

# Gabriel's Horn

January, 2008

The official newsletter of the San Gabriel Valley section  
of the American Society for Quality  
[www.asq702.org](http://www.asq702.org)

## **Message from the Chairman**

Happy and prosperous New Year to all ASQ members,  
I am very happy to announce the revival of the Gabriel Horn, the voice of the ASQ 702, published from our section. It is only coincidental that it comes at the start of the year 2008.

The section has made good strides in the last few months. To augment the recent progress the board members and with help from senior section members we wish to provide the member services that were lacking for past few years. Special mention must be made of contribution from Larry Phelan and Akhilesh Gulati who are instrumental in the revival of the newsletter.

A section is as good as its member's participation and support. To this end, I am inviting all section members to take some active role in the section and support section activities. We need your support to take this section to new heights and shine as a star in worldwide ASQ organization. Please contact any board member and we will be happy to help you find a role suitable to your skills. You are invited to attend a board meeting and see for yourself how the board functions.

The main events of the year will be published ahead of time to allow our members to plan their schedules and attend the section meetings. We can boast of some excellent speakers in coming months.

We want to hear from you and meet your expectations.

It is my sincere hope that the newsletter meets your expectations.

C.G.Mistry  
Section 702 Chair

## **Announcements of Coming Programs and Activities**

This month's spotlight on one of the very necessary Chapter positions.

### Membership Chair

The Membership Chair is responsible for recruitment and retention efforts.

**Term** One year: July 1 to June 30

**Specific Duties and Responsibilities**

Work with leadership committee to set goals/metrics to support the management process as it relates to member recruitment and retention.

Communicate/report to the leadership committee activities performed, status of performance against goals/metric set, etc. for member recruitment and retention. Be the advocate for member value, satisfaction and loyalty.

Work with the leadership committee to obtain necessary information regarding member demographics and expectations to recommend appropriate programs and services.

Download membership information monthly, or request data from appropriate volunteer.

Develop and implement, or maintain, welcome program for communicating with new members and introducing them to programs and services.

Ensure that all members are being communicated to regularly and in accordance with their preferences.

Develop and implement, or maintain, program for following up with unpaid members to encourage them to renew their ASQ membership and to continue accessing programs and services.

Develop and implement, or maintain, a recruitment program. Promote participation in the Society member-get-a-member program (Each One Reach One).

Attend leadership committee meetings and general membership meetings.

Uphold Society Bylaws, and Policies and Procedures.

**Qualifications**

Must be an ASQ member in good standing.

Preferably will have served as a committee chair or other position within the member unit.

Knowledge and experience in market research and promotions is helpful.

Preferably will have strong written and verbal communication skills.

**Time Commitment**

Approximately 3 hours per month (outside of executive committee meeting minutes).

**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](mailto:DickGouldCSP@aol.com)) or Dennis ([dennis@auditguy.net](mailto:dennis@auditguy.net)).  
Classes are limited to 30 participants and pre-registration is required.

Chapter 702 \*\*\* 2008 Meeting Calendar \*\*\*

January 7 executive board meeting  
January 16 meeting  
    Joint meeting of Chapter and Biomedical Discussion Group  
    LEAN/Six Sigma speaker: Larry Bartkus  
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  
    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 of Chapter and 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 Chapter 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 Chapter and Biomedical Discussion Group  
    Program to be announced

## **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.

### **Looking for a few good members to be editors of sections of this chapter newsletter.**

It is a big cold world out there, and we all look to our chapter to be a source of information and knowledge to help better prepare us to do our jobs. The social contact that we get by being a member is secondary.

Therefore the content of this newsletter needs to be information relevant to our industries and information that assists us with our personal improvement efforts. I need to hear from the membership on which industries should be covered in this newsletter. The ones in this edition are just my suggestion and if I don't hear from you the members I will not know which ones to drop and which ones to include.

Also, I am looking for members to become the editors of these sections. You do not have to be a subject matter expert if you have a true passion for the industry or topic you will do GREAT. What we are looking for is people to supply information to people.

## **Industry News**

### Service Industry

Looking for an editor for this section

### Food Industry

Looking for an editor for this section.

### **HHS Unveils Plan to Strengthen, Update Food Safety Efforts**

The plan calls for enhancing FDA's information systems related to both domestic and imported foods to better respond to food safety threats and communicate during an emergency.

To read the entire press release, go to:

<http://www.hhs.gov/news/press/2007/pres/11/pr20071106a.html>

### **Trader Joe's cuts Chinese Imports**

Due to rising consumer concerns about the safety of food imported from China, the U.S. Grocery store chain Trader Joe's has discontinued single-

ingredient food products imported from China. The retailer will continue to sell food products containing ingredients from China. The decision to discontinue single-ingredient Chinese products was due to consumer concerns that Chinese food quality and organic food standards are not adequate. Based in Monrovia, California, Trader Joes's is owned by German investors that also own the Aldi food chain. Numerous food safety issues, including melamine in pet food and antibiotic drug residues in fish, have been linked to China during the past year. Despite the new policy, Trader Joe's issued a statement to express confidence that "all of our products from China meet the same high quality standards that we set for all of our products."

Reference: Business Brief from Siliker, Inc.

### IT/Software Industry a coming attraction

Editor: Kandy Senthilmaran

### Pharmaceutical Industry

Looking for an editor for this section.

#### **FDA – Guidance for Industry: Smallpox (Variola) Infection: Developing Drugs for Treatment and Prevention**

The guidance focuses mainly on drugs that are expected to act by inhibiting vaiola virus replication: however, sponsors of drugs proposed to act against smallpox by other mechanisms are encouraged to consult this guidance for relevant content, as well as to discuss questions and proposals directly with the appropriate review division at the Food and Drug Administration (FDA).

To review this guidance, go to:

<http://www.fda.gov/cder/guidance/7423dft.html>

### Medical Device Industry

#### **Judge denies Shelhigh's bid to modify consent order**

A federal judge has denied the bid of Union, N.J.-based device maker Shelhigh to rewrite the terms of a voluntary-consent decree it signed with the FDA after the agency found problems in its manufacturing processes. The company asked for the release of its inventory of medical devices for export in Europe and to contest the fines against the company's founders for noncompliance. [The Star-Ledger \(Newark, N.J.\)](#) (1/11)

#### **Japan's Pharmaceutical Affairs Law (PAL) on Medical Devices**

All medical products must be registered with the Japanese Ministry of Health, Labor, and Welfare (MHLW), Japan's equivalent to the FDA. Products grandfathered in prior to 2005 must comply with the revised

PAL law when their existing regulatory approval expires or when they make a significant change to a product.

The Japanese government requires each foreign device manufacturer to maintain a physical presence in Japan. Each foreign manufacturer must appoint a marketing authorization holder (MAH) this can be a subsidiary/sales office or through the use of a representative in Japan. Also, foreign manufacturers of all classes of medical devices are required to obtain manufacturing accreditation for their manufacturing facilities, and after April, 2007, had to comply with ISO 13485 2003 and some additional requirements.

Japan divides medical devices by risk into four classifications and just who can certify the product conformance is dependent on this classification. Class 1 (Extremely low) are self-declared; Class 2 (Low) can be by designated third parties; Class 3 & 4 require ministry approval. More information on the Japanese PAL and other foreign government requirements can be obtained from the U.S. International Trade Commission's publications such as <http://hotdocs.usitc.gov/docs/pubs/332/pub3909.pdf>

## Quality Topics

Looking for contributing editors for this section

### ATTRIBUTE GAGE R&R

In many industries, cosmetic inspection is a necessary step in the process. However, cosmetic inspection is subjective and based on the inspector's perception. To remove the subjectivity, cosmetic standards are implemented that clearly demonstrate the defects. An important question remains - how do we calibrate the operators and establish if the inspection is reliable? The answer to this question lies in a statistical tool I came across known as Attribute Gage R&R.

Gage R&R is a tool used typically with variable data measurement systems to calculate the repeatability and reproducibility of measurement systems. Repeatability means that the same operator, measuring the same thing, using the same gage, should get the same reading every time. Reproducibility means that different operators, measuring the same thing, using the same gage, should get the same reading every time. Typically an experiment is set up where two or more operators measure a certain number of parts multiple times. Analysis is performed based on ANOVA techniques to compute the percent repeatability and reproducibility in relation to the total measurement variation.

A variant of this tool can be used to analyze a measurement system that gives attribute results. For example, a cosmetic inspection for injected molded

parts for inclusions may result in parts being accepted or rejected. A group of ten parts, five acceptable and five with cosmetic defects, are randomly distributed between two inspectors. The parts are uniquely identified. The inspector inspects each part independently and records the part number and the results as “Accept or Reject”.

Minitab® Release 14 offers two methods for performing this analysis: Attribute Agreement Analysis and Attribute Gage R&R. I have used the former and found it to be user friendly. The Attribute Agreement Analysis gives you a Kendal Coefficient of Concordance and the Attribute Gage R&R gives you a statistical measure of bias.

With both these techniques, an assessment of agreement between two operators performing attribute inspection can be made. Furthermore, if it is found that agreement is not acceptable, corrective action such as retraining or improving the cosmetic standards can be undertaken. The correct use of this statistical tool can help us improve processes and ensure that reliable and safe products are released to our end users.

*Anil Khakhria – CQE, MS.Chemistry  
Lead Quality Engineer  
STAAR Surgical Company*

References:

[www.minitab.com/support](http://www.minitab.com/support)  
[europe.isixsigma.com/library/content/c070516b.asp](http://europe.isixsigma.com/library/content/c070516b.asp)

LEAN

Add to your info sources.

The LEAN Enterprise Institute, a non profit organization  
It was founded by Jim Womack, who is one of the primary people who brought the Toyota Manufacturing Process to the United States

[www.lean.org](http://www.lean.org)

### **Networking for Quality Professionals**

ASQ Orange Chapter [www.asqorangeempire.org](http://www.asqorangeempire.org)  
ASQ Los Angeles Chapter [www.asqla.org](http://www.asqla.org)  
ASQ Inland Empire Chapter [www.asq711.org](http://www.asq711.org)  
ASQ Temecula Valley Chapter [www.asqtemecula.org](http://www.asqtemecula.org)  
ASQ San Fernando Valley Chapter [www.asqsfv.org](http://www.asqsfv.org)

## **Educational and Professional Developments**

Personal Improvement Plan for 2008: At each ASQ chapter meeting, introduce yourself to another chapter member. Each of you have already demonstrated that you a common interest, Quality. Now find out what industry they work in and what they do in Quality. Exchange eMail addresses and/or business cards.

**ASQ Weekly — a member benefit from the American Society for Quality 11-9-07**

### **ASQ Membership Is Valued at \$10,000**

What dollar value do ASQ members place on their benefits? According to focus groups conducted at the ASQ World Conference on Quality and Improvement – about \$10,000. The focus groups have been conducted since 2005 by Rigsbee Research, which conducted two sessions during each of the conferences. Participants were given a list of ASQ benefits (which could include products or services) and were asked to place a dollar value on each of the items. Over the course of three years, the participating members said they received an average of more than \$10,000 from their membership benefits. The top ASQ items in terms of member value are:

1. Recognized Certification \$2,583
2. Networking \$1,183
3. Training \$1,058
4. Sections \$1,042
5. Opportunities for Involvement and Leadership \$860
6. Credibility With Customers \$600
7. Divisions and Forums \$46

Thank you to everyone who came through on such short notice to furnish material for 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