008

A pioneering architect of the science of managing for quality, Joseph M. Juran, passed away February 28 at the age of 103. Known as the "father" of quality, he said, "It is most important that top management be quality-minded. In the absence of sincere manifestation of interest at the top, little will happen below."

LEAN

Value stream: All activities, both value added and nonvalue added, required to bring a product from raw material state into the hands of the customer, bring a customer requirement from order to delivery and bring a design from concept to launch.

Value stream mapping: A pencil and paper tool used in two stages. First, follow a product's production path from beginning to end and draw a visual representation of every process in the material and information flows. Second, draw a future state map of how value should flow. The most important map is the future state map.

Use your ASQ membership to obtain information on LEAN at the ASQ website.

Networking for Quality Professionals

You have been attending the section meetings. Have you started communicating with your fellow member?

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

One third of 2008 has come and gone, how are you progressing on your personal improvement plan? Hopefully you are doing well.

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