

Gabriel's Horn

May, 2008

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

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 Chairman

Dear members,

The long days of summer are coming soon. We have to ensure that we stay safe and also help promote safety awareness among the lives we touch. In my tenure as quality professional I have always considered safety ahead of quality.

The leadership training in Palm Springs was very successful. Senior leadership from ASQ was present and enlightened us on many perspectives of managing the section affairs.

I had the pleasure of representing our section at the ASQ world conference in May. It was a wonderful experience for me and saw, for the first time, a gathering of approximately 2000+ quality professionals. Some of the speeches were fabulous. The community that he had dedicated his life to eulogized Dr. Juran. There were numerous training sessions in various disciplines of quality. Our section received two awards. The SMP and quality management awards. They were the result of hard dedication and work of all board members.

Once again I would like to invite the members to get involved in the section meetings and help the board members help them in running the section affairs.

Towards end of April our section hoisted a Minitab workshop that was very well received. We had over 30 participants. Another advanced session is being contemplated to be held in coming months.

Our section has continued the remarkable growth achieved in recent months and I am confident we will continue to grow with help from all of our members. I look forward to

all to lend the helping hand in our efforts to reach the status we deserve in the ASQ community.

We have many vacant positions on the board. The board is also actively looking for volunteers to fill important positions in the board. I am requesting and challenging young people to come forward and provide the much-needed boost to the section. Please contact any board member to participate in the board. All you need is to give a few hours of your time per month towards your profession for a noble cause. You will have rewards of earning points towards recertification and feeling of self respect of helping an organization that helps quality professionals like all of us stay together and work towards common goals of self improvements and bettering the organization.

Sincerely Yours,
C.G.Mistry,
Chair Section 702

Announcements of Coming Programs and Activities

May Program – Joint meeting with Southern California FD&C Discussion Group

The Challenges of HACCP (Hazard Analysis Critical Control Points) in the Food Industry

Speaker: Mas Hori – Retired California DHS FDB Investigator/Food Consultant

Mr. Hori will be discussing the issues and problems that HACCP has presented to the food industry.

Mr. Hori has over 27 years of experience in the food, pharmaceutical, medical devices and cosmetic industries in regulating these products for GMPs and HACCP. During his career, he has trained over 1600 individuals in HACCP for the seafood and food industries. He also is a Certified HACCP Auditor by the American Society for Quality. In 2004 he retired from the state of California as a supervising Food Drug investigator in Southern California. He holds a bachelor's degree in Biology from California State University at Los Angeles.

The meeting will be held at Golden State Foods, Corp. in the City of Industry. This event has a limit as to the number of attendees. You must register to attend this event. NOTE in order to tour Golden States Foods and hold the meeting, this event starts at 5:00.

April Program - A Practical Approach to Risk Management

Regardless of whether you are in a regulated industry such as pharmaceuticals or medical devices or not, Mike Wakshull's presentation on a Risk Management process was a good

one. For those of us in either pharmaceuticals or medical devices, his comparison of the two industry standards was a much better way to understand either standard than having been taught only one. I work in the medical device industry and while I thought I knew ISO 14971, by seeing the two standards in comparison, I came to appreciate just what each element of 14971 was trying to achieve.

In both industries, the applicable risk management standard is listed as recommended. But Mr. Wakshull pointed out you can not make a product submission or pass a design control audit without having a risk management process. Mr. Wakshull enlightened us that the expectations of a risk management process have evolved from a one time event during design of the product into a full Life Cycle model. He stressed the need to consider variables beyond just the product and to look for these interfaces and include them in the risk thinking.

Mike Wakshull is the president of Q9 Consulting, Inc., a contract provider of risk management services that include training and development of quality risk management processes.

April Workshop – Capability Analysis using Minitab

The Saturday workshop the section held on using Minitab was a huge success. The thirty-two attendees want more of these on other applications of Minitab. Participants commented that the four hours went by too fast.

The section is working on setting up more of these.

Prepare for ASQ Certification

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

A number of our members attended the Region 7 Leadership Training seminar April 12th, held in Palm Springs.



Two of our members attended the World Conference on Quality and Improvement in Houston, Texas.



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.

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.

The section is looking for some one to be the web master. If you have any interest, please contact a member of the board, or send an eMail to chair@asq702.org.

New Members

Section 702 would like to welcome the new members

Chris Mondragon
Garen Garabidian
Edward Torres
Cory Ward

Achieving Global Food, Drug and Device Protection Through Partnerships

The Association of Food and Drug Officials (AFDO), a non-profit organization of local, state and federal government officials, academia and industry leaders will hold its 112th annual Education Conference at the Crowne Plaza Resort Hotel in Anaheim, June 7-11.

For more information, go to:

<http://www.afdo.org/afdo/Conferences/>

Regulatory Affairs: Expanding to Global Horizons

The FDA Los Angeles District Office and the Orange County Regulatory Affairs Discussion Group are presenting the 11th Annual FDA-OCRA Educational Conference June 11-12, at the Irvine Marriott. This is THE meeting where Washington comes to the West Coast.

For more information, go to:

<http://www.ocra-dg.org/meetings.htm>

Chapter 702 * 2008 Meeting Calendar *****

- May 5 executive board meeting
May 21 Joint meeting with Food, Drug and Cosmetic Division
speaker: Mas Hori
meeting at Golden States Food, Corp. in the City of Industry
special start time 5:00
June 18 meeting – Installation of section’s new Board
Subject not yet finalized
speaker: Chris Christensen
July 7 executive board meeting
July 16 meeting
Joint meeting with Biomedical Discussion Group
Program to be announced
August 20 meeting
ASQ’s International Team Excellence Awards
speaker: Kandy Senthilmaran
September 1 executive board meeting
September 17 meeting
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 of Section and Biomedical Discussion Group
Program to be announced
November 3 executive board meeting
November 19 Joint meeting with Food, Drug and Cosmetic Division
Program to be announced
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.

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

E-mail chair@asq702.org

**Looking for a few good members
to be editors of features of this section's newsletter.**

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

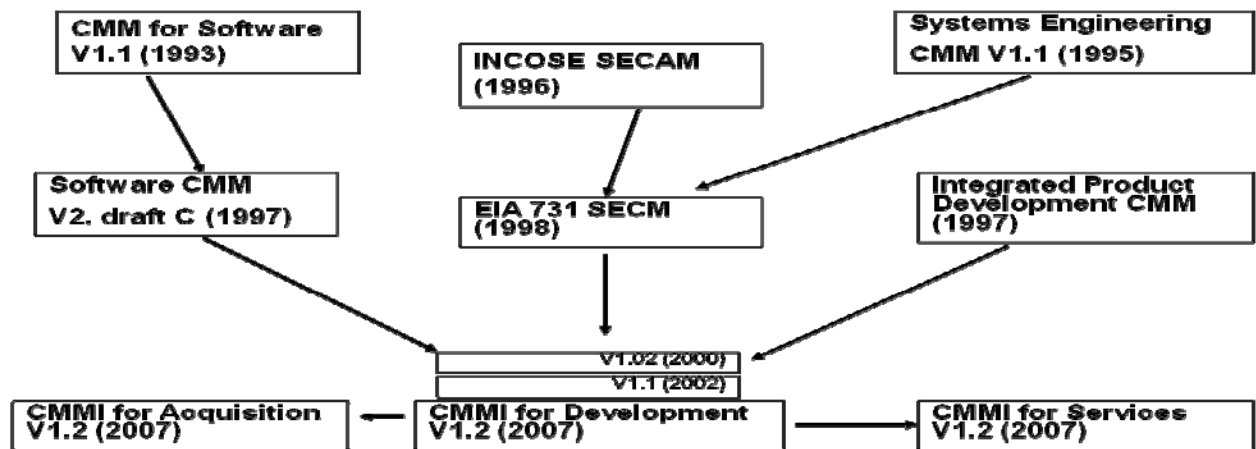
**THE APPLICABILITY OF VARIOUS QUALITY MODELS/METHODOLIGIES
IN AN IT ORGANIZATION**

This is the second in series of the articles in our newsletter illustrating the applicability of various quality models/frameworks/methodologies in an IT organization. Let's consider CMMi for this month.

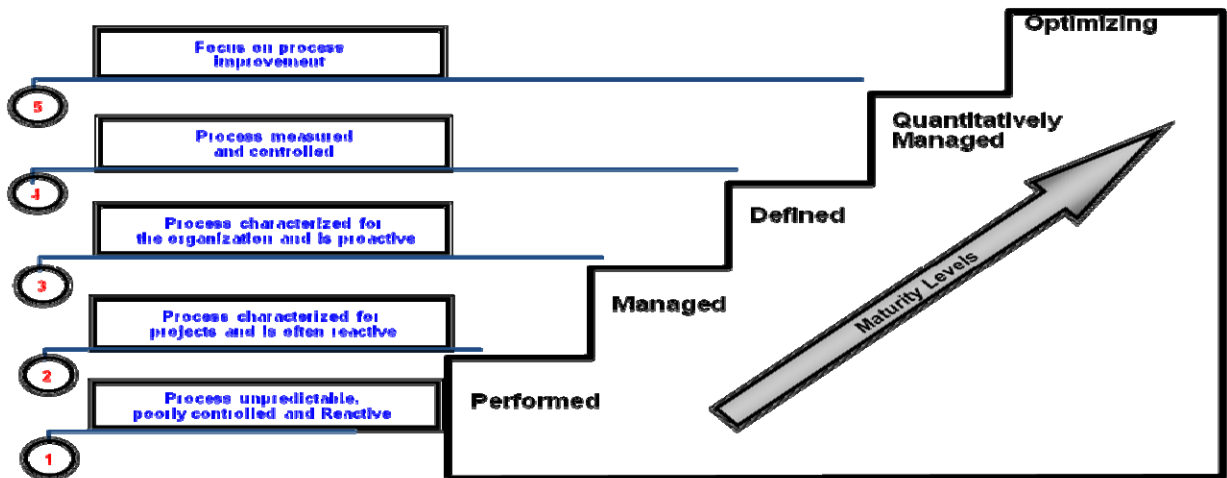
What is CMM (Capability Maturity Model)?

A common-sense application of process management and quality improvement concepts to software development and maintenance. It was developed by Software Engineering Institute (SEI) of Carnegie Mellon University in partnership with the industry.

How does CMMi evolve?



What are the various maturity levels of CMMi?



A maturity Level is a well defined evolutionary plateau on the path to becoming a mature organization. Each level is a layer in the foundation for continuous process improvements. Each level is a level in the foundation for continuous process improvements.

What are the benefits of CMMi?

Table given below represents the results achieved in one or more of the six categories of performance measures from 13 different organizations that adopted CMMI model

Improvement	Low	Med	High	# of data points
Cost	5%	20%	83%	7
Schedule	15%	66%	95%	11
Productivity	11%	28%	60%	4
Quality	20%	47%	72%	6
Customer Satisfaction	10%	33%	55%	3
ROI	2:1	3.8:1	13:1	4

Data Source: NDIA/SEI CMMI Presentation -- November, 2004

CMMi V 1.2 is more suitable for a software development and a maintenance organization. Even though many organizations does not want to go or find usefulness in going for external certifications or does not consider CMMi is not going to work for their organizational culture but want to reap the benefits or CMMi are coming forward to use CMMi's goals and objectives as a industry best practice model and leverage them in their process improvement journey.

CMMi comes in two representations, staged and continuous. Organizations want to proceed by the maturity level can choose staged and organizations wanting to improve specific process capability can go by continuous model.

SCAMPI (Standard CMMi based Appraisal Methodology for Process Improvement) is appraisal methodology and there are numerous SEI authorized trainers and appraisers who can assist organizations embarking on the CMMi journey.

I had managed large process improvement teams based on CMMi and lead CMMI assessments for multiple IT organizations. From my experience, CMMi can be utilized in one form or another in majority of software development organizations and getting to CMMi L2 is the most challenging part of the journey and once you are there and are able to sustain it, you will start to reap the fore mentioned benefits.

Pharmaceutical Industry

Editor: Randall Wong

For those whose jobs are in Regulatory Affairs (besides your job in Quality), you may know of the latest FDA requirement for drug applications.

Effective January 1, 2008, any Drug Product Application (e.g. NDA or ANDA) that is submitted to the FDA in electronic format, must now be in the form of an electronic Common Technical Document (eCTD). This means that any other electronic format, such as eIND, eNDA or eBLA, will not be accepted. Paper submissions are still accepted in lieu of an electronic submission, however the emphasis is now on electronic (e.g. paperless) regulatory filings.

For further information and specifications on the eCTD format, go to www.fda.gov/cder/regulatory/ersr/ectd.htm

Look for the following documents

- ICH eCTD Specification 3.2
- US: Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
- FDA eCTD Table of Contents Headings and Hierarchy

The future for all Regulatory Submissions in the US and abroad is the Common Technical Document (CTD), published and submitted in electronic format (eCTD).

Medical Device Industry

Editor: Larry Phelan

May 9, 2008: FDA Commissioner Andrew von Eschenbach met with lawmakers after an appeals dispute between the agency and TMJ Implants of Golden, Colo. TMJ and the FDA have conducted an ongoing four-year dispute, which began with an agency warning letter about indication for its medical devices. In April, Reps. Joe Barton, R-Texas, and John Shimkus, R-Ill. Defended TMJ implants, and sent a letter to von Eschenbach,

questioning the agency's practice of telling companies they can appeal a decision when it intends to proceed with enforcement actions.

During last week's meeting, the commissioner acknowledged that the agency's handling of the device company's warning letter appeal was a "process failure", as defined in the April 30 letter from Barton and Shimkus. In the letter to the commissioner, the lawmakers noted that von Eschenbach said that FDA staff is addressing problems with the dispute process.

The FDA said it will follow up with the House Oversight and Investigations Subcommittee staff to discuss details of its new internal operating guidelines and other steps taken in response to the lawmakers' concerns.

Quality Topic

Radical Thinking

By Akhilesh Gulati

In many professional association meetings, it's quite common to overhear, "We have adopted the Kaizen philosophy to help us to achieve our goal to become as 'Lean' as possible."

Follow on clarifications may include:

"In order to minimize preconceived ideas on how it "should be" done, the majority of our team members were chosen from outside of that work area. Management then supplied the team with a problem definition, scope, time frame, and constraints. The team was then empowered to take action within these constraints without any approvals."

"Kaizen Blitz was a rational way for us to go about change. We got the managers to define a problem, labeled all the parts of the process that seemed wasteful, brainstormed ideas for the removal of said waste, and instantly implemented the change to those who worked in the operations. It gave people an idea how much change could be created in a short period of time (a few days), and now we are planning on this continuous improvement through the whole organization."

"One of our major customers wanted us to do lean so that they could get JIT deliveries. We were able to get free training and we were all required to do a lean project. It was great; you should see the savings we had!"

"Management defined the process(es) that we needed to tackle; we mapped these processes, decided on the problem, redesigned the process and all within the existing service standards and targets! It felt good!"

The so called 'success stories' go on. Yet, from the customers' standpoint, do they really see any improvement coming from these organizations? What they would/should hope to see would include things like improved quality, improved delivery times, reduced cost,

etc. Internally we should expect to see less complexity, simplified flow, reduced inventory, faster approvals and a change in culture after the training or the kaizen event are over. However, that is rarely the case.

Why, then, does 'kaizen' supposedly perform wonders? The answer, perhaps lies in the fact that many of these organizations are playing 'pretend lean'. They are enshrining activities rather than taking a systemic approach to improvement. Most of them do not have an end-to-end Value Stream Map, nor do they have a lean strategy showing where and how kaizen events align with the organization's overall strategy, and its vision/mission/values. The focus is on NOW and action!

Although kaizen activities are a great way to start momentum on the improvement continuum, they must be part of an overall strategy that identifies organizational constraints and is understood by all concerned. Running a few 5S events, putting in some visual management tools, reengineering selected processes and making minor improvements is not analogous to 'LEAN'. Random training and scattered kaizen events or improvement projects do not a 'LEAN' make! As Stuart Corrigan of Vanguard Scotland states, "Lean works on the basis of understanding value from a customers' point of view and then analyzing the system responsible for the creation of that value end-to-end."

Unless kaizen events are part of a defined lean strategy, the act of enshrining activities seldom addresses the right problem or organizational constraint. It is a selective process, which while showing local results, may end up pushing the problem around the organization, thereby never getting at the source of the issue nor showing up as an improvement in the eyes of the customer. Are you enshrining activities?

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

Networking for Quality Professionals

You have been attending the section meetings. Have you started communicating with your fellow member?

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

If anyone knows of any Quality courses being held by a local junior college or at a nearby state college or university, please send information on it.

Thank you to everyone who contributed to this newsletter.

To all 702 MEMBERS, tell 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