

Gabriel's Horn

Newsletter of San Gabriel Valley ASQ

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Message from the Chair

Dear ASQ San Gabriel Valley Members,

It's section election time. We will be having elections for elected positions (Chairman, Secretary and Treasurer) if we have more than one nomination. If you are interested in volunteering for these positions, please send your nomination to Dwane Nesser (d.nesser@upsilab.com) by March 15th. We will have the new section officer's installation by July'09. All the new section officers elect will go through one day ASQ Regional member leader training at Palm Springs on April, 18th.

March 5th and 6th, we had our ASQ's 21st Quality Management Conference at Irvine. Our section ably supported this conference with volunteers for moderating the conference presentations. I would like to thank the volunteers for taking time off from work and making the conference successful.

CG is leading our Quality Day' 2009 event in partnership with LA and SFV sections. The planning for this event is going on in full swing with volunteers from all the three sections working very actively to make this event a comparable like a conference in terms of quality of the speakers and presentation but at a very low registration price. We are targeting for 200 attendees for the quality day.

The JPL NASA tour is finally being scheduled in June' 09. I am having meeting with the APICS and PMI chapter chairs this week to discuss the modalities of registration and follow up presentation to be done by JPL insiders.

Keep an eye on our section website (www.asq702.org) for any new jobs which we are getting through our recruiting agency networks and from our section members. If you are looking for a job or having a job opportunity in your organization, send me an email. We have also formed "ASQ San Gabriel Valley (702)" group at www.linkedin.com. This will be a platform for networking and professionally connect with our peers. Once you are LinkedIn, search the groups, by our group name and send a request to join, I will approve it. We already have members joining this group.

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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

Cheers,
Kandy Senthilmara

ASQ News

World Conference on Quality and Improvement

May 18 - 20, 2009
Minneapolis, Minnesota

The Culture of Quality: Serving Customers, Organizations and Communities

Learn new and classic quality tools, methodologies and techniques.
Make an immediate impact on your organization's bottom line.
Attend in-depth breakout sessions.
Network with more than 2000 attendees and exhibitors.
Benchmark best practices in International Team Excellence Award Process.
Gain inspiration to take back to your workplace.

For more information go to <http://wcqi.asq.org>

Our own section chair, Kandy Senthilmaran, is a presenter at this year's conference.

Section News

Announcements of Coming Programs and Activities

Leadership Training

On April 18th, a Saturday, Region 7 is holding its annual Leadership Training in Palm Springs at the Palms Springs Hilton. You may want to consider attending this training if you currently hold a position in the section or are considering doing so in the future. If you are interested in attending, please contact Jean Flores [jeanflores1988@yahoo.com] or Kandy Senthilmaran [kanthassamy@hotmail.com] so that they can get you registered.

Minitab Workshop

On May 16th, a Saturday, the section is holding an all day workshop on Minitab. This is your chance to learn about Minitab to add to your "tools" or to improve your Minitab skills. More details coming.

Quality Day

Building on the success of last year's Quality Day, your Section is working with the Los Angeles and San Fernando Valley sections to make this year's event even better. The section's own CG Mistry is leading this year's Quality Day project. Quality Day is held in October of each year. We will keep you posted as the plans are developed.

?? Certification Refresher Courses ??

The section will set up Certification refresher courses if enough of the section members show an interest. All interested members should contact any of the board members telling them you are interested in a refresher course and which certification you are interested in.

Section 702 Received 2 Awards

ASQ recognizes sections for their achievements. In order to do this, each section must develop and submit an annual business plan, operating budget, meet all ASQ submission deadlines and show improvement on specific measures. The section must basically follow a PDCA cycle. We make a plan, we execute to the plan, we measure our performance to our plan, and we make improvements along the way and in the following year's plan.

For 2007-08, the San Gabriel Valley section received the Total Quality Award. This means we achieved 75% of the goals set forth in our annual business plan.

Also for 2007-08, the San Gabriel Valley section received the Silver Quality Excellence Award. To achieve this award, the section must first achieve an acceptable level of their Quality Plan and independently, the ASQ measures our members' satisfaction, retention and loyalty (this is the Email survey you receive directly from ASQ). A silver award means the Section achieved two of the three measures.

March Program

Using TRIZ Creative Problem Solving to Accelerate Quality Improvement

TRIZ is the systematic innovation methodology that helps you find creative solutions to all kinds of business and technical problems. Instead of waiting for inspiration to strike, you can be creative when YOU need to be creative. TRIZ is fully compatible with Six Sigma, Lean, and other quality improvement systems - they tell you what your problem is, and TRIZ helps you find the solution. TRIZ is analytic, data-based creativity, not brainstorming, and it WORKS. This will be an interactive, hands-on presentation, so you can experience a few of the TRIZ techniques for yourselves.

For more information see http://www.triz-journal.com/archives/what_is_triz/ "

ABOUT THE SPEAKER

Ellen Domb is the founder of the PQR Group and editor of The TRIZ Journal. TRIZ is Dr. Domb's 6th career: she has been a physics professor, an aerospace engineer, an engineering manager, a product line general manager, and a strategic planning/quality improvement consultant.

In 2005, she was named by Quality Digest Magazine as a leading voice for the future, citing the integration of TRIZ for innovation in quality improvement and quality planning systems. Ellen is a very active speaker for ASQ-in 2009 she has been with the chapter in Racine WI, represented San Diego as the keynote speaker for National Engineers Week, and did both the keynote and workshop for ASQ's AICE meeting in Iowa. ASQ-in 2009 she has been with the chapter in Racine WI, represented San Diego as the keynote speaker for National Engineers Week, and did both the keynote and workshop for ASQ's AICE meeting in Iowa.

February Workshop

Design of Experiments Workshop

Report by Jean Flores

The Section held a two Saturday Design of Experiments Workshop last month. This was my first exposure to DOE. Larry Bartkus, in his always humorous method of teaching, took us on a DOE journey starting from the basics, for us beginners. He started with a manual example on the white board to show how to set up a DOE using an everyday example of driving different cars on different routes to work to determine the largest affect on gas mileage. He then used Minitab as his application of choice to show similar examples. The second day, several attendees brought their computers and students were afforded the opportunity of downloading some case studies (of different DOE examples) and we walked thru them step by step too. We did a real life in-class example with paperclips and 's different "treatments" to analyze their performance.

This was my first exposure to DOE and I was under the impression previously that DOE's were really, really difficult, which I guess they could be for very complex cases. This workshop broke the ice and helped all of us to gain a better understanding of how DOE's are created manually first, so that we would better understand what is going on with DOE software (in particular Minitab)

Even very experienced DOE users that attended the class indicated that this workshop cleared up some of their questions and gave them a much better understanding DOE.

Well worth the cost and of very good value for all attendees.

February Program

FDA Inspections and Inspection Management

Presenter: Jim Kozick

For anyone in the Medical Device industry which is inspect by the U.S. FDA, this was a must attend meeting. Mr. Jim Kozick, a 29 year veteran of the FDA, shared many behind the scenes pieces of information on how inspectors are trained and techniques that inspectors use while conducting an audit.

Jim involved a great many in the audience while demonstrating actual inspection techniques. He subjected many of us to his inspection questioning and in a number of cases we gave the "deer in the head lights" response. He stressed that as our company's experts on FDA inspections, we need to know what an inspector is allowed to do as defined in the Investigations Operations Manual (IOM) available at http://www.fda.gov/ora/inspect_ref/iom/

Jim gave us insight into how by what an inspector sees and how people answer questions during the inspection the inspector determine if Management is actually supporting Quality and Regulatory Compliance.

But along with the FDA view, Jim pointed out a number of best practices that companies have implemented to handle actual inspections. Some of these are:

- Inspection Coordinator overseeing the whole process
- In addition to the audit room to have a Back Room to stage the documents and prepare the presenters
- To connect the audit room and the back room with an electronic link

Have dedicated individuals to take notes
Conduct daily internal debriefings to focus on issues/concerns of the day's inspection and prepare for the next day.

Through out the presentation Jim asked the audience for any question or topics they might want to specifically cover.

Without a doubt, everyone in attendance took home several items from Jim's lively presentation.

Election

The following is a list of positions with a brief description of the duties that are currently necessary to support the operation of Section 702. And there is always the need for more.

All terms are one fiscal year, July 1 to June 30.

The candidate must be a full member of the ASQ or higher to hold an office.

Chairs must complete the action items assigned to them and report the status of their function at Executive Board meetings. Chairs are expected to attend the regular Section meetings and the Executive Board meetings.

Arrangements Chair

Oversees arrangements for all regular meetings of the section and other special programs and conferences as assigned by the Section Executive Committee or other committee chairs

Audit Chair

(this position is filled by the past chair of the section)

The audit chair coordinates and manages the auditing function based on ASQ section requirements, as determined by Society policies and procedures.

Certification Chair

Coordinates and manages section activities related to the ASQ certification program.

Division Liaison

Promote Divisions and interest groups within the sections and coordinates access to division/interest group experts to bring topics of interest to the section.

Education Chair

Plans and implements educational programs for the Section such as conferences and/or special seminars.

Membership Chair

Responsible for section efforts to recruit and retain members, ensuring member value and satisfaction to promote section growth.

Newsletter Editor

Ensure that section members receive an informative newsletter on a consistent and timely basis by coordinating the content, publication and mailing of the Section newsletter in a manner consistent with the member's preferences for communication.

Nomination Chair

(this position is filled by the past chair of the section)

Identifies and nominates, with the nominating committee, qualified individuals for the elected section positions of chair, chair-elect and/or vice chair(s), secretary and treasurer.

Program Chair

Responsible for planning and implementing programs and activities of the Section.

Recertification Chair

Coordinates and manage section activities related to ASQ's recertification program. Help section members with recertification process.

New Members

Section 702 would like to welcome our new members:

Mr. Robert Gonzales

Mr. Richard Bastiansen of Pioneer Electronics Technology, Inc.

Ms. Fabiola Beltran of IMS, Limited

Mr. William Hatmaker of Alliance Dynamic Group

Mr. Carlos Nieves of Solrac Manufacturing

Please introduce yourself at the next meeting.

***** 2009 Meeting Calendar *****

month's Executive Board meeting are not sure he is holding up so well.

Kandy I am sure I speak for all our Section's members in saying Congratulations and wishing you and your family nothing but the best.

But Kandy, we do expect an article next month.

Medical Device Industry

FDA's 510(k) Premarket Review Process By Larry Phelan

In general, class I and II device types subject to Premarket review are required to obtain FDA clearance through the 510(k) process, and class III device types are required to obtain FDA through the more stringent PreMarket Approval (PMA) process. However, certain types of class III devices that were in commercial distribution in the United States before May 28, 1976 and those determined to be substantially equivalent to them may be cleared through the less stringent 510(k) process until FDA publishes regulations requiring them to go through the PMA process or reclassifies them to a lower class

Note, there a number of devices that are exempt from FDA premarket review. Manufactures of these devices are required to register with the FDA and provide a list of these devices that are exempted from premarket review.

The FDA reviews each 510(k) submission to see if the device is a new intended use. If it is, then it is deemed not substantially equivalent and must go through the PMA process. If the submission is not a new intended use, it is next examined for new technology. If it is new technology, it is reviewed to see if the new technological characteristics raise new types of safety or effectiveness questions. Devices that use new technology must submit sufficient performance data to support their safety and effectiveness claims. If the device passes this review, it is deemed substantially equivalent and can use the 510(k) process, if it does not pass this review, then it must use the PMA process.

The time it takes to complete a review of a device submission in the 510(k) process is generally faster than the PMA process. And the cost for reviewing submissions in the 510(k) process is substantially lower than the PMA submission process.

The Government Accountability Office (GAO), at the direction of the Congress conducted a review of the 510(k) process. They reviewed all submissions from 2003 through 2007. Their conclusion is, "The 510(k) process is a well-defined, science-driven method used by the FDA as part of a comprehensive regulatory framework to meet the needs of patients and the diversity of medical technology. This Premarket review process involves extensive consideration of specifications and performance testing information, including in many cases clinical data, before the agency determines whether a device can be made available for patients."

In establishing device classes in 1976, Congress envisioned that all class III devices would eventually be required to undergo Premarket review thorough the more stringent PMA process. This requires the manufacturer to provide evidence, which may include clinical data, providing reasonable assurance that the new device is safe and effective. However, certain preamendment class III device types may be reviewed through the 510(k) process until such time the FDA publishes regulations requiring them to go through the PMA process. In 1990 the Safe Medical Device Act direct the FDA to take action on the remaining preamendment class III device types by reclassifying

to a lower class or requiring them to remain in class III and go through the PMA process. But the GAO found 14 years later the FDA has not completed this effort. The GAO is concerned that a number of these class III devices include implantable devices, life sustaining devices or pose a significant risk to health, safety or welfare of a patient.

The GAO recommended to the Secretary of Health and Human Services to direct the FDA to expeditiously take steps to issue regulations for each class III device type currently allowed to enter the market through the 510(k) process. It is another case of insufficient resources. The full GAO report can be obtained at www.gao.gov and search on report GAO-09-190.

Quality Topic

Lets Discriminate - between Problems and Opportunities ! Radical Thinking ? By Akhilesh Gulati

You have quality problems, causing you to resort to excessive inspection, handling customer complaints re-running product, crediting services, etc. - all affecting your costs and bottom-line. It also creates longer lead times, not to mention disgruntled customers who might take their business elsewhere.

That is a problem that needs to be solved and quickly if you are to stay in business. Does it mean that you have an opportunity to improve quality and reduce cycle time? Absolutely! Does that mean problems and opportunities are the same? Not quite!

Many times these words (problems and opportunities) are used interchangeably. While using this terminology is a positive way of addressing 'problems', this substitution can be rather limiting and potentially stifle the 'opportunity' for improvement!

Lets start by looking at the Wikipedia definition of both terms:

Problem - A problem is an obstacle that makes it difficult to achieve a desired goal, objective or purpose. It refers to a situation, condition, or issue that is yet unresolved. In a broad sense, a problem exists when an individual becomes aware of a significant difference between what actually is and what is desired. In business and engineering, a problem is a difference between actual conditions and those that are required or desired. Often, the causes of a problem are not known, in which case root cause analysis is employed to find the causes and identify corrective actions. An optimization problem, on the other hand, is finding the best solution from all feasible solutions. A good example of this type of problem is the traveling salesperson problem that is based on calculating the most efficient route between many places."

Opportunity - An opportunity is defined as an appropriate or favorable time or occasion; a situation or condition favorable for attainment of a goal; a good position, chance, or prospect, as for a advancement or success. In the business world, it may be defined as an exploitable set of circumstances with uncertain outcome, requiring commitment of resources and involving exposure to risk.

People who would replace the 'problem' concept with 'opportunity' might agree with Joseph Sugarman who said, "Each problem has hidden in it an opportunity so powerful that it literally dwarfs the problem. Greatest success stories were created by people who recognized a problem and turned it into an opportunity," This statement clearly distinguishes between problem and

opportunity.

Many organizations are currently implementing lean strategies and streamlining their processes. Those that have 'leaned' their operations and implemented 'flow' to the hilt, have a 'six-sigma' culture, and are recognized as a world-class leader, do not have 'problems' in its processes. Does that mean they do not have any opportunities to exploit existing solutions?

In some cases, there are problems that do not lend themselves to cost-effective solutions; or are limited by technology or knowledge capabilities. But that does not prevent an organization from seeking alternatives that may alleviate the situation. Entrepreneurs are known for finding opportunities and creating needs where no problems existed.

There is nothing wrong with calling 'problems' 'opportunities,' positive feeling might be created and issues resolved. But, in the process of solving the problem, real opportunities might be missed. Most time is spent 'problem solving' (read 'firefighting') and while some of the associated solutions might create 'pockets of excellence' in the short term, real long term 'opportunities' could be overlooked or not considered.

Organizations need to first discern and then discriminate between problems and opportunities. A problem may be focused on an internal or an immediate issue, while an opportunity addresses those situations that are beyond the immediate, to the outside world and its application to create new products and enter new markets. For example, if we use fasteners that corrode, causing failure, we have a problem that needs to be solved. In the parlance described above, it would be presented as an opportunity to create a fastener that does not corrode. That truly is not an opportunity, simply a problem that needs to be solved in order to stay in business. An opportunity, on the other hand, would be to ask the question 'who else might want a fastener that doesn't corrode?' In this case we have identified an opportunity. Not only is the problem fixed, but a new might also get identified.

Problems happen and they need to be addressed; priority one is to stay in business. And while problems / fire-fighting take up a substantial amount of our time at work, it is important that we learn not only to recognize opportunities, but to take full advantage of them.

Either way, let's first learn to discern, then discriminate - between problems and opportunities!

Akhilesh may be contacted by E-Mail at gulati@pivotmc.com

Or visit his website at <http://www.pivotmc.com> for more information on services he can provide.

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

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

