



Gabriel's Horn

November, 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,

It's time to share with you all our section member survey results. The survey participation was encouraging. Totally 59 members took the survey. Please refer to the survey results in the newsletter.

We are directly using the topics our members wanted to setup our 2009 section program plan.

A key decision which has been taken during our 11/3 executive board meetings is to disintegrate the joint division meetings with our section. So in a month when a joint division meeting is planned, we will have two separate meetings. This will enable our section to cater to all our members with a regular section meeting as we usually have and the joint division meetings will happen on a different day.

This month's joint meeting with Food, Drug and Cosmetics division is the last event for our section before we take a break in December for holidays. We will reconvene again in Jan'09.

(Message from the Chair, continued on page 2)

ASQ NEWS

21st Annual Quality Management Conference March 5 thru 9 in Irvine, California

Results through People, Processes and Performance, offers many learning opportunities for attendees to participate in a variety of forms – pre and post conference workshops, presentations, keynote address and interactive sessions. Quality Management Division has partnered with the Software Division to provide several current “Hot Topics” relevant to quality managers and software professionals.

To be held at the Hyatt Regency in Irvine

For details and registration go to <http://www.asq-qm.org>

(Message from the Chair, continued from page 1)

Looking back at this year, we have so many highlights such as our quarterly special events, joint events with bio-medical and food, drug & cosmetics divisions, quality day, bringing back our section newsletter, increased member attendance at our monthly meetings to list a few.

I can promise that in 2009 our section will be able to exceed member expectations. We are already into intensive planning on the programs front. We are looking to expand our success in quality day by partnering with all our neighboring sections. Hopefully the quality day will fill the void of not having an annual ASQ conference in SoCal.

In these tough times of market downturn, it reinforces the needs for us to sharpen our skills and prepare ourselves to the rapid changing market needs. With this in mind, we are bringing advanced Design of Experiments (DOE) 2 day workshop and Minitab applications workshop.

For our monthly member meetings we are making every effort to bring in accomplished speakers to share their knowledge and experience. You should be able to see many new faces in the process.

We are also doing a Jet Propulsion Labs (JPL) NASA industrial tour. Tentatively it's scheduled for Feb'09. We are doing this tour in partnership with APICS and PMI chapters. Keep an eye out for this. Number of participants will be limited; you don't want to miss this out!

Our section newsletter is going to come to you. Yes, we are introducing e-newsletter. Our newsletters chair – Larry Phelan is doing a great job and he deserves our wholesome appreciation.

I wish all our members and their families a very happy thanksgiving and a happy new year. Safe holidays!

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 Senthilmaran

Announcements of Coming Programs and Activities

Six Sigma Discussion Group December 4, 2008

Section 702 with the Six Sigma Discussion Group will be holding an on-line session December 4, 2008.

Watch for the announcements.

Design of Experiments Workshop

A 2-day DOE workshop coming in January/February. This will be an all day (2 Saturdays) workshop. Day 1 will cover the basics of DOE, and Day 2 will delve into the more advanced DOE tools. The instructor will be Larry Bartkus. More details coming.

November Program –

Sampling for Release & Audits and for Validation/Verification in Food, Drug and Cosmetics An Industry Roundtable Discussion

Wednesday, November 12, 2008 5:30 - 8:30 pm

LOCATION:

Golden State Foods
640 South Sixth Avenue
City of Industry, CA 91746

Topic outlines: "Attributes Acceptance Sampling is not as boring as ANSI Z1.4 or ISO 2859 would have you think."

1. Cautions in the use of ANSI Z1.4 (e.g. AQL Indexing Values & Switching Required) Assumptions: Representative Samples, Small Sample of Large Lots and Inspection Success Rate.
2. Critical Points in the Behavior of Sampling Plans
3. How Sampling Plans Work to Protect Manufactures AND Customers
4. How to Justify Confidence Statements regarding the Quality of Processes and Products

Discussion Leader: John F. Haury Ph.D., CQE, CQM (ASQ certifications)

John Haury graduated from UCSD with high honors and earned a research-based Ph.D. from Harvard University (degrees in biology). He earned American Society for Quality certifications as a Quality Engineer and Quality Manager. He was the Total Quality Management Statistician at Ore-Ida Foods. As a company statistician and quality improvement consultant, John applied and taught Six Sigma methods. He was the company expert on statistics for continuous improvement of measurement systems, production processes and experimentation. For the last ten years, John worked for Amgen. Dr. Haury held positions of increasing responsibility including associate director of Six Sigma and quality engineering. He introduced a series of eight introductory-to-advanced problem solving and stats classes which became the basis for Amgen Improvement Methods and then Six Sigma.

John Haury is now a full time consultant and owner of www.Applied-Stats.com. His consulting practice specializes in sampling for lot acceptance and for validation / verification using confidence statements. His expertise includes sampling for improving measurement systems, sampling for process control (SPC) and data analysis for capability improvement (variation and error reduction). Finally, John is an expert in

design and analysis of experiments, the single most effective and efficient method for breakthrough improvements in quality, cost reduction and through-put (capacity).

This Roundtable Discussion will utilize the synergy of our well-versed Subject Matter Expert along with your Regional Industry Peers. Please submit your discussion questions on-line and help make this a valuable experience for everyone.

October Program –

Root Cause Analysis

If you have never attended a presentation by Larry Bartkus you have missed one of the joy's in life. An interesting note, Larry's presentation at the recent Quality Day held at Cal State Dominguez Hills was the most attended presentation of the day.

The topic of Larry's presentation to the section was Root Cause Analysis and this gave him the opportunity to teach us all the most Obnoxious tool in the Quality professional's tool box. I am sure that everyone in attendance is just looking for an opportunity to apply it.

Larry highly recommended that we all add the book "Root Cause Analysis - Simplified Tools and Techniques" by Anderson & Fagerhaug, available from the ASQ store, to our personal Quality libraries.

And while Larry walked us through the steps in dealing with a problem from the material in the book, the real learning was in his real-life cautions and stories at each of these steps. For instance, in his example that if the person who derived the specifications for a part is not involved in the analysis of the rejected part you are missing a whole piece of knowledge (how do you know the specifications aren't the problem?). Larry's casual presentation style helped him develop real interaction with the people in attendance (well it was suppose to be a discussion group).

And for those of you that did not attend Larry's presentation, the most Obnoxious tool is the five why's. Because by the time you use this to drive down to the real cause, you can really irritate people.

ASQ Certification

The following members of section 702 were recently **RECERTIFIED**:

Carol Blischke – CSQ
Chris Chen - CQE
Louie Farnacio – CQA & CSSBB
Stephen Sheng - CQE
Joan Strings – CQA

2008 ASQ Certification Schedule

<u>Certification</u>	<u>Application Deadline</u>	<u>Exam Date</u>
Quality Engineer (CQE)	Closed	Dec. 6, 2008
	Jan. 30, 2009	Mar. 7, 2009
	Apr. 17, 2009	Jun. 6, 2009
Quality Auditor (CQA)	Closed	Dec. 6, 2008
	Jan. 30, 2009	Mar. 7, 2009
	Apr. 17, 2009	Jun. 6, 2009
Six Sigma Green Belt (SSGB)	Closed	Dec. 6, 2008
	Jan. 23, 2009	Mar. 1, 2009
	Apr. 27, 2009	Jun. 6, 2009
Software Quality Engineer (CSQE)	Closed	Dec. 6, 2008
	Jan. 30, 2009	Mar. 7, 2009
	Apr. 17, 2009	Jun. 6, 2009
Quality Improvement Associate (CQIA)	Closed	Dec. 6, 2008
	Jan. 30, 2009	Mar. 7, 2009
	Apr. 16, 2009	Jun. 6, 2009
Calibration Technician (CCT)	Closed	Dec. 6, 2008
	Apr. 17, 2009	Jun. 6, 2009
	Closed	Dec. 6, 2008
Quality Process Analysis (CQPA)	Jan. 30, 2009	Mar. 2009
	Apr. 16, 2009	Jun. 6, 2009
	Jan. 16, 2009	Mar. 7, 2009
Six Sigma Black Belt (SSBB)	Aug. 21, 2009	Oct. 17, 2009
	Jan. 16, 2009	Mar. 7, 2009
	Jan. 16, 2009	Mar. 7, 2009
Manager of Quality/Organizational Excellence (CMQ/OE)	Aug. 21, 2009	Oct. 17, 2009
	Jan. 16, 2009	Mar. 7, 2009
	Jan. 16, 2009	Mar. 7, 2009
Quality Inspector (CQI)	Aug. 21, 2009	Oct. 17, 2009
	Jan. 16, 2009	Mar. 7, 2009
	Jan. 16, 2009	Mar. 7, 2009
Quality Technician (CQT)	Aug. 21, 2009	Oct. 17, 2009
	Jan. 16, 2009	Mar. 7, 2009
	Jan. 16, 2009	Mar. 7, 2009
Biomedical Auditor (CBD)	Aug. 21, 2009	Oct. 17, 2009
	Jan. 16, 2009	Mar. 7, 2009
	Jan. 16, 2009	Mar. 7, 2009
Reliability Engineer (CRE)	Aug. 21, 2009	Oct. 17, 2009
	Jan. 16, 2009	Mar. 7, 2009
	Jan. 16, 2009	Mar. 7, 2009
HACCP Auditor (CHA)	Aug. 21, 2009	Oct. 17, 2009
	Jan. 16, 2009	Mar. 7, 2009
	Jan. 16, 2009	Mar. 7, 2009
Pharmaceutical GMP Professional	Aug. 21, 2009	Oct. 17, 2009
	Apr. 17, 2009	Jun. 6, 2009

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

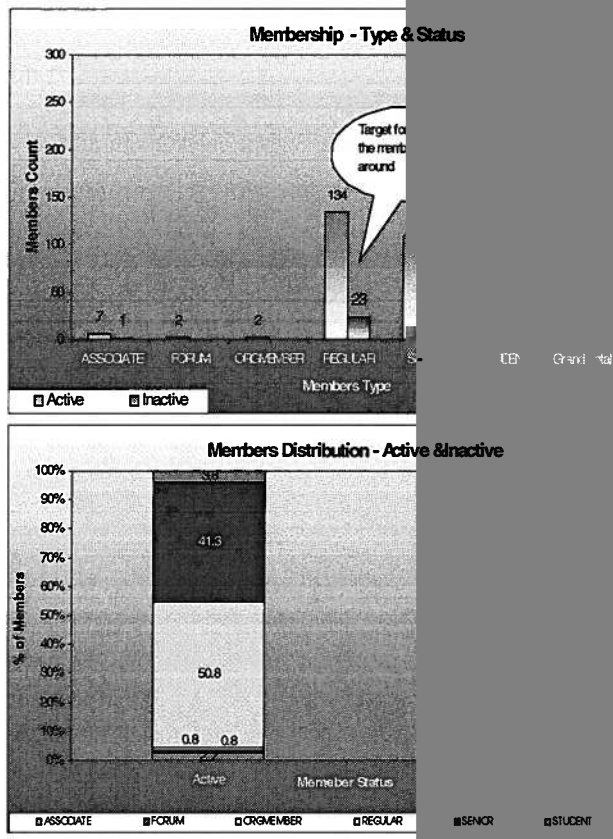
New Members

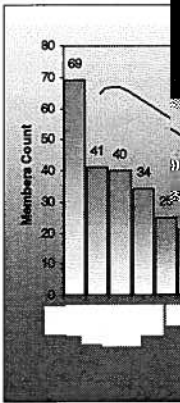
Section 702 would like to welcome the new members:

Juan Ramirez
Russell Glahn
Stell Herrera
Ravihandran Rathinam
Susan Stevens
Vivek Thakkar

Member Survey Results

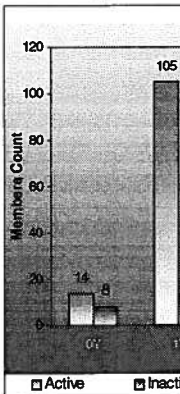
Here are the results from the recent member survey compiled by Ravi Rathinam.





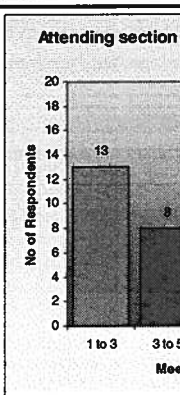
Membership - Indu Type

Target for Monthly Topic selection



Section Membership Association

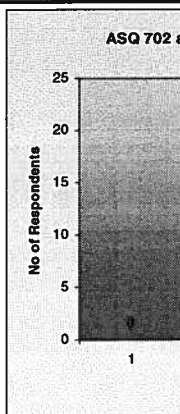
Target for improving the membership turn around



Attending section meeting in a year

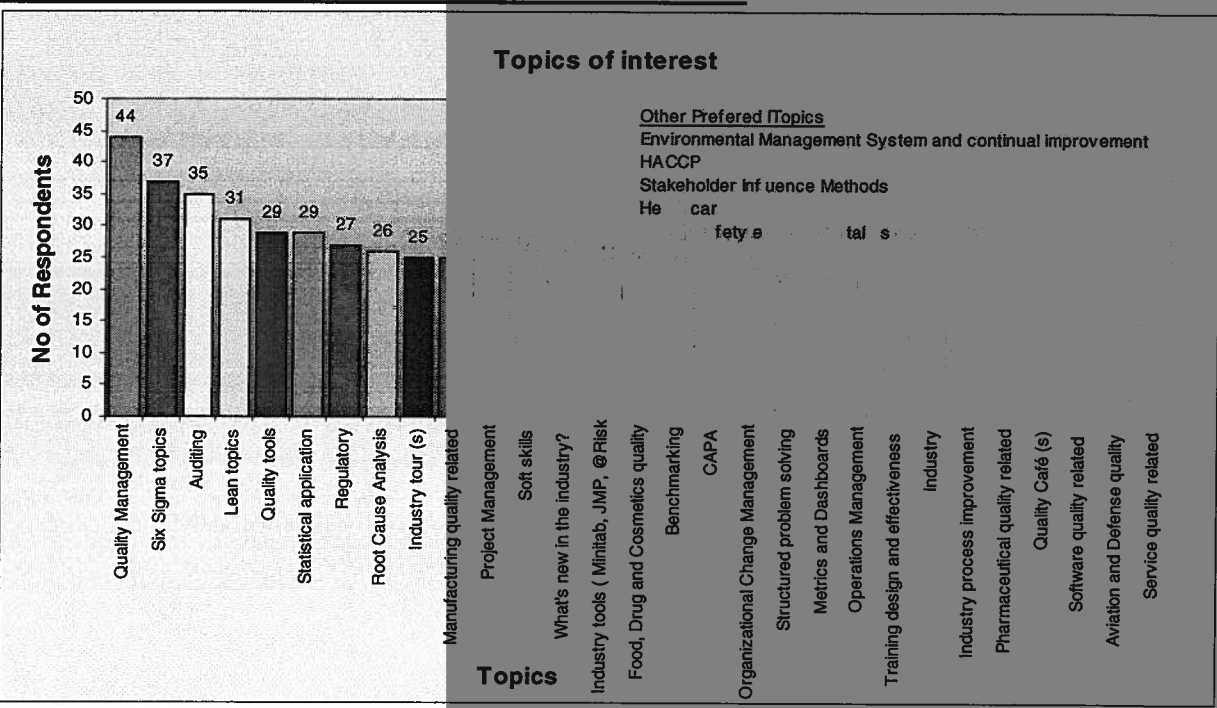
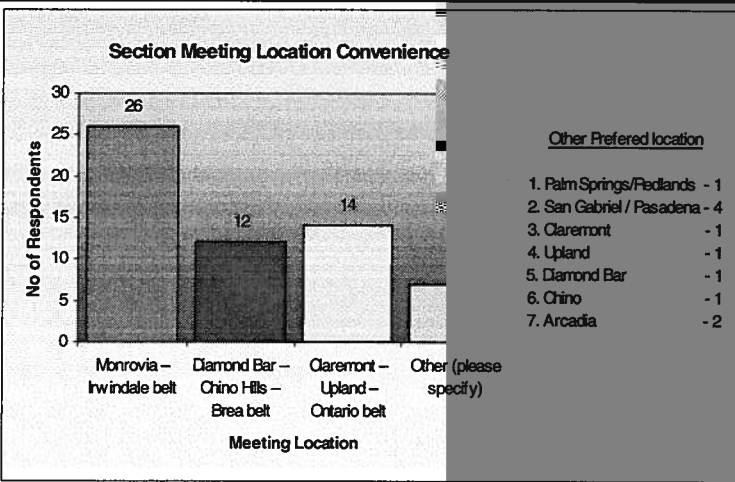
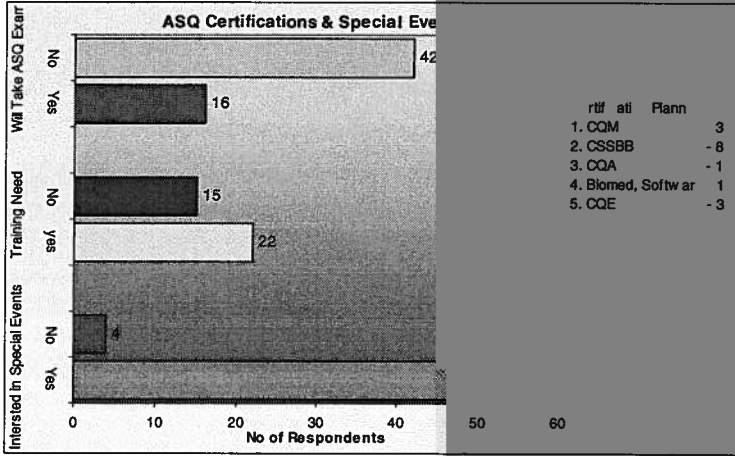
Reasons for not able to attend

1. Location compared to where I live in Indu
2. Traveling
3. Don't know meeting schedules, also busy work schedule due to SAP implementation preparation.
4. Subject
5. Off my feet because of surgery
6. I belong to another section
7. Wednesday nights are bad for me
8. Not a convenient location for me
9. extremely busy- also Wed. often not a good day
10. Busy with family commitments
11. Not enough notice to make daycare arrangements
12. Schedule conflicts
13. Evening commitments make attendance difficult
15. I have monthly health and safety meeting the same day as the ASQ meeting are set.
16. Location issue
17. Job requires alot from me
18. The meeting schedule
19. Start time is a bit early



ASQ 702 ability to meet network or skill enhancement needs

Rating Scale



Improving existing members attendance for the monthly meetings and special events

- **Address the suggestions and concerns from Survey**
- **Keep the monthly Topics to cover all the members group (At least one topic specific to the industry in a year, we can target at least 4 groups in 2009).**
- **All Topics shall be based on members interest**
- **At least 1 special event in a quarter**
- **Organizing Industrial tours every quarter**

Improving Membership through Existing members

- **Special discounts for members bringing in new members to the section. Free entry for a special events**
- **Continue the existing benefit of accumulating the \$ gained for introducing the members and using the cost for continuing membership, add a complementary quality book for them**

Improving Membership through Organization

- **Association with other chapters and groups. (Special discount for members from other professional bodies)**
- **Special discounts for sustaining members moving to the Regular membership**
- **Reach out to employers for sustaining membership**

Membership improvement through Advertisement

- **Career workshops for students**
- **ASQ Certification courses (Will enable continuing the existing membership and also bring new members)**

Chapter 702 * 2008 Meeting Calendar *****

BOLD text indicates new/change

November 12

Joint meeting with Food, Drug and Cosmetic Division
Sampling for Release & Audits and for Validation/Verification in
Food Drug and Cosmetics
Speaker: John F. Haury, Ph.C.
To be held at Golden State Foods

December no meeting

***May Your HOLIDAYS be FULL of JOY
and You have a HAPPY NEW YEAR***

2009

January 5 executive board meeting

January 21 meeting

Presentation: LEAN

Presenter: Tim Olson

January tbd Workshop - Design of Experiments (Day one of two)

Instructor: Larry Bartkus

Saturday 8:00 to ?

February tbd JPL Tour

Tour begins a 1:00 pm Note, tour limited for first 40 people

Section 702 is teaming up with PMI

February tbd Workshop - Design of Experiments (Day two of two)

Instructor: Larry Bartkus

Saturday 8:00 to ?

March 2 executive board meeting

March 18 meeting

Program to be announced

April 15 meeting

Program to be announced

Election of Section Officers and appointment of committee chairs

May 4 executive board 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, everyone is invited to attend.

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

Project Performance Metrics

What are project performance metrics?

The project performance metrics provides visibility into how well the projects are executed. It basically captures the key performance indicators for the quadruple constraints like Time, Cost, Quality and Customer Satisfaction. It does not mean that all the possible metrics and qualitative indicators should be collected and reported to measure project performance. I would like to bring in the customer perspective as I had written about in one of our earlier section newsletters on how to setup dashboards using a critical to quality (CTQ) process. We will do SIPOC first to establish process boundaries and the customers along with the inputs, outputs and the suppliers. Based on the services the customer needs are identified and the CTQ is using drive the quantifiable metrics to measure the customer needs.

Author (Kandy Senthilmaran) is Director – Process Center of Excellence with CSC Covansys Corp is an organizational change agent and had successfully managed change for deployment of new tools and systems in an IT organization. If you any questions or comments, he can be reached at KSenthilmara@CSC.Com/ 517-290-6663

Medical Device Industry

Editor: Larry Phelan

Human Factors

While the Quality System Regulation does not call out Human Factors by name, the FDA has interpreted several places in the regulation to mean human factors techniques are required. Ref. 820.30

(c) Design Input "... including the needs of the users..."

(f) Design Verification To carry out design verification, manufacturers should conduct human factors activities throughout the design program.

(g) Design Validation "...actual or simulate use conditions."

The FDA has issued 'Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management' guidance document, available from the FDA web site on the subject.

In analyzing product corrective actions reported to the agency, the FDA has become very concerned by the high number of these corrective actions where the cause is attributed to Use Error. The agency believes as high as fifty percent of these use errors can be attributed to the manufacture not having an effective human factors program.

Incorporating human factors into product design is not just a requirement of the FDA. IEC 60601 -1-6, “Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability” requires it. Also IEC 62366:2008, “Medical Devices – Application of Usability Engineering to Medical Devices” requires it.

Good “first time users needs” treatises on the subject are AAMI’s Human Factors Engineering standards HE74 and HE75.

The FDA believes that a human factors program should be fully integrated into the overall design process. It should not be an after thought that gets addressed late in the design cycle. So during the audit of the Design Control process, you want to point out human factors considerations in the Design Input, and how they were derived. Then show how these inputs were incorporated into the design, and lastly how these human factors requirements were tested in the validation and verification of the product.

Lastly, in the audit of the manufacture’s CAPA process, the FDA will be looking to see if the manufacture is investigating feedback (customer complaints and field service data) to see that use errors are being tracked and trended for product corrective actions (and not just the issuance of warning labeling) both in the current product and in the next generation of product.

Quality Topic

Rules for determining Lack of Control

What are the four common rules used for determining if a process has gone out of control while plotting a control chart? (often referred to as the Western Electric Rules)

1. Whenever a single point falls outside the (3 sigma) control limits on either average chart or the range chart.
2. Whenever at least 2 out of 3 successive values fall on the same side of, and more than 2 s.d. away from the central line.
3. Whenever at least 4 out of 5 successive values fall on the same side of, and more than 1 s.d. away from the central line.
4. Whenever at least 8 successive values fall on the same side of the central line.

Networking for Quality Professionals

ASQ Los Angeles Section Present

Barry Craner Recipient of the 21st Simon Collier Quality Award

Wednesday, November 12, 2008

6:00 - 7:00 P.M. Dinner

7:00 P.M. Business Meeting

7:15 P.M. Presentation

Cost of dinner:

\$30 reservation after November 7

\$35 at the door

LOCATION:

Holiday Inn Torrance

19800 So. Vermont Avenue

Torrance, CA 90502

Please join the Los Angeles Section for its Simon Collier Quality Award member dinner meeting on Wednesday, November 12, 2008. The meeting will take place at the Holiday Inn Torrance.

Barry Craner has been awarded the twenty-first Simon Collier Quality Award by the Los Angeles Section of the American Society for Quality (ASQ). Mr. Craner will be honored for his conspicuous and excellent long-term service in the Quality Assurance profession, the Biomedical Industry, and ASQ, as a community volunteer, and a mentor in industry at large.

Barry Craner is an Assistant Professor at California State University, Dominguez Hills in the MSQA program, lectures widely on Design Control and Risk Management, and teaches semi-annual classes in the Northern California region on Auditing, Design Control, and Risk Management in FDA-regulated industries. He has presented numerous papers at professional society conferences, and has consulted for Abbott, Baxter, Boston Scientific, and several other companies. He has been Chair of the ASQ Biomedical Division, and was also Chair of our sister ASQ San Diego Section. Recently, he was the Director of Quality Assurance, Lipid Sciences, Inc., a virtual company with a mission to create/market the first practical lipid and cholesterol extraction devices to treat both cardiovascular and major viral disease states. Lipid Sciences could not raise financing, and as of October 3, he is consulting short term. He was responsible for Corporate Quality Assurance, Quality Systems creation/integration, Compliance, and was on the R&D Team.

Following the award, Barry will make a presentation entitled:

**"Understanding Leadership in Volunteer Organizations,
or How to Maximize Our Success with ASQ".**

<http://www.acteva.com/booking.cfm?bevaid=169549>

You are welcome to attend the business meeting & presentation without dinner - please register for this option.

Contact Lane Parrott at 310 543-3949 or email lane.parrott@morganstanley.com with questions

For more information regarding the programs and directions to please go to <http://www.asqla.org/>

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 end of 2008 is fast approaching; it is time to examine on how you did on achieving your 2008 personal Quality improvement goals. And while I agree that activity does not necessarily show progress towards achieving a goal, I have found that without activity, there can be no progress.

So I would like to recommend you consider setting some activities as 2009 goals. Simple things like reading one article in each issue of Quality Progress magazine; or attending six ASQ sections meetings; or attending one Quality Workshop or Quality Conference. Build these into becoming knowledgeable on specific Quality topics, and build this into obtaining an ASQ certification.

Learning is a life long process.

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