

Gabriel's Horn

April , 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,

Spring has come and will soon be gone. Nature has showered mankind with beautiful flowers, vegetables and fruits. We have to emulate the nature and share with the society the knowledge we have gained through our life and experiences.

Our section has achieved remarkable growth in recent months and I am confident we will continue to grow with help from all of our members. I look forward to all to lend the helping hand in our efforts to reach the status we deserve in the ASQ community. I am very happy to see the attendance increasing at the section meetings.

The organization for quality day in October 2008 is progressing at a steady pace. More details will be coming soon.

We have many vacant positions on the board. 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

----- Workshop -----

Capability Analyses using Minitab

Saturday, April 26th there will be a workshop from 8:00 to 12:00 (Sign-in/Registration 7:30 to 8:00) on the Capability analysis using Minitab, by Joel Smit, Minitab Inc. The workshop is being held at Biosense Webster, 15715 Arrow Highway, Irwindale. The cost for the workshop is \$40.00. Seating is limited, so it is highly recommended that you register on-line through Actevia. <http://www.acteva.com/booking.cfm?bevaid=156914> Questions, contact Kandy Senthilmaran at 517-290-6636 or E-mail Kanthassamy@hotmail.com

Learn how to use Capability Analyses and related statistical and graphical tools to assess and improve quality in any organization using Minitab. Joel will illustrate good data collection techniques, tools to assess the quality of your data and introduce various data types in explaining what capability analyses can do for you.

Joel Smit is a BMG certified six sigma black belt with a BS in Chemical Engineering from Rose-Hulman Institute of Technology and has a MS in Statistics from Virginia Tech. Some of the programs that Joel has given are “Advanced Tips and Tricks with Minitab”, “Assessing Quality with Non-normal Data”, “Statistical Applications from Dr. Deming”, and “Ranking College Football Teams: An Objective Approach”.

Announcements of Coming Programs and Activities

April Program

Please join us for a presentation on **A Practical Approach to Risk Management** using ICH Q9 & ISO 14971 by Mike Wakshull
Meeting Date: April 16, 2008 at 6:00pm

Risk management is a component of a quality management system. Implementing ICH Q9 (Quality Risk Management) for pharmaceutical products and ISO 14971:2007 (Risk management for medical devices) are recommended guidance. Used together, the standards complement each other, creating a powerful approach to managing risk for the life of the product.

ABOUT THE SPEAKER

Mike Wakshull has more than 15 years experience in the risk management field in a variety of industries including biotechnology, financial, information technology and airport. He is the president of Q9 Consulting, Inc., a contract provider of risk management services that include training and development of quality risk management processes.

March's Program

Deriving sample size is part of every Quality professional's job. Linda Howe Garriz didn't beat around the statistical bush, she used eight real life examples to cover about all the situations you are going to encounter. If you have to learn how to select sample size (or any part of statistics for that matter) using real life examples is the way to learn.

Linda's guidance on how to develop a hypothesis (Complete the sentence, "I am trying to prove that") is about as simple as you are ever going to find. By the end of her presentation we were all painlessly applying chi-squared and f-tests to compare variation.

So unless you could follow Linda around on her job and learn from her as she develops sampling plans, this presentation was as good as it gets. Note, Linda instructs the statistical portion of the refresher courses for several of the ASQ Certified professional designations.

If you would like to be an editor of one of the sections of this newsletter, 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

Jose Rodriquez
Sandeep Bhavsar
Carol Blischke
Susan Butkus
Joawph Candelaria
Naomi Haynes
Joshua Highsmith
Fred Madrigal
Henry Salazar (Student)

Achieving Global Food, Drug and Device Protection Through Partnerships

The Association of Food and Drug Officials (AFDO), a non-profit organization of local, state and federal government officials, academia and industry leaders will hold its 112th annual Education Conference at the Crowne Plaza Resort Hotel in Anaheim, June 7-11.

For more information, go to:

<http://www.afdo.org/afdo/Conferences/>

Regulatory Affairs: Expanding to Global Horizons

The FDA Los Angeles District Office and the Orange County Regulatory Affairs Discussion Group are presenting the 11th Annual FDA-OCRA Educational Conference June 11-12, at the Irvine Marriott. This is THE meeting where Washington comes to the West Coast.

For more information, go to:

<http://www.ocra-dg.org/meetings.htm>

Chapter 702 * 2008 Meeting Calendar *****

- 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
- February 18 meeting

Section meetings are the third Wednesday of the month.

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

**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.

IT/Software Industry

Editor: Kandy Senthilmaran

**THE APPLICABILITY OF VARIOUS QUALITY MODELS/METHODOLIGIES
IN AN IT ORGANIZATION**

In a world of rapid change, where quality improvement models, methodologies and frameworks are constantly evolving, a genuine need exists for IT leadership and quality professionals to be aware of what tools are at their disposal, and perhaps most importantly – which is suitable for their organization. In today's world, there is no single prescription for a complete cure. In fact, often times success is a combination of multiple models/methodologies/frameworks which create the foundation for higher process capability in an IT organization. As there are two sides to a coin, we can see organizations openly embracing the industry models for process improvement, while others desire output from these models without embracing them for fear that it might lead to more work, higher cost, and other cultural implications of the organization.

I can relate this scenario to a quote that many of us would have heard – “Our profession is similar to that of a carpenter where the end customer need not be aware of what tools and techniques are being used to do the work as long as the quality of the work is to their expectation”.

I myself am conflicted regarding this statement. First of all, I agree that our customers do not necessarily need to know about the tools and techniques we use in our line of work. However, I am of the opinion that educating our customers on the tools and techniques will go a long way in assuring them that recognized tools and methods are being applied while performing their work. They need not know how the tools and methods work, but educating them on the basis of our work will not only set us apart from our competitors, but increases the value quotient of the work we deliver. Finally, as a quality professional (carpenter) we should be up to speed with the ever evolving industry models/methodologies/frameworks. It is imperative that we be proficient in all

tools and techniques which we can leverage to enable IT to deliver quality solutions to our business partners (end customers) with speed and precision.

In the near future, I will embark upon a series of articles in our newsletter section regarding various industry models/methodologies/frameworks for quality improvement in an IT organization. Among the list of topics, you can expect to see the following:

- SEI CMMi

- COBiT

- ITIL

- Six Sigma

- SOX

Other references - PMBOK, Gartner's 21 best practices etc

I also hope to engage with you further in an "IT Quality café" during one of monthly section meetings after this series to discuss similar topics.

If you have any questions or comments, please contact me at:

KSenthilmara@CSC.com

Kandy Senthilmaran – Director – Process Center of Excellence – CSC Covansys Corp

Pharmaceutical Industry

Editor: Randall Wong

The major news in the pharmaceutical industry recently has been the tainted Heparin active ingredient that was manufactured in China and formulated into various parenteral preparations. The adulterated product has led to hundreds of serious adverse reactions in patients and more than 50 deaths since late 2007. Those are astounding figures given the long and well known history of the drug and has put the entire Pharmaceutical industry on alert. The affected companies (primarily Baxter International) have had to recall all suspected products and halted manufacturing and distribution until the matter is resolved. The economic loss is in the tens and maybe hundred of millions of dollars. The suspected cause of all this is contamination of the crude Heparin API with a chemically similar compound to Heparin that is not detectable by routine analytical testing. The FDA has yet to determine if the contamination was inadvertent or malicious.

What this reinforces to all of us in the Pharmaceutical and Health related industries is that we must be ever diligent in our GMP's, such as:

- Supplier Qualification and Certification, including periodic on-site auditing of suppliers of critical materials and components
- Material Qualification (initial and periodic)
- Raw material testing and release (appropriate to assess the suitability of the material for use)

- Validated methods appropriate for the intended use
- Storage, warehousing and distribution controls – throughout the supply chain
- Change Control and notification of change (including prior approval)
- Revalidation and/or requalification
- Risk Assessment and Hazard Analysis
- CAPA

Unfortunately, even with strict adherence to these principles and controls, it would still probably not have prevented these events from occurring if it found to be due to the willful actions of individuals acting in a fraudulent or criminal manner.

Medical Device Industry

At a recent presentation on CAPA by Ms. Katherine Jacobitz, of the U.S. Food & Drug Administration, Supervisory Investigator, Los Angeles District, Ontario Post, she reported that she was in the process of hiring twenty new inspectors for this year.

Quality Topics

Looking for contributing editors for this feature.

LEAN

In the LEAN environment, the focus is on defect prevention; never produce anything that does not have value to the Customer. The role of the Quality professional is to provide leadership and support in quality planning, monitoring, training, applying statistics and problem solving. Further more, the quality professional must take the lead, guiding the integration of quality with all functions in the organization and assisting management in the systematic review of all aspects of the business.

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

Remember there are resources to help members and students with scholarships and Stipends. Here are a few.

<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>

The Statistics division does have a scholarship for Masters level -

<http://www.asqstatdiv.org/awards.html>

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