



Gabriel's Horn

September, 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,

We are just a month away from the “Organizational Excellence through Quality” Day on Oct 11th. I am sure all of you would have received the invitation from our section. Our section has been working very closely with the ASQ LA section over the last six months in putting together this event. I am sure the Quality Day is loaded with sessions which will be of interest to all of us. It has Six Sigma, CAPA, Metrics and Dashboards, Software Quality, Pharmaceuticals, Aeronautics, Kaizen, Quality Management related sessions with popular speakers from the industry speaking to us. The early bird registration has been extended till Sept 15th and the seating is limited to first 80 registrants. Please register yourself soon.

(Message from the Chair, continued on page 2)

Microsoft Office Project 2007 Workshop

DATE: Saturday, September 27, 2008

TIME: 8:00 am to noon

LOCATION: Beckman Coulter, Brea

250 S. Kraemer Blvd., Brea, 92821

(located on the east side of Kraemer, between Imperial Hwy and Lambert Rd.)

This Project introductory session covers the skills and knowledge you will need to get started using Microsoft Office Project 2007. This includes exploring the Project 2007 user interface, as well as creating new Project 2007 project plans. This course covers creating Projects tasks, linking tasks, and setting up a Project calendar. It covers the skills and knowledge you will need to work with resources using Project 2007 project plans, and it will cover the skills and knowledge you will need to track progress of your project using Microsoft Office Project 2007. Finally, it will explain how to set up Project to generate reports.

This MPP workshop will cover the following:

- MS Project 2007 new Features and getting started
- Setting up new Project and Creating a Project Plan
- Creating, Editing and Managing Tasks
- Working with Resources
- Base lining and Tracking Progress of your Project
- Formatting and Printing Reports
- Demonstrating advanced features

(Workshop, continued on page 2)

(Workshop, continued from page 1)

About the Speaker

Aditya Chinni has 15 years of experience in Information Technology, and 4 years as a consultant specializing in project management training and consultancy. Aditya honed his PM skills at Sun Microsystems and CSC while successfully delivering multimillion E-commerce, ERP, CRM, and other IT projects.

After delivering many successful PMP Prep training sessions to various PMI Chapters and Tech giants like Sun, HP, Oracle, CSC; Aditya has started CertSchool, a training and consultancy business from scratch. Within a short span CertSchool achieved highly accredited "Registered Educational Provider" status from PMI, Inc.

<http://CertSchool.com> now provides well recognized, instructor-led, cost effective, public Project Management training.

Aditya is author of PMP Prep training material "Path to PMP" and successfully runs PM Tutorial web at <http://aditya369.com>.

Aditya graduated in Mathematics and received a Masters in Computers. He also received his Project Management Professional certification (PMP) from the Project Management Institute, Prince2 Project Management certification from Office of Government Commerce, UK, and prestigious Advanced Project/Portfolio Management certificate from the Stanford University.

To register for this workshop, please go to

<http://www.acteva.com/booking.cfm?bevaID=166569>

ASQ Members: \$40.00

Non-ASQ members: \$50.00

You must register in order to gain entry to Beckman Coulter.

Enter the Beckman facility through the Employee entrance, which faces Kraemer Blvd. (not the main lobby) in the south most 2-story building. There is plenty of open parking.

(Message from the Chair, continued from page 1)

As announced earlier our section will be sponsoring two lucky winners from our monthly meetings for the Quality Day. Last month a first timer to our section and an USC student – Vivek Thakkar was the first lucky winner and the other lucky winner will be selected this month, it maybe you!!

After the very successful Minitab training we did for our members in April, our section has put together another special event for September. It's the Microsoft Project Plan (MPP) Workshop on Sept 27th (Saturday) by Aditya Chinni, a PMI accredited training provider. It's a 4 hour workshop cum training for quality professional like us to learn MPP on how to use in our job. It's targeted at basic to intermediate level of proficiency. Please refer to the short write up by CG later in this newsletter on the MPP workshop. So do not miss out this opportunity. Invitations has been sent out all our members for this event, please register yourself, if you are interested. Please feel free to pass the invite to your friends and co-workers for them to benefit from this workshop.

I would like to thank Larry Phelan, our section newsletter chair for helping our section to get the Beckman Coulter facility at Brea for conducting the MPP workshop.

Also, we had to change our September session from our earlier planned session by Sara Mayo on "How to setup an operational center of excellence". Sara is still on maternity vacation and hence had to reschedule this session for a later time. Akhilesh Gulati our longtime section leader was magnanimous to do the session this month on an excellent topic –"Training Return on Investments". This is an area where many organizations are lacking or do not have visibility. I am sure with Akhilesh session, we can take our learning's back to our work and put to use to the benefit of our organization.

Thank you Larry and Akhilesh for your continued section support.

Another key thing which was discussed in our section's executive board meeting in August is to put more structure on a personalized coaching/mentoring for our members, like for taking certifications or career counseling etc. This is currently work in progress and I will keep sharing information with you on this on an ongoing basis.

Last but not the least; our section newsletter is undergoing a revolution. Yes, it's going to come to you in your emails. This is a quantum leap as a value adds to our members and increases the newsletter reach to all our registered section members from the current hard copy handover to the members who are attending our monthly meetings. Once again thanks to Larry Phelan for his outstanding effort in reinventing the newsletter and make it successful in such a short time frame. As our customers, let us know on what you think about the newsletter. Please be our critic, feel free to contact Larry directly at LePhelan@Beckman.com.

Please be in look out for our section survey soon. It will be immensely helpful for our section to understand the needs of our section members holistically to better cater to your needs.

As always, I am looking for your feedbacks on how well we are doing and where we can improve. Do not hesitate to reach me at Kanthassamy@hotmail.com / 517-290-6663

Note: - I will be in Bethesda, MD for the ASQ's World Congress for Software Quality during this month's section meeting date. I will meet you all in the next upcoming section events.

Cheers,

Kandy Senthilmaran

ASQ NEWS

Announcements of Coming Programs and Activities

QUALITY DAY October 11th

Organizational Excellence Through Quality

DATE: Saturday, October 11, 2008

TIME: 8:00 am 6:00 pm

LOCATION: Cal State Dominguez Hills

AGENDA:

8:00 - 8:30 am: Registration and

Continental Breakfast

- 9:00 - 10:00am: Keynote Speaker Ron Gill,
on Boeing's 2008 Journey to the International Team Excellence
Gold Award
- 10:00 - 10:15: Break
- 10:15 -12:15: Morning Sessions: Choose One
- Track 1: Six Sigma,
presented by Holly Duckworth
- Track 2: Corrective and Preventative
Action,
presented by Joe DeSimone
- Track 3: ICH/Pharmaceuticals,
presented by Bob Mehta
- 12:15 - 1:30: Lunch and networking
- 1:30 - 3:30: Afternoon Sessions: Choose one
- Track 4: Quality Tools and Statistics,
presented by Larry Bartkus
- Track 5: OPEN
- Track 6: Metric and Dashboards,
presented by Diane Kulisek
- 3:30 - 3:45: Break
- 3:45 - 4:45 : Late Sessions: Choose One
- Track 7: Software Quality,
presented by John Belbut
- Track 8: Kaizen Events,
presented by Glenn Rogers
- 4:45-5:00: Closing Remarks and Surveys
- 5:00 - 6:00 Exhibitor Interaction and networking

Topics subject to change and will be updated as sessions are finalized. For current list,
go to ASQ702.org
Choices selected during registration are for administrative use only. Final selection will
be made at the event.

1.0 RU will be awarded for attending this event
ASQ Members \$90.00 Non-members \$105.00

Sign up thru Acteva:

<http://acteva.com/booking.cfm?bevaId=164367>

September Program –

Training Return on Investment

presented by Akhilesh Gulati

Organizations are increasingly spending more and more resources on employee training. While it might be easy to quantify the benefits of specific job-skills training, at other times it can be rather difficult, especially for supervisory or management training. Yet, the more money an organization spends on training, the greater the concern that these highly skilled people will leave and take their knowledge somewhere else. This results in a loss of knowledge and a poor return on the organization's investment in training. However, research has shown that training actually reduces turnover and absenteeism. Employees will stay where they can grow and develop.

Given the tight economic times and the competitive need to increase the amount of employee training, it is imperative that we understand that training is an investment and not an expense and treat it as such.

Akhilesh Gulati has more than 18 years experience in operations and process improvement, innovation, design and quality management. He is a Six Sigma Master Black Belt and an experienced trainer/leader in Six Sigma, Lean enterprise, reengineering, benchmarking, kaizen, total quality and waste reduction. Akhilesh holds a M.B.A. fro UCLA, a B.S. in Naval Architecture and Marine Engineering and a M.S. in Marine Systems Management from the University of Michigan, Ann Arbor. He is a Senior Member of ASQ and past chair of Section 702.

August Program -

The A to Z of CAPA and Common Pitfalls to Avoid

Bernadette Low, from Abbott Vascular (formerly Guidant), took the audience through everything you ever wanted to know about CAPA. With her vast experience, she provided both the required information on the classical CAPA process and detailed real life experiences with actual opportunities encountered while running a large multi-site CAPA system.

Her presentation met the needs of both people just learning about CAPA and people routinely involved with the CAPA process.

Ms. Low pointed out that even after all these years, the CAPA system still receives the highest number of nonconformances in FDA audits. So most people that are involved with their company's CAPA system have questions, "How do other companies do this?" and "What are other companies experiencing?" I am sure that everyone appreciated the operational information she shared.

A topic of interest to a number of people in the audience was the kind of training that people in the CAPA process receive. She shared information on the various training and

retraining that is employed. She was candid on root-cause investigation training and good documentation practices.

She explained how Abbott has certified investigators that conduct the actual investigation on each event that is elevated to CAPA investigation.

Her insight on communication of incidents and corrections to everyone is an issue I think we all have. I am sure the guidance she gave on keeping management and upper management informed on the CAPA situation was appreciated by the audience.

Everyone that attended this presentation learned some thing and the discussions that took place during the question and answer portion of the meeting just added to this excellent presentation.

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)	Aug. 22, 2008	Oct. 18, 2008
HACCP Auditor (CHA)	Aug. 22, 2008	Oct. 18, 2008

For the latest information on dates and locations go to
www.asq.org/certification/dates.html

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](#)

Other Section Activities

New Members

Section 702 would like to welcome the new members:

- Lewie Casey
- Hanumantha Hari
- Marian Reyes
- Oscar Salazar
- Sorm Wiltshire

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.

Chapter 702 * 2008 Meeting Calendar *****
BOLD text indicates new/change

August 25 executive board meeting (rescheduled because of holiday)

September 17 meeting

Training Return on Investment

Speaker: Akhilesh Gulati

September 27 Microsoft Project 2007 Workshop ½ day

Speaker: Aditya Chinni

Workshop at Beckman Coulter, Brea (see announcement)

October 11 Quality Day joint effort with L.A. Chapter

Cal State Dominguez Hills

Organizational Excellence (see announcement in this Newsletter)

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 5 executive board meeting

January 21 meeting

Joint meeting of Section and Biomedical Discussion Group

Program to be announced

February 2 executive board meeting

February 18 meeting

March 2 executive board meeting

March 18 meeting

Program to be announced

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

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.

Pharmaceutical Industry

Editor: Randy Wong

Implementation of United States Pharmacopeia (USP) General Chapter <467> Residual Solvents, effective July 1, 2008

The revision of General Chapter USP <467> Residual Solvents (formerly titled "Organic Volatile Impurities) became effective July 1, 2008. The testing requirements outlined in USP<467> apply universally to all existing USP Monographs where it is assessed that the presence of residual solvents "may be likely" in the drug product, drug substance, or excipient. The Residual Solvents listed and classified in USP<467> are the same as that in ICH Q3C.

Notice of this planned revision was announced back in 2006 in the Pharmacopeia Forum and originally planned for official implementation by July 1, 2007, but was delayed until July 1, 2008 after comments were received from Industry regarding the time needed to implement and comply with the new requirements.

Additionally, the FDA (CDER) has recently issued a draft guidance document in August 2008, titled "Guidance for Industry – Residual Solvents in Drug Products Marketed in the United States".

In the guidance, FDA has stated:

Beginning July 1, 2008, FDA will require that U.S. marketed drug products with an official USP monograph meet the residual solvents requirements in the revised General Chapter <467>.

Drug Product manufacturers may demonstrate compliance with the requirements of USP <467> by:

1. Determine that no testing is required if it is known that solvents are not used or formed in the manufacturing process for the drug substance or excipient, nor is added or used in the formulation of drug product.
2. If solvents are used or known to be present in the drug product, drug substance, or excipients:
 - a. Obtain data for each drug substance and excipients used in the final drug product formulation and assess whether each component meets the acceptable concentration limit (ppm) for the class of residual solvent
 - b. Determine that the cumulative total of each residual solvent from all component sources in the drug product comply with the stated Permitted Daily Exposure (PDE) limit.
 - c. Or lastly, test the final drug product for compliance with applicable PDE limits

Use of USP methods for determination of Residual Solvents is specified; however, other suitably validated alternative methods are acceptable. Manufacturers should note that prior to using one of the USP methods, they should demonstrate and verify that the selected USP method is suitable for its intended use (e.g qualification).

More information is available at the USP and FDA websites.
www.usp.org/USPNF/notices
www.fda.gov/cder/guidance

IT/Software Industry

Editor: Kandy Senthilmaran

Make or Buy of IT solutions – How it will impact quality?

More and more business facing software organizations are moving towards acquiring vendor software products then developing software solutions themselves. This is a big shift from the traditional business model where we develop new software every year to cater to the business needs or problems. Many organizations are boldly making policy statements such as “Make only when we cannot buy”. We have to look at this transformation from two fronts; first, few years back there were not many vendor software products in the industry which can be leveraged for the business needs. We had few but we did not have the options and capabilities in market as we do today. The second one is that, almost all software organizations have outsourced the application development and hence do not have in-house technical capability to develop solution for multiple concurrent business needs or problems and then to engage with the outsourcing vendors to develop the software without impacting the product cycle times. This has created the needed to look at the market for existing solutions and this assisted with various vendor solution options, make it easier for the organizations to buy instead of make.

This change comes with the impact on the quality of the solutions. When a decision is made to buy a vendor solution, invariably it must be integrated with the existing software

infrastructure in the organization to provide seamless services to the business customers. But the vendor software products are driven by the market needs and not by the specific organization's business needs. Also a vendor software product might not meet all the requirements of a specific business need and hence additional functionalities must be built into what's being purchased. So when a buy decision is made the organization's software delivery process should be capable of handling the rigor of deploying the vendor software products. If you look at the high level it might seem that only the project management aspect is the only difference between a traditional software development methodology and vendor package implementation methodology and that's how many organizations are handling the vendor software package deployments. This is exactly where the quality of the solutions is let under the floodgate with a notion that quality of the solution delivered to the business is the quality of the vendor software package and hence there is no need for us to worry about it.

If you look at the following key aspects in which the quality of the overall solution might get impacted.

- Criteria for selecting vendor software products for making the make or buy decision
- Things need to be considered for integrating and institutionalizing the vendor software product within the organization
- Enhancements and customizations to be done on the vendor software product and how it will impact the existing functionalities of the vendor software product
- Compatibility with organization's existing architecture and infrastructure
- Testing the new functionalities developed on the top of the vendor software product without access to the source code of the vendor software product
- Deployment and maintenance of the solution on an ongoing basis
- Future releases and support

The hypothesis that traditional custom software development methodology with more focused project management is going to suffice for the deployment of vendor software packages will not be true anymore. This calls for a specialized vendor software package methodology with required process steps focusing on the points illustrated above. Unless we have a documents process steps to be used for executing vendor software package implementation projects, quality will be an unknown factor but for our customers it is a very critical factor. Many organizations are introducing vendor package implementation as a separate methodology along with the existing custom software methodologies. There are many industry best practices like Software Engineering Institute's ACQ (Acquisition) Framework and EPIC (Evolutionary Process for Integrating COTS-Based Systems) and also COBIT's A&I (Acquire and Implement) process control. Author (Kandy Senthilmaran) is Director – Process Center of Excellence with CSC Covansys Corp and have enabled many large software corporations in developing their

process methodologies for handling vendor software package implementations. If you have any questions or comments, he can be reached at KSenthilmara@CSC.Com/ 517-290-6663

Medical Device Industry

Editor: Larry Phelan

FDA Hires 1,317

The FDA has filled 1,317 positions; 770 are new jobs and 547 are posts that were vacant. The FDA's enforcement branch is getting 245 of the new people. The bulk of the new hires are going to the Center for Drug Evaluation and Research, the smallest number are going to Food Safety. FDA's commitment to Congress was to hire 1,300 people by September 30th. Historically after the agency staffs up, Congress has not supplied the funding necessary to keep the people.

Quality Topic

Radical Thinking

by Akhilesh Gulati

"How To . . .": Articulating the Business Problem!

"We have had a series of power outages even though we have central and local UPS (Uninterrupted Power Supply) systems. This disruption causes a loss of service to our customers. While we do not necessarily lose data, it is an irritant, and also results in loss of productivity. Perhaps we could attribute it to the lack of adequate UPS capacity. Alternatively, the independent UPS systems also contribute to the disruption, as we do not keep track of these stand-alone units. Neither do we perform any maintenance on these units; thus some of these units may be past their useful life. This is generally accepted practice but not what is called for in our procedures. We understand that this is reality and there will always be stand alone UPS units. We really need to solve the problem to avert future disasters. By the way, we don't even know how many of these units we have in use and although our policies do not allow the use of these stand-alone units, I have seen them in the IT department itself!"

When reading this statement, how easy is it to discern what problem is trying to be solved? This paragraph does not provide a clear problem statement; rather, it is background information that helps in understanding the importance/relevance of the issue. You have to dig through this commentary to find the real "problem".

Unfortunately, often these type of statements are presented as problem definitions; when, in actuality you have to sift through them to find the real issue!

A clear problem definition should transform the issue into a logical/sequential problem that can be investigated, analyzed and, hopefully, solved. It should provide clear & common direction. When used as the context for a team activity it should reflect their purpose for getting together as a team in the first place. It should help establish clarity in the scope of the problem that the team has been tasked to resolve.

There is an old adage, "Well begun is half done." It is true in problem solving as well, whether these are lean or six sigma type projects. Many times projects are jump started by either collecting data or implementing solutions - without necessarily coming to a common problem definition. Often, team members have their own definitions and assumptions, but don't realize they exist or what the differences are.

An easy way to remedy this common problem is to take the time upfront to develop the problem statement and clarify any associated terms, background information, or assumptions. Starting the team on the same playing field will eliminate confusion and subsequent rework later. When coming up with a problem statement, think "action orientation". Without answering the question, it provides direction for a group to follow. For the previous issue, here are a few examples of potential problem statements:

- How to reduce the number of UPS power failures

- How to reduce the use of stand-alone UPS systems and the related power outages

- How to prevent power outages in the IT department so as to reduce possible loss of data

Although they all come from the same information, each of these statements leads the problem solver(s) in a different direction. Each problem definition is concise and clearly states the expected end result of the problem solving effort. It is easy to understand and includes a statement of purpose with associated goals and leaves nothing to ambiguity. It does not include any of the "fluff" seen in the earlier problem description. Clear "deliverables" will drive the type and activities associated with data collection and analysis.

Having said this, it does not mean that background information is not important either. On the contrary, it is very important. It provides a potential problem solving team with enough general information to understand the topic and provide context of the issue and its associated rationale. In addition, background information should be included for all available data or any prior related initiatives (success or failure). It is important to understand the big picture and should be kept separate from the problem statement itself.

While organizations spend a lot of time solving problems, many do not take the time upfront to actually state the problem clearly and succinctly! Articulating the business problem? Remember 'How to?

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

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>

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