



Gabriel's Horn

August , 2008

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

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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 Chair

Dear ASQ San Gabriel Valley Members,

With the new section board in place, we spent the last month in collaborating for development of the Quality Management Plan (QMP) for our section. Please refer to our finalized QMP plan in our newsletter. We would like to get your inputs, if any on enhancing the QMP plan. Also, we seek your participation and contribution to the section in successfully achieving our QMP.

I am very pleased to share with all of you that we have all the plans in place for the Quality Day (Joint event with ASQ LA, our section and California State University, Dominguez Hills) to commemorate ASQ's Quality Month and very soon everyone would get the invitation to attend the Quality. Trust me, this time; we are getting well recognized speakers in the industry to speak for us in the Quality Day. I am sure everyone will be thrilled to attend the Quality. It's October 11, 2008, please mark your calendars.

As announced during our last month meeting, the section will be sponsoring two winners (one every month for August and September) of the lucky dip at the end of the section meeting.

With the tremendous response we got the Minitab training we did this April, we are encouraged to have more special programs as a real value to our section members. We are in the planning process for having a 4 hours session in September on "How to use Microsoft Project Plan" at the basic and intermediate level. As quality professionals, we will be using the Microsoft Project Plan to our plan our activities or the programs for which we are assuring quality. This is a must to have skill for a quality professional. So do not miss out on this.

We are also planning for a section membership survey, to reach out all of our 400 or so members for understanding their real needs from our section. This will tremendously help our section in really focusing on delivering definite value to our members. Please make sure that you provide your responses to the survey without fail.

As always, we welcome new volunteers to take up responsibilities in administering our section duties.

Please feel free to reach out to me anytime, with bouquets or brickbats at Kanthassamy@hotmail.com / 517-290-6663

Cheers,
Kandy Senthilmaran

ASQ NEWS

In order to receive announcements and communications distributed by E-mail, you must keep your E-mail address at ASQ Headquarters up to date.

Here is how to update your E-mail address:

- Go to www.asq.org
- Enter your member number and password in the “Log in Now” section
- Select the “Manage Your Membership” blue box in the upper right-hand corner of the page.
- Update your E-mail address under “Change Contact Information”
- If you need additional help, E-Mail ASQ Customer Care at help@asq.org or call 800-248-1946 (U.S. and Canada only)

Announcements of Coming Programs and Activities

QUALITY DAY October 11th

Microsoft Project Workshop

Half-day Saturday workshop in September. Details coming

August Program -

The A to Z of CAPA and Common Pitfalls to Avoid

When do you initiate a CAPA?

How do you review triggers and determine trends?

What constitutes good documentation?

How to do a root cause analysis?

Risk management integrated into CAPA?

How to write a good effectiveness check?

Review and approval cycles?

Cross site review?

Training requirements and training programs?

Preventive versus Corrective actions.

The presentation will walk through the creation of a CAPA and highlight some of the common pitfalls and how to avoid them! It will discuss some key good documentation practices based upon practical experience in a large medical device company.

Learning Objectives:

- CAPA from A to Z and its common pitfalls.
- What are some of the common questions asked by auditors?
- The advantages and challenges of a global system and areas of caution when going electronic.

The presenter and discussion leader will be Bernadette Low. Bernadette has been with Abbott (formerly Guidant) for over 16 years initially at a pilot facility in the UK and latterly at the Temecula, CA plant. She has held a variety of management positions, including Complaint Handling, Regulatory Affairs, Supplier Development and Quality Systems Improvement. Most recently she led a cross divisional team introducing a new CAPA process and electronic tracking system across Abbott Vascular. This was successfully rolled out to multiple sites in 2007. She is currently responsible for the CAPA department-monitoring CAPA timeliness, trends and assisting owners with their investigations-and a Quality Systems Group working on aligning to one Quality system across the division.

Prior to joining Abbott, she worked for the Department of Health in the UK as a technical expert. She audited medical device manufacturers all over the world for compliance to UK requirements, with particular emphasis on sterilization and hygiene.

Bernadette has a Bachelors degree in Microbiology and is RAC certified both for EU and US.

**July Program –
Value Stream Mapping to Add Value and Eliminate Muda**

Larry Phelan presented the basic components of value stream mapping. He showed examples of its application in the LEAN process. The presenter considers value stream mapping to be one of the eloquent tools and a must to be included in every Quality professional’s tool kit. Value stream mapping is simple, it achieves what it is suppose to do and it is self-documenting so that others at a later date can use the document and know exactly what the author meant without having any additional input on the process.

ASQ Certification

2008 ASQ Certification Schedule

<u>Certification</u>	<u>Application Deadline</u>	<u>Exam Date</u>
Quality Engineer (CQE)	Oct. 10, 2008	Dec. 6, 2008
Quality Auditor (CQA)	Oct. 10, 2008	Dec. 6, 2008
Six Sigma Green Belt (SSGB)	Oct. 10, 2008	Dec. 6, 2008
Software Quality Engineer (CSQE)	Oct. 10, 2008	Dec. 6, 2008
Quality Improvement Associate (CQIA)	Oct. 10, 2008	Dec. 6, 2008
Calibration Technician (CCT)	Oct. 10, 2008	Dec. 6, 2008
Quality Process Analysis (CQPA)	Oct. 10, 2008	Dec. 6, 2008
Six Sigma Black Belt (SSBB)	Aug. 22, 2008	Oct. 18, 2008
Manager of Quality/Organizational Excellence (CMQ/OE)	Aug. 22, 2008	Oct. 18, 2008
Quality Inspector (CQI)	Aug. 22, 2008	Oct. 18, 2008
Quality Technician (CQT)	Aug. 22, 2008	Oct. 18, 2008
Biomedical Auditor (CBD)	Aug. 22, 2008	Oct. 18, 2008

Reliability Engineer (CRE)
HACCP Auditor (CHA)

Aug. 22, 2008 Oct. 18, 2008
Aug. 22, 2008 Oct. 18, 2008

ASQ launched three new Web-based certification preparation programs to help you prepare for the ASQ Certified Quality Auditor, Certified Biomedical Auditor, or Certified HACCP Auditor exams by identifying your strengths as well as your additional areas of study. These programs provide enough questions for at least three completely unique exams. After answering each question, you will receive an explanation and the correct answer. Once you have completed the program, you will receive a graphical summary of your scores. For more information, please visit:

[Certified Quality Auditor Question Bank: CQA Certification Preparation](#)

[Certified Biomedical Auditor Question Bank: CBA Certification Preparation](#)

[Certified HACCP Auditor Question Bank: CHA Certification Preparation](#)

Other Section Activities

New Members

Section 702 would like to welcome the new members:

Linda M. Howe-Garriz
Jody L. Donaldson
Lina Cheung
Dianna L. Cooper
Brent A. Covan
Richard M. Pagano
Helen Reynoso
Gregory E. Singleton

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.

August 4 executive board meeting – Quality Management Plan
August 20 meeting
 Joint meeting with Biomedical Discussion Group
 A to Z on CAPA
 Speaker: Bernadette Low
August 25 executive board meeting (rescheduled because of holiday)
September ?? Workshop ½ day
 Microsoft Project
 Speaker: tbd
September 17 meeting
 How to setup a Center of Excellence
 Speaker: Sara J. Mayo
October 11 Quality Day joint effort with L.A. Chapter
 Cal State Dominguez Hills
 Organizational Excellence
October 15 meeting
 Joint meeting with Biomedical Discussion Group
 Root Cause Analysis
 Speaker: Larry Bartkus
November 3 executive board meeting
November 12 (**rescheduled**)
 Joint meeting with Food, Drug and Cosmetic Division
 Program to be announced
 To be held at Golden State Foods
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.

**Recertification Units (RU's) are
awarded for attending Section Presentations**

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

Business Plan for Section: **San Gabriel Valley / Section 0702**

as of 08/06/2008

#	Objective	Activity Title	Activity Description	Activity Date(s)	Measure	Goal	Contact+	Status*	% of Goal Achieved^	Notes
1	Increase member value	Section meetings	Conduct regular meetings	2007-2008	Sign-in list	Minimum 9 meetings	Jean Flores	O	100	
2	Increase member retention	Recognition of new members	Publicly recognize new members attending meetings	2007-2008	Introduce and welcome new members attending monthly meetings	All eligible members	CG Mistry/ Bennet Chin	O	100	
3	Increase new member participation	Welcome Gift for 1st time member attendees	Present thank you gift	2007-2008	Present new members with a gift at regular meetings	Have gifts on hand at each regular meeting	Jean Flores	O	100	Not to include joint meetings with Biomedical Division.
4	Communication to members	Timely communication	Notice of section meetings	2007-2008	# of days between posting invitation and meeting	Send at least one week before the meetings	Jean Flores	O	100	
5	Increase Board Participation	Board member drive	Recruit new members to participate on Board and cross train for next years required positions	2007-2008	Confirm Board members for 08-09 year and cross train as needed	by June 30, 2008	CG Mistry	O	100	Kandy - chair Nal - Treasurer Jean- Secretary CG-Audit Dwayne - Nominating
6	Communication to members	Implement communication plan	Publish business plan (SMP)/status/results	2007-2008	Updated SMP plan presented at member meetings or Board meetings	Publish quarterly (Jan, April, July)	Jean Flores	O	68	Jan - Complete April - incomplete July - complete
7	Communication to board members	Implement communication plan	Publish meeting attendance and satisfaction survey results	2007-2008	Survey result report	Provide Survey Report to E-Board electronically monthly	Bennett Chin/Team	O	91	10/11
8	Communication to members	Update website	Update New Officers List, FAQ page and Contact Page by November 15th	August - November 15, 2007	Website	Update by Nov. 15th	Stephen Soukup/Webmaster	O	100	
9	Community Outreach	Public relations	Contact at least 1 of our local colleges and provide ASQ pamphlets and monthly flyer/invitation for posting	2007-2008	Were pamphlets and monthly invite provided to contact?	Provide pamphlets and monthly invites by November 30, 2007	CG Mistry and Larry	O	80	

* This can be used for tracking progress. A common legend to use:

- A (ahead of schedule)
- B (behind schedule)
- O (on schedule)
- C (completed)
- H (on hold)
- D (dropped)

^ These columns must be filled in when plan is submitted for the Total Quality Award.

+ Who is responsible for this activity?

10	Recognition of members	Recognition of Certification	Publicly recognize members who pass certification examinations or receive recertification	2007-2008	Website OR at Meetings	Public recognition of all eligible members	Kandy	O	100	
11	Recognition of volunteers	Recognition of involvement	Recognize services of the volunteers	by 07/31/2008	Presentation of awards	Recognize all volunteers	CG Mistry	O	100	
12	Recognition of members	Recognition of participation	Award members based on the attendance at section meetings	by 07/31/2008	Presentation of awards	Award all members attending more than 50% of the meetings	CG Mistry	D		Dropped 2/08

1039

Percent Achieved:

94

* This can be used for tracking progress. A common legend to use:

- A (ahead of schedule)
- B (behind schedule)
- O (on schedule)
- C (completed)
- H (on hold)
- D (dropped)

^ These columns must be filled in when plan is submitted for the Total Quality Award.

+ Who is responsible for this activity?

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.

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

Sarbanes – Oxley Controls in IT

Gone are the days when Sarbanes – Oxley compliance was optional, now it is mandatory to establish controls and to report the compliance for Sarbox. Organizations are setting up process controls specific to Sarbox requirements (see below the 11 titles which describes the requirements) and auditing the controls for compliance both by internal and external auditors. The audit results must be shared by the board of governance and any corrective and preventive actions on the open non compliance issues must be endorsed by the board. Sarbox is not only about financial controls for the procurement process but also touches upon all other internal process, example, in an IT environment, the requirements gathered and documented must be explicitly approved by the appropriate stakeholders before expending dollars to develop solution for it.

Here is more information on Sarbox, which is available in the public domain

The Sarbanes-Oxley Act of 2002 also known as the Public Company Accounting Reform and Investor Protection Act of 2002 and commonly called SOX or Sarbox; is a United States federal law enacted on July 30, 2002 in response to a number of major corporate and accounting scandals including those affecting Enron, Tyco International, Adelphia, Peregrine Systems and WorldCom.

Sarbanes-Oxley contains 11 titles that describe specific mandates and requirements for financial reporting. Each title consists of several sections, summarized below.

- 1) Public Company Accounting Oversight Board (PCAOB)

Title I consists of nine sections and establishes the Public Company Accounting Oversight Board, to provide independent oversight of public accounting firms

providing audit services ("auditors"). It also creates a central oversight board tasked with registering auditors, defining the specific processes and procedures for compliance audits, inspecting and policing conduct and quality control, and enforcing compliance with the specific mandates of SOX.

- 2) Auditor Independence

Title II consists of nine sections, establishes standards for external auditor independence, to limit conflicts of interest. It also addresses new auditor approval requirements, audit partner rotation policy, conflict of interest issues and auditor reporting requirements. Section 201 of this title restricts auditing companies from doing other kinds of business apart from auditing with the same clients.

- 3) Corporate Responsibility

Title III consists of eight sections and mandates that senior executives take individual responsibility for the accuracy and completeness of corporate financial reports. It defines the interaction of external auditors and corporate audit committees, and specifies the responsibility of corporate officers for the accuracy and validity of corporate financial reports. It enumerates specific limits on the behaviors of corporate officers and describes specific forfeitures of benefits and civil penalties for non-compliance. For example, Section 302 implies that the company board (Chief Executive Officer, Chief Financial Officer) should certify and approve the integrity of their company financial reports quarterly in order to establish accountability.

- 4) Enhanced Financial Disclosures

Title IV consists of nine sections. It describes enhanced reporting requirements for financial transactions, including off-balance-sheet transactions, pro-forma figures and stock transactions of corporate officers. It requires internal controls for assuring the accuracy of financial reports and disclosures, and mandates both audits and reports on those controls. It also requires timely reporting of material changes in financial condition and specific enhanced reviews by the SEC or its agents of corporate reports.

- 5) Analyst Conflicts of Interest

Title V consists of only one section, which includes measures designed to help restore investor confidence in the reporting of securities analysts. It defines the codes of conduct for securities analysts and requires disclosure of knowable conflicts of interest.

- 6) Commission Resources and Authority

Title VI consists of four sections and defines practices to restore investor confidence in securities analysts. It also defines the SEC's authority to censure or bar securities professionals from practice and defines conditions under which a person can be barred from practicing as a broker, adviser or dealer.

- 7) Studies and Reports

Title VII consists of five sections and are concerned with conducting research for enforcing actions against violations by the SEC registrants (companies) and auditors. Studies and reports include the effects of consolidation of public accounting firms, the role of credit rating agencies in the operation of securities markets, securities violations and enforcement actions, and whether investment banks assisted Enron, Global Crossing and others to manipulate earnings and obfuscate true financial conditions.

- 8) Corporate and Criminal Fraud Accountability

Title VIII consists of seven sections and it also referred to as the "*Corporate and Criminal Fraud Act of 2002*". It describes specific criminal penalties for fraud by manipulation, destruction or alteration of financial records or other interference with investigations, while providing certain protections for whistle-blowers.

- 9) White Collar Crime Penalty Enhancement

Title IX consists of two sections. This section is also called the "*White Collar Crime Penalty Enhancement Act of 2002*." This section increases the criminal penalties associated with white-collar crimes and conspiracies. It recommends stronger sentencing guidelines and specifically adds failure to certify corporate financial reports as a criminal offense.

- 10) Corporate Tax Returns

Title X consists of one section. Section 1001 states that the Chief Executive Officer should sign the company tax return.

- 11) Corporate Fraud Accountability

Title XI consists of seven sections. Section 1101 recommends a name for this title as "*Corporate Fraud Accountability Act of 2002*". It identifies corporate fraud and records tampering as criminal offenses and joins those offenses to specific penalties. It also revises sentencing guidelines and strengthens their penalties. This enables the SEC to temporarily freeze large or unusual payments.

Congressmen lead charge to overhaul FDA

Representative John Dingel and Senator Chuck Grassley are using the numerous crises to propose an overhaul of the FDA. Rep. Dingel calls the FDA's response to the recent salmonella outbreak a "disaster". The FDA regulates industries that account for nearly a quarter of the U.S. gross national product.

The lawmakers want to restructure the FDA to build in much more separation and independence between the agency and the industries that it regulates. The lawmakers want to give the agency the authority to recall drugs (which it can not do today); impose significant fines on companies for safety violations; to inspect generic-drug makers before approving their product; implement additional user fees for medical device manufactures to fund the inspection process; require the FDA to inspect both foreign and domestic manufacturing facilities every two years; extend the current FDA authority to detain unsafe medical devices discovered during the inspection process (currently the FDA has to obtain a court order to detain product); create a real-time registry of all drug and device facilities that product products that enter U.S. commerce; appoint a tough FDA commissioner completely independent from the industry; and, review television commercials for prescription drugs.

FDA officials have spent hundreds of hours testifying before Congress. Congressmen that have been friendly to the FDA in the past are keeping their distance because of the current controversies and the November elections.

It is this editor's opinion that all of us in industries regulated by the FDA can expect to see a FDA that takes a much tougher stance in the years to come. This will translate into additional or increased fees, more data and detail in filings with the FDA and more frequent and tougher inspections.

Quality Topic

Radical Thinking

by Akhilesh Gulati

Reengineer the Best!

Quality gurus, Michael Hammer and James Champy describe Business Process Reengineering (BPR) as the fundamental reconsideration and radical redesign of organizational processes to achieve drastic improvement in performance (e.g. cost, services, and speed). This approach differs from the more common Continuous Improvement model. BPR assumes that the current process is irrelevant, it does not work, or it is broken. The only way to "fix it" is to start over.

This clean slate approach enables process designers to disassociate themselves from the current process and focus on the new one. Practitioners are expected to ask themselves what the "to-be" environment should look like, what the customers want it to look like, how best-in-class companies do it, etc.

The premise is that the current process is broken so start from ground zero. However, the flaw with this methodology is that we are still trying to "fix" or tweak something that is broken. What if we took the opposite stance and tried to improve what is already at its best? It is not broken. It does not need fixing. It is the best it can be and cannot be changed in traditional ways - it needs to be reengineered! This is where one truly starts with a clean slate by getting away from previous methods, developing radical designs, and achieving a magnitude of improvement in performance. Trying to reengineer a broken process means still trying to "fix" it - kind of like the analogy of garbage going in and garbage coming out, but now its throughput is faster! Reengineering the best means taking a completely radical approach and heading in a completely different direction.

This is not a radical idea, although it might be in its application to business processes. Although not recognized as such, recent examples of BPR include some of the following:

Using the internet to buy/sell items via public auctions. This was certainly a radical change in the process of selling unwanted items (e.g. ebay).

Printing books or watching movies on demand. As this becomes the norm, holding books/movies in inventory at storefronts or in our homes on bookshelves, will no longer be necessary. Early adopters may well achieve drastic improvements in performance in cost, services, and speed.

Using self-checkout stands at stores is changing the way retail outlets are staffed. It is responding to the growing need to keep costs down, use technology, and in some cases, improve customer satisfaction. Most places that offer self-checkout lanes usually experience shorter checkout lines even though there are fewer checkout clerks.

Another growing phenomena are global networks made up of individual subject matter experts that provide services to organizations, yet operate as one. They share resources, expertise, and referrals with each other yet client management and infrastructure activities (e.g. project management, invoicing) are centralized. This seamless approach of multiple companies/individuals working together is becoming more attractive to client organizations who previously bought only from the larger and established organizations. These "reengineered" service providers are becoming preferred vendors as the purchased services are integrated, current in capabilities, yet cost effective (e.g. physical offices, office equipment, and support personnel are minimal).

In all of these cases, nothing was broken. But, the only way to improve it was to totally reengineer it. Although the term "reengineering" seems to have grown out of favor these days, it is still weaving its way around in a totally different way, usually in the context of "innovation". Even R&D functions have started thinking about reengineering their

thinking processes and are using the TRIZ methodology to help them reframe the way they approach product development.

While business process thinkers such as George Kaplan introduced us to the balanced scorecard concept, Eli Goldratt is challenging us to reengineer our thinking in terms of throughput accounting with a minimum of measures. This is business process reengineering at its best - not fixing what is perceived as broken, but radically changing the best to improve performance in cost, services, and speed.

If it ain't broken, if it is the best . . . reengineer it!

Akhilesh's website is <http://www.pivotmc.com> or you can E-mail him at gulati@pivotmc.com

Quality resources available to you

by Holly Duckworth

ASQ members have a wealth of information and resources at their finger tips through ASQ.org. This is such a rich website that it can be intimidating to navigate. I'd like to share a few of my favorite parts of this important website. Check it out...get the full value out of your membership!

From the ASQ.org home page...here are some of my favorites, going down the left side of the home page....

“My ASQ” – provides a quick link to my account information, and my sections and divisions. There are 27 divisions of interest in ASQ...full members are a member of both a section and a division. The section is your geographical area for networking, the division is your focused area of interest. Use “my ASQ” to connect to your division.

“Knowledge Center” – provides a great link, through “Hot Topics in Quality”, to the latest news pertinent to the quality professional. These are the critical issues in the world news important for members.

“Areas of Use” – provides a link to news and information for my interest, manufacturing. This part of the website helps to focus the information I need toward my interest in manufacturing. Your interest may be different, use this site to focus on those issues important to your focus.

“You Need” – puts all of the “things” I need in one place. My favorites here include, the bookstore (with incredible discounts for members...go here before using any other on-line bookstore for professional books), careers in quality for job offerings (even if you're not looking for a job this information may be of interest to help others looking, or to look for hiring trends), networking and events (my favorite here are the blogs), and training (look for training in your local area or web training).

There's so much information on the ASQ website that it can be hard to navigate. Use that left hand column from the homepage to get you to where you need to go.

Holly Duckworth is the ASQ Region 7, Director. She writes and supplies materials to the Sections in Region 7. She is just one of the many people supporting YOU the Quality professional.

Networking for Quality Professionals

Have you visited any of the other ASQ sections' websites? The local sections share many of their resources, etc. So if you see anything you are interested in, tell one of your board members. They will inquire to see if we can bring it to section 702.

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

The University of California at Irvine is offering a free on-line course on Medical Device development, production and regulations through its extension program. The course is titled, "Medical Quality Product Systems". The course is part of the university's OpenCourseWare initiative. It is a web-based resource at <http://ocw.uci.edu/courses>

Request from newsletter chair. I am compiling a list of all the Quality courses being held by any local junior college or any near by state college or university. So if you know of any such courses, please send information to me, so that I may include it in the newsletter to let others know of it.

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