

Gabriel's Horn

June, 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 Chair

Dear members,

This is my last message as chair for the section. I was very honored to serve as chair of the section for last two years.

I want to thank all the board members and the ASQ 702 members for their support in my tenure as the chair. I wish success for the incoming chair Kandy. He has great potential to lead the section. I urge all members give him a helping hand in making our section the cynosure of the ASQ region 7 and the ASQ community at large.

This newsletter is being revived by Larry Phelan for some time and the next step is to put in on the ASQ 702 website. We intend to achieve this goal in coming months. I am again asking for volunteers to come forward and help the board to run the section as a team of all ASQ members.

The Quality Day planned for October 11 2008 is on target. Please make sure that you reserve the day and attend the event. It is like mini world quality congress and has very reputed and talented professionals addressing the gathering. More information will be coming soon. We are calling for volunteers to help promote the event at their place of work or business. We are also looking for sponsors.

In the end, I wish all of you are well, and continue to promote safety and quality in all areas of life.

Sincerely,
C.G.Mistry

Announcements of Coming Programs and Activities

June Program – Quality in China, India and other Exotic places by Chris Christensen

Mr. Christensen will explore the issue of quality in Asian suppliers in this talk, and will challenge the quality community to do a better job to ensure that products and services obtained from Asia meet the highest quality standards. Some of the areas that he will explore are: Are the reports over-stated or is there a real problem with Asian suppliers? How deep is the poor quality problem in products and services provided by Asian suppliers? What are the causes of poor Asian supplier quality? What should a U.S. company do to guarantee better quality? Do the U.S. company practices need to be totally revamped or can they be refined to resolve poor supplier quality?

Chris Christensen is president of Christensen Associates, Inc., a management consulting firm in Playa del Rey. <http://www.camcinc.com> He can be contacted at chris@camcinc.com

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

This was a joint meeting with Southern California FD&C Discussion Group at Golden State Foods, Corp.

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

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

Executive Board for 2008 – 2009

Chair person – Kandy Senthilmaran

Treasurer – Nal Lokeshwar

Secretary – Jean Flores

Nomination chair – Dwayne Nesser

Certification/Proctor – Kandy

Senthilmarian

Liaison w/Biomed – Marina Guevrekian

Liaison w/ FD&C – Isabelle Gartner

Program chair – C. G. Mistry

Membership chair – Bennet Chin

Newsletter chair – Larry Phelan

Audit chair – C. G. Mistry

Recertification – Lori Benson

Education chair – Dwayne Nesser

Arrangements – Dwayne Nesser

These are your board members for the coming year.

It takes a great amount of work to keep an ASQ section running and improving.

Support from you the members is essential. Please speak-up and tell the board what you like, what you don't like, and what you need.

The board is made of section members just like you, except they have picked-up the challenge to put in their time and hard work and make it happen.

There are many things the board can not undertake at this time because of lack of people to help make it happen. So if you have an interest in making it happen, please speak to one of the board members, or better yet, come to a board meeting.

New Members

Section 702 would like to welcome the new members

Susan C. Mechler

David C. Broadbent

Doug Stahl

Pedro F. Canola

Sean P. Mullan

Diana M. Smith

Warren Lee Zike

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.

Chapter 702 * 2008 Meeting Calendar *****

- June 18 meeting – Installation of section’s new Board
Quality in China, India and other Exotic places
speaker: Chris Christensen
- July 7 executive board meeting
- July 16 meeting
Value Stream Mapping
speaker: Larry Phelan
- August 20 meeting
Joint meeting with Biomedical Discussion Group
Topic to be announced
speaker:
- 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 with 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

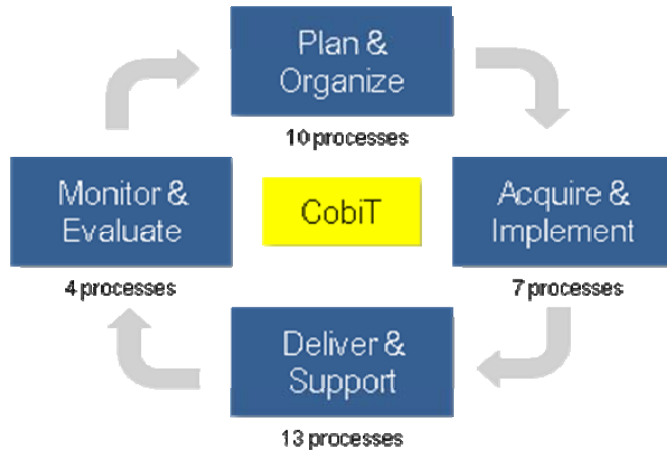
Editor: Kandy Senthilmaran

COBIT

The Control Objectives for Information and related Technology (COBIT) is a set of best practices (framework) for information technology (IT) management created by the Information Systems Audit and Control Association (ISACA), and the IT Governance Institute (ITGI) in 1992. COBIT provides managers, auditors, and IT users with a set of generally accepted measures, indicators, processes and best practices to assist them in maximizing the benefits derived through the use of information technology and developing appropriate IT governance and control in a company.



The architecture of COBIT is as follows,



COBIT is subdivided into four domains and 34 processes providing an end-to-end view of IT. It is compatible with other IT frameworks/methods.

COBIT structure

COBIT covers four domains:

- Plan and Organize
- Acquire and Implement
- Deliver and Support
- Monitor and Evaluate

Plan and Organize

The Planning and Organization domain covers the use of information & technology and how best it can be used in a company to help achieve the company’s goals and objectives. It also highlights the organizational and infrastructural form IT is to take in order to achieve the optimal results and to generate the most benefits from the use of IT. The following table lists the high-level IT processes for the Planning and Organization domain.

HIGH LEVEL CONTROL OBJECTIVES

Plan and Organize

PO1	Define a Strategic IT Plan and direction
PO2	Define the Information Architecture
PO3	Determine Technological Direction
PO4	Define the IT Processes, Organization and Relationships
PO5	Manage the IT Investment
PO6	Communicate Management Aims and Direction
PO7	Manage IT Human Resources
PO8	Manage Quality
PO9	Assess and Manage IT Risks
PO10	Manage Projects

Acquire and Implement

The Acquire and Implement domain covers identifying IT requirements, acquiring the technology, and implementing it within the company’s current business processes. This

domain also addresses the development of a maintenance plan that a company should adopt in order to prolong the life of an IT system and its components. The following table lists the high level control objectives for the Acquisition and Implementation domain.

HIGH LEVEL CONTROL OBJECTIVES

Acquire and Implement

AI1	Identify Automated Solutions
AI2	Acquire and Maintain Application Software
AI3	Acquire and Maintain Technology Infrastructure
AI4	Enable Operation and Use
AI5	Procure IT Resources
AI6	Manage Changes
AI7	Install and Accredite Solutions and Changes

Delivery and Support

The Delivery and Support domain focuses on the delivery aspects of the information technology. It covers areas such as the execution of the applications within the IT system and its results, as well as, the support processes that enable the effective and efficient execution of these IT systems. These support processes include security issues and training. The following table lists the high level control objectives for the Delivery and Support domain.

HIGH LEVEL CONTROL OBJECTIVES

Deliver and Support

DS1	Define and Manage Service Levels
DS2	Manage Third-party Services
DS3	Manage Performance and Capacity
DS4	Ensure Continuous Service
DS5	Ensure Systems Security
DS6	Identify and Allocate Costs
DS7	Educate and Train Users
DS8	Manage Service Desk and Incidents
DS9	Manage the Configuration
DS10	Manage Problems
DS11	Manage Data
DS12	Manage the Physical Environment
DS13	Manage Operations

Monitor and Evaluate

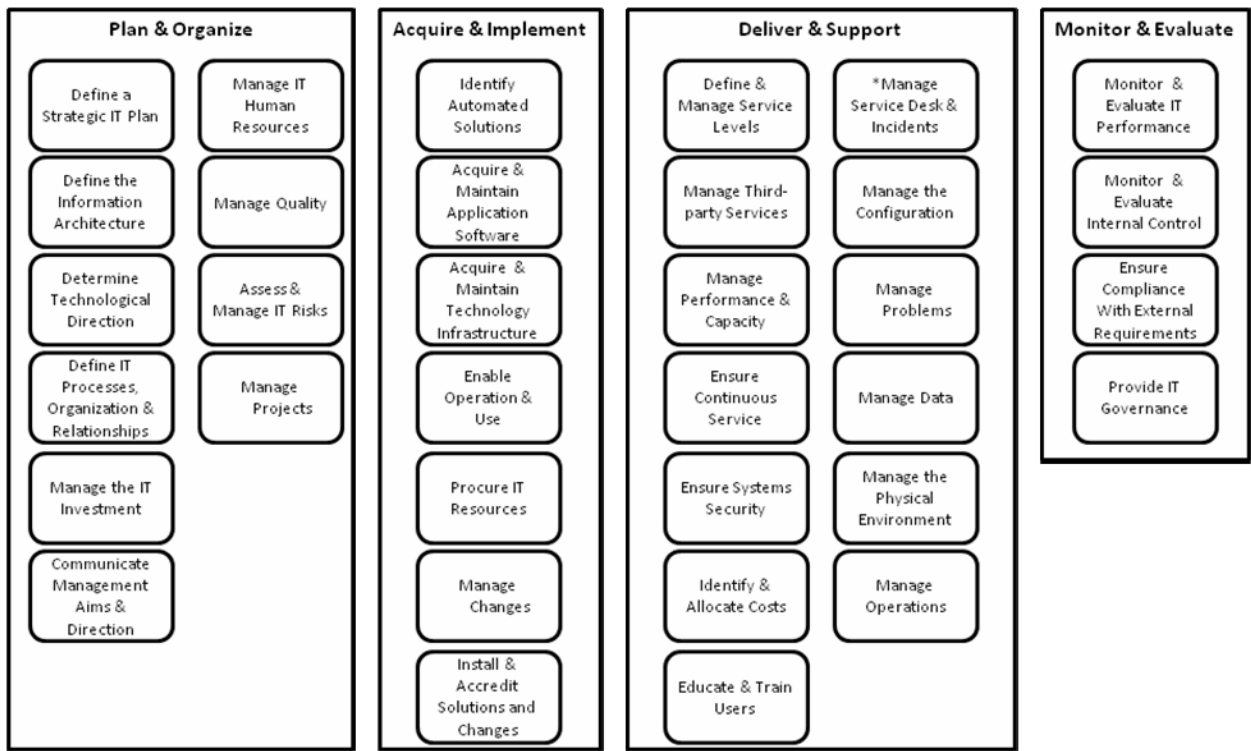
The Monitoring and Evaluation domain deals with a company’s strategy in assessing the needs of the company and whether or not the current IT system still meets the objectives for which it was designed and the controls necessary to comply with regulatory

requirements. Monitoring also covers the issue of an independent assessment of the effectiveness of IT system in its ability to meet business objectives and the company's control processes by internal and external auditors. The following table lists the high level control objectives for the Monitoring domain.

HIGH LEVEL CONTROL OBJECTIVES

Monitor and Evaluate

ME1	Monitor and Evaluate IT Processes
ME2	Monitor and Evaluate Internal Control
ME3	Ensure Regulatory Compliance
ME4	Provide IT Governance



The latest version of COBIT (V 4.1) introduces maturity model for performing capability assessments in line with CMMI generic practices.

COBIT 4.1 can be used to enhance work already done based upon earlier versions; it does not invalidate that previous work. When major activities are planned for IT governance initiatives, or when an overhaul of the enterprise control framework is anticipated, it is recommended to start fresh with the most recent version of COBIT.

Reference <http://www.isaca.org/COBIT>

Pharmaceutical Industry

Editor: Randall Wong

The FDA and EMEA announced a pilot program for joint good manufacturing practice (GMP) inspections under a bilateral agreement. The joint inspections program will apply to facilities in both the U.S. and the European Union (EU), the EC said. Joint inspections of active pharmaceutical ingredient (API) facilities in countries outside the U.S. and the EU will be part of the program as well.

The agencies will also pilot a GMP information exchange covering inspection schedules and results. Information on facilities that have been inspected would be shared so the agencies could get greater inspection coverage and better identify API production sites in countries outside the U.S. and the EU.

The FDA had previously announced that it will attempt to hire more than 1,300 biologists, chemists, medical officers, mathematical statisticians, investigators, inspectors and other professionals by Sept. 30, the end of the fiscal year. More than 700 of the jobs to be filled are existing positions that are currently or will be vacant because the employees in them have announced plans to leave. The FDA said it will hold job fairs around the country to recruit needed professionals and has 15 scheduled between May 15 and September 16.

Warning Letters

As of the beginning of June, the following thirteen Pharmaceutical companies had received Warning Letters for GMP violations since the beginning of 2008. The complete Warning Letters may be viewed on the FDA website.

<u>Company Name</u>	<u>Date Warning Letter Issued</u>	<u>Issuing Office</u>	<u>Subject</u>
Noven Pharmaceuticals, Inc.	1/04/08	Florida District Office	CGMP for Drugs/Manufacture, Processing, Packing, Holding/Adulterated
American Hormones, Inc.	1/10/08	New York District Office	New Drug/Adulterated/Misbranded
Tomita Pharmaceutical Co., Ltd	1/14/08	Center for Drug Evaluation and Research	CGMP/Active Pharmaceutical Ingredients/Adulterated
Lyne Laboratories, Inc.	1/17/08	New England District Office	CGMP for Finished Pharmaceuticals/Adulterated
Novartis Vaccines and Diagnostics	1/24/08	Center for Biologics Evaluation and Research	CGMP Deviations
Vintage Pharmaceuticals, LLC	2/01/08	New Orleans District Office	CGMP/Adulterated
Midland Pharmaceutical LLC	3/03/08	Kansas City District Office	CGMP for Finished Pharmaceutical/Adulterated
Catalent Pharma Solutions	3/28/08	Office of Enforcement	CGMP Deviations
Changzhou SPL Company, Ltd (a/k/a	4/21/08	Center for Drug Evaluation	CGMP/Active Pharmaceutical Ingredients/Adulterated

"Kaipu")		and Research	
Merck & Company, Inc.	4/28/08	Office of Enforcement	CGMP Manufacture of Licensed Biological Vaccine Products/Bulk Drug Substances/Components
Legacy Pharmaceuticals International	5/07/08	San Juan District Office	CGMP for Drugs/Manufacture, Processing, Packing, Holding/Adulterated
Elge, Inc.	5/08/08	Dallas District Office	CGMP for Drugs/Manufacture, Processing, Packing, Holding/Adulterated
Jer-Vic Inc., dba Foy's Pigeon Supplies	5/14/08	Philadelphia District Office	CGMP/New Animal Drug Application/Adulterated/Misbranded

Medical Device Industry

Editor: Larry Phelan

New Chinese Requirements may delay importation of Medical Devices

Changes proposed by China's State Food and Drug Administration will require a device with even minor improvements since its previous registration to under go type testing. This will result in an unnecessary burden on device manufactures and is likely to delay or interruption the importation of products to China. Only products with no change are exempt from this type of testing.

The Chinese State Food and Drug Administration issued 73 industry standards for medical devices to take affect next year. Thirty-three of the standards are mandatory and forty are recommended.

AdvaMed has sent a response the Chinese State Food and Drug Administration on the proposed review process noting that neither the U.S. nor Europe require prior review on changes that do not affect safety or efficacy.

Quality Topic

Profound Knowledge

Deming, W. Edwards, The New Economics

“As a good rule, profound knowledge comes from the outside, and by invitation. A system can not understand itself. The transformation will require leaders.”

In Dr. Deming's system of Profound Knowledge, he divided it into four parts

- Appreciation for a system
- Knowledge about variation
- Theory of knowledge
- Psychology

In this time of rapid change, Dr. Deming's system is as relevant today as the day he wrote.

Radical Thinking

By Akhilesh Gulati

Visual Thinking! Solve it with pictures!

Since one of the pillars of Lean Thinking is the Visual Workplace, why hasn't it been taken to the next level of visual problem solving in the workplace?

A popular tool that visually shows activity is the documenting of procedures in a flowchart format. It can be used to show what is currently happening, what could be happening, or what should be happening. The last example is a great opportunity to show where there may be a disconnect between procedures and reality. It also provides a pictorial display of where problems occur and where/how proposed solutions may or may not solve the issue.

This pictorial display is used throughout our life - not just in the workplace. Consider being new to the sport of baseball or American football. Using just words to explain the game can be a bit difficult to follow, however, when paired with pictures drawn on a napkin, various positions and plays become quite obvious. 'Say it with pictures' - why did we not use it more often?

Using pictorial displays is not a new approach in problem solving or process improvement. Both Lean and Six Sigma use pictures extensively - qualitatively (e.g., value stream mapping, fishbone diagrams, affinity diagrams) and quantitatively (e.g., pie charts, histograms, control charts, radar charts).

These tools / concepts are not new and some of the more popular examples include, but are not limited to:

- Flow charts (aka process maps, box & wire diagrams) have been used extensively throughout history - in all functions and all industries (e.g., software development, project management).

- Gantt charts (bar charts) have been used to visually represent the length of time it takes to complete a specific task, in the order of occurrence and with associated dependencies.

- Statistical Process Control (SPC) uses charts (pictures) to show when a process is going out of control and when actions need to be taken to keep it within control.

- Time series charts tell stories which can be very valuable in identifying problems (e.g., special causes) and shows not only when remedial action needs to be taken but also in helping to predict failures.

Author Edward E. Tufte has written many books on visual display. He demonstrates how using data graphics to visually display measured quantities through a combination of points, lines, a coordinate system, numbers, symbols, words, shading and color, makes it much easier to not only understand difficult information, but to also communicate such information to non-technical folks. These graphics can then

be used for analyzing and solving problems. He also shows how visualization can be useful in strategic decision-making.

Author Eliyahu Goldratt, in his explanation of the Theory of Constraints, draws upon visual tools (e.g., Reality Trees, Evaporating Clouds, Drum Buffer Rope, Throughput, Push/Pull, Perceptions of Value) and he does so not with extensive use of quantitative data, rather simple linked boxes to better understand conflicts and constraints, to identify areas of resistance, to expose wrong assumptions, and to get buy-in from folks who will be required to make changes.

Probabilistic Decision Making uses Decision Trees extensively to facilitate decisions with a higher probability of achieving the desired outcome. These too are not fancy illustrations, just everyday pictures (dots, circles and lines) that highlight choices and possible outcomes.

Why then is it that we do not use these simple tools more often? Is it because we believe that we do not know how to draw? Or is it because we do not want to be seen as too simplistic? After all, using big technical words makes us sound more professional and deem us to be more 'knowledgeable' than others.

Every educated person has heard 'a picture is worth a thousand words'. Why then do we not use pictures wherever we can? Microsoft's *PowerPoint* has become an ubiquitous tool, almost to the point of becoming a crutch; using bullet points and reading the presentation has become the norm and has resulted in losing some of its impact. Drawing simple pictures on a whiteboard to explain concepts or sketching boxes on a flip chart to show linkages, albeit not quite as neat, is much more powerful. It draws people in, gets them involved, brings out the issues, identifies constraints, and gets us to results.

Make *Visual Thinking* the norm in your organizations and *Solve It With Pictures!*

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, 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