

Dear Quality Colleagues,

The Silicon Valley American Society for Quality (SVASQ) Section brings you this monthly email newsletter to give you a quick look at the news about the Silicon Valley Section, the ASQ and the local quality world. If you have an information posting to share with our quality colleagues, please send it to the SV ASQ E-News Editor, m.shovlin@comcast.net. And be sure to check out information on the website at <http://www.asq-silicon-valley.org>.

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Take our online Member Survey. Just click here and spend a few minutes telling us about how we can better serve you:

http://www.surveymonkey.com/s.aspx?sm=2frGVTvl4Ao_2bQvgKD1Sv_2fQ_3d_3d

To have a look at all the fun from our SV ASQ Second Annual picnic, click on the Picnic picture link following:

http://picasaweb.google.com/4kondas/ASQSVPicnic?authkey=0J_tJBGaKYk

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1) Upcoming Special Events:

- **Special ISO Forum: “ISO the Foundation to Build Upon – Quality Management Systems”** - Don't miss out on this quality-focused forum being held **September 19, 2007** at the **Crown Plaza, San Jose, CA**. QMS expert presenters will be focused to increase your knowledge and awareness of today's quality standards. The sessions will include:

- **“Top Management Involvement For ISO Success”**
 - Mr. Scott Weyburn, President/CEO Axeon
- **“Six Sigma – Why It Fails and How to Make It Work”**
 - Mr. Chuck Mignosa, President Business Systems Architects, L.L.C., ASQ Chapter #0613 Section Officer
- **ISO Roundtable – “ISO, The Foundation to Build Upon”**
 - Mr. Skip Greenaway, President/CEO EAGLE Registrations, Inc.
- **“ISO IT Technology - ISO 20000 & The State of Service Management Systems”**
 - Mr. Burjor Mehta, President/CEO of ISSI
- **“How Lean Techniques Improve Process Understanding”**
 - Mr. Lee Walthousen, Senior Staff Engineer at International Rectifier Aerospace and Defense

- The presenters' goals in this EAGLE sponsored event are to provide added Business Prospective, the Strategic Benefits of ISO and **Take-Home Value!** To learn more, contact EAGLE Registrations, Inc. at www.eagleregistrations.com/CAforum or call Nancy at 1-800-795-3641.

- Silicon Valley ASQ Leadership Meeting for September will be held Wednesday, September 5.

Please join us Wednesday, September 5, 2007, at 100 N. Winchester Blvd., San Jose. Contact [Chandru Idnani at cidnani@yahoo.com](mailto:ChandruIdnani@yahoo.com) to RSVP.

Participate in your Section planning and activity implementation throughout the year!

- PMI Northern California 2007 Symposium: New Horizons in Project, Program and Portfolio Management

Identifying and applying Project Management Best Practices, Methodologies, and Trends that Enable Organizations to Succeed in a Global Economy
Monday, September 17, 2007, Mission Bay Conference Center at UCSF, San Francisco, CA.

KEYNOTE SPEAKER: Harold Kerzner, M.S., Ph.D., Engineering and M.B.A. is Senior Executive Director with International Institute for Learning, Inc. and Professor of Systems Management at Baldwin-Wallace College. Dr. Kerzner's expertise is in the areas of project management, and strategic planning. Dr. Kerzner has previously taught engineering at the University of Illinois and business administration at Utah State University. He obtained his industrial experience at Thiokol Corporation where he held both program management and project engineering responsibilities on a variety of NASA, Air Force, Army, Navy and independent IR&D programs. In addition, Dr. Kerzner has provided training and consulting services for such companies as Dow Chemical, Federal Reserve Bank, Progressive Insurance, The Department of Defense, and Disney, among others.

REGISTER to ATTEND and EARN 7 PDUs TODAY:

<<http://www.pmisfbac.org/displayconvention.cfm?conventionnbr=4040>> [Northern California 2007 Symposium Registration](#)

Golden Gate Section September 18, 2007 Dinner meeting: Orchestrating Your Leadership, 6:00 to 8:30 PM, Scott's Restaurant, Jack London Square, Oakland, CA.

Presentation Abstract: As a V.P., manager, teacher, coach or parent, you are a leader. Are you confident in your leadership? In this fun, interactive session Craig Harrison teaches you how to become a more successful and effective leader whom others will follow, respect and support. Speaker: Craig Harrison. Craig Harrison founded Expressions of Excellence!™ to inspire sales and service leadership in professionals.

As a leader Craig is: Past president of the National Speakers Association's Northern California chapter, Past president, International Customer Service Assoc. for SF Bay Area and Silicon Valley, Vice-chair of the Storytelling Association of Alta California, Past chairman of the Sales Trainers Professional Experts Group (PEG) of NSA, Past chairman of the board, KKUP 91.5-FM radio station in San Jose, CA, Past district governor for Toastmasters International, with over 30 published articles in *The Toastmaster* magazine.

Registration: Please send your registration and check made payable to "ASQ Golden Gate Section" to ASQ0618, P.O. Box 360985, Milpitas, CA 95036-0985, or register by credit card by September 18, 2007 on the internet at: <http://www.acteva.com/booking.cfm?bevaid=140792>. Payment by check or cash may be accepted at the door with an additional \$5.00 charge per attendee. For more information, email tom.norton.b@bayer.com or/and BChatterjee@pharmatechassociates.com.

Golden Gate Section October 23, 2007 Dinner meeting: Driving Performance Improvement From The Top: Identification and Deployment of Strategic Business Objective, 6:30 to 8:30 PM, Scott's Restaurant, Jack London Square, Oakland, CA.

Speakers: **Jerry Mairani and Eileen Clark**

Presentation Abstract: This presentation will cover what is perhaps the weakest link in most organizations ability to drive performance improvement, taking strategies and effectively engaging actions to attain them. This proven metric approach is successfully used by major corporations such as G.E., DuPont, and Ford to achieve measurable corporate level goals. This presentation is for all industry types. If you are an executive, middle manager, or quality professional you should attend this presentation.

Speaker Bios: Jerry Mairani is a Past President and Chairman of the American Society for Quality. He is a 20 year quality professional, Six Sigma Master Black Belt, and a current Professor for National Graduate School where he wrote their Lean Six Sigma Program and is now instructing it. He is a past Statewide Service and Results Director for Pacific Bell, and a consultant who has assisted organizations such as H. J. Heinz, Davis Instruments, Delta Dental, Siemens, Coherent and State of California departments with strategic planning, Six Sigma, performance measurement, and Baldrige.

Eileen Clark is also a 20 plus years quality professional working with major corporations such as Allied Signal and Delta Dental. For the past eight years Eileen has implemented and applied quality methods at Delta Dental. She brought the first service quality methods to their organization as manager of their first Quality Department. Through her efforts quality has continued to expand into other departmental areas. She joins Jerry in this presentation to bring a service industry prospective to this presentation.

Registration: Please send your registration and check to made payable to "ASQ Golden Gate Section" to ASQ0618, P.O. Box 360985, Milpitas, CA 95036-0985, or register by credit card by October 18, 2006 on the internet at:

http://www.acteva.com/organizer/act_display.cfm?eventid=140839. Payment of both check or cash can be accepted at the door with an additional \$5.00 charge per attendee. For a better headcount, email tom.norton.b@bayer.com or/and BChatterjee@pharmatechassociates.com for reservation.

- **Northern CA Biomedical Discussion Group, September 26, 2007 Meeting, 7 to 9 PM, at Stiefel Laboratories (formerly Connetics Corp.)**

Topic: ISO 14971 Risk Management Standard for Medical Devices, with Geetha Rao, Principal Macronus Group, moderator Ken Miles, former FDA investigator and President AQA Consulting.

Presentation will cover 2007 updates to ISO 14971.

To register: <http://www.acteva.com/booking.cfm?bevaid=141649> at Acteva.com.

Upcoming NCBGD events are posted on the ASQ Biomedical Division Event page at <http://www.asq.org/biomed/events/index.html>

- **ISQED 2008 CALL FOR PAPERS - 9th International Symposium & Exhibits on**
<<http://www.isqed.org/>>**QUALITY ELECTRONIC DESIGN**

March 17-19, 2008. San Jose, CA, USA

<<http://www.isqed.org/>>**www.isqed.org**

Leading Design for Quality & Manufacturability: Paper Submission Deadline: September 30, 2007; Acceptance Notifications: November 23, 2007; Final Camera-Ready paper: January 3, 2008

ISQED is the pioneer and leading international conference dealing with the design for manufacturability and quality issues front-to-back. ISQED spans three days, Monday through Wednesday, in three parallel tracks, hosting near 100 technical presentations, six keynote speakers, two-three panel discussions, workshops /tutorials and other informal meetings.

Papers are requested in the following areas: A pioneer and leading multidisciplinary conference, ISQED accepts and promotes papers related to the manufacturing, VLSI design and EDA. Authors are invited to submit papers in the various disciplines of high level design, circuit design, test & verification, design automation tools; processes; flows, device modeling, semiconductor technology, and advance packaging.

<<https://www.softconf.com/starts/isqed08>> **Submission of Papers**

Paper submission must be done on-line via the conference web site at

<<http://www.isqed.org/>>**www.isqed.org**. Authors should submit FULL-LENGTH, original, unpublished papers (Minimum 4, maximum 6 pages) along with an abstract of about 200 words.

Please check the as-printed appearance of your paper before uploading. To permit a blind review, do not include name(s) or affiliation(s) of the author(s) on the manuscript and abstract.

The complete contact author information needs to be entered separately.

2) Monthly SV ASQ Section Meeting

Join us on Wednesday, September 19, 2007, for the September Dinner Meeting & free Tutorial, 5:30 - 6:30; Dinner 6:30 – 8:30 at the Biltmore Hotel, 2151 Laurelwood Rd, Santa Clara, CA 95054 (408) 9881. Meeting location: <http://www.hotelbiltmore.com/html/bay-area-family-getaways.asp#6> . Register at <http://www.asq-silicon-valley.org>.

We will have a drawing for a quality book for attendees and invite new members (joining in July, August & September, 2007) to attend as our guests. New members, please contact

cidnani@yahoo.com to RSVP.

Tutorial Presentation:

"ISO 9001 to ISO 13485 Bridging the Gap" & "Upcoming Changes in the Standards"

Presenter: Mr. Scott Weyburn, President/CEO of Axeon; Sponsored by EAGLE Registrations, Inc. For the first half of this tutorial presentation, Scott will offer an overview and lead a discussion related to the key differences and interpretations between ISO 9001 and ISO 13485. He will focus on challenges between the concepts of "Continuous Improvement" verses "Improvement by Maintaining".

During the second half of this tutorial session, Scott will discuss "projected" changes to ISO 9001, how the changes will impact your current ISO system and real-world suggestions for compliance preparation.

After Dinner "Interactive" Presentation:

"Practical Approaches to Root Cause Analysis – Interactive Workshop"

Corrective Action Plans and Root Cause Analysis are among the leading areas of frustration in managing your Quality Management System. Mr. Weyburn will give detailed overviews on two of the most popular Root Cause Analysis processes: **5 Why's/Fishbone (Cause and Effect)** and the **8 D's**. The ASQ Chapter will be broken into groups and presented with a typical audit finding that they will analyze with their team to find the root cause of the non-conformance. Scott will finish with a recap on his approach to the findings and then open the floor to Q & A.

Presenter Bio: *Scott Weyburn, President/CEO, Axeon.* Scott has 20 years experience in quality, manufacturing and management in the aerospace, computer, metal and pharmaceutical industries. Scott is a previous voting member of the TAG to TC 176 and is currently an observer member. He serves as the sub-committee chair for auditor competency for RABQSA. Scott also serves on the ISO 9001 U.S. interpretations committee.

Please use the website (www.asq-silicon-valley.org) to sign up for the meal, rather than sending emails to the various chairs. We use the website registrations to make sure we have enough food planned. The food reservations are made Monday morning, but anyone who signs up on the website by Tuesday night is given priority for walk-in reservation, at the regular (\$30) price. Walk-in price is \$40., so please plan ahead.

3) Future SV ASQ Dinner Meetings & Events

September 19: Tutorial: *"ISO 9001 to ISO 13485 Bridging the Gap" & "Upcoming Changes in the Standards"*

Dinner Presentation: *"Practical Approaches to Root Cause Analysis – Interactive Workshop"*

October 17: "Improvement Discussion Process as a Vehicle for Organizational Progress" with Jack Hahn of Stanford Linear Accelerator

November 21: Panel on Future Developments in the Biomedical Industry – Joint Section Meeting!

December: No Dinner Meeting – Happy Holidays!

January 18, 2008: Dr. Maurice Ghysels on Continuous Improvement Parallels with Industry and Education – Real Life Experiences

February 20, 2008: Panel and open discussion on "Best Practices to Achieve Success in Certification Exams"

March 19, 2008: James Harrington on the Total Quality Equation

April 16, 2008: Brian Martin on “Current Global RoHAS Requirements”

May 21, 2008: Chuck Mignosa on “Quality is Magical but Quality Doesn’t Magically Happen”

We are planning our 2008 meetings and looking for innovative ideas. Is there a place you want to tour to see their quality system at work that you want to tour? Do you have a topic you want to speak on? Do you have a speaker for us? Contact m.shovlin@comcast.net to share your suggestions!

4) ASQ Section Volunteer Position Openings – Come where the action is – be a part of the SV ASQ Section Leadership in these arenas:

- **SV ASQ Officers and Leadership for 2007-2008: New Officer and leadership information is available on the Section website at <http://www.asq-silicon-valley.org/ExecCom/SectionOfficertbl.html>**
- **Audit Committee Chair:** Our Audit committee member, Deborah Blackmon, requests anyone with auditing experience who would like to lead the Audit committee in developing an Audit Plan for 2007-2008 to contact her at Blackmon.deborah@gene.com
- **Program Chair:** help plan & implement programs and activities; contact potential speakers & work with others to design programs. This is a fantastic position for making new contacts valuable in the world of Quality!
- **ENEWS Editor** – Gather the news from the Leadership Team, assemble in Word, then upload into our cool newsletter email program. Takes about 1 – 2 hours per month – and you learn a new software tool!

For more information about any of these critical positions, please contact cidnani@yahoo.com and/or attend the **Silicon Valley ASQ Leadership Meeting, the first Wednesday of the month, September 5, 6 PM, at 100 N. Winchester Blvd., Third Floor Conference Room, San Jose.**

5) SV ASQ Special Projects

- Member Re-Certifications for 2007, to date:

Latest Recertifications – Congratulations to:

Haney Abdelwahed, CQE, CSQE; Barrett Craner, CQA, CQE, CRE, CQA-Bio; John R. Crepeau, CQE, CRE; Manthos Economou, CQE, CRE, CQM/CSSBB; H. James Harrington, CQE, CRE; Suvarna Jalundhwala, CQA; Jay King, CSQE; Charlotte Roberta Smith, CSQE; Prior Certifications: Dale L. Anderson, CQE; Peter B. Ashaolu, CQE; Lawrence A. Baugher, CQE; Warren P. Butts, CQA; Michael Chaba, CQA, CBA; Jackson W. Chang, CQA, CQE, CRE, CQM; Rick Chapsadle, CQA, CQE, CQM; Udey Chaudhry, CSSBB; Daniel E. Chu, CQA; Brian Claes, CQA, CQE, CRE; Sarita Dave, CQA; Shaalini Doan, CQA; Eliot L. Eng, CQA, CQE; Don M. Fallon, CQE, CQA, CBA; Rhonda Farrell, CSQE; Anwar Ghazi, CRE; Glen Hansen, CQA, CQE; Rafi K. Khawaja, CSQE; Derrick Kidani, CSSBB; Romeo Mayo, CQE; Carlos Mena, CQE; Damon Moreland, CQE; Dami Patel, CQM; Kenneth W. Paxton, CQA, CQE; Hortensia Pinon, CQE; Saeko Reignierd, CQA, CQE; Krina Shah, CQE; Winifred J. Sloan, CQA; Richard Spano, CQA, CQE, CQA-Bio; **Kelly S. Stone, CQE**; John Taber, CSQE; Terry L. Taylor, CRE; Robert W. Trietley, Jr., CQA; Neil Vanden Brook, CQE; Janice Walker, CQE

6) Section Special Interest Meetings

- SSQA MONTHLY MEETING: Tuesday September 11, 2007, 6:30 - 8:15

TOPIC: TBD

NEW MEETING LOCATION: UCSC Extension, 1180 Bordeaux Dr, Room 111 (check lobby directory for room update), Sunnyvale, CA 94089 <<http://www.ssqa-sv.org>><http://www.ssqa-sv.org>

CONTACT: Ken Doran, ASQ-CSQE, CQMgr, Chair, SSQA
<<mailto:kendoran9@yahoo.com>>kendoran9@yahoo.com

CELEBRATING 20 YEARS OF SSQA

- Statistics Discussion Group will meet September 12, at Applied Materials, 6 to 8 PM.

Topic: Early Reliability Testing with Mr. Mike Silverman and Dr. Arthur Zingher

Abstract: Almost every industry is competing on Reliability and therefore, there is a need to develop more reliable products faster. However, reliability testing and improvement often are performed when development is nearly complete, when the product is nearly frozen, when time is short, and when improvements are more difficult and costly. Instead, Early Reliability Testing is a development tactic that can provide higher reliability and quality, with less cost and time for development, and less development risk.

The big drawback to early testing are: low test coverage, low number of samples, and samples with immature manufacturing processes. However, all of these issues can be addressed and overcome, and when this happens, the benefits of early life testing are substantial.

In this presentation, we shall illustrate many of the techniques we use for Early Reliability Testing, point out all of the benefits and cost-savings, and show how to work around the potential issues.

Speaker Bio: Mike is an experienced leader in reliability improvement through analysis and testing. He has also led numerous quality system development programs. He has 22 years of reliability and quality experience, the majority in start-up companies. Mike is also an expert in accelerated reliability techniques, including HALT and HASS. He set up and ran an accelerated reliability test lab for 5 years, testing over 300 products for 100 companies in 40 different industries. Mike is founder and managing partner at Ops A La Carte, a Professional Business Operations Company that offers a broad array of expert services in support of new product development and production initiatives. Through Ops A La Carte, Mike has had extensive experience as a consultant to high-tech companies, and has consulted for over 100 companies including Cisco, Ciena, Siemens, Intuitive Surgical, Abbott Labs, and Applied Materials. He has consulted in a variety of different industries including telecommunications, networking, medical, semiconductor, semiconductor equipment, consumer electronics, and defense electronics. Mike has authored and published 7 papers on reliability techniques and has presented these around the world including China, Germany, and Canada. He has also developed and currently teaches 8 courses on reliability techniques. Mike has a BS degree in Electrical and Computer Engineering from the University of Colorado at Boulder, and is both a Certified Reliability Engineer and a course instructor through the American Society for Quality (ASQ), IEEE, Effective Training Associates, and Hobbs Engineering. Mike is a member of ASQ, IEEE, SME, ASME, PATCA, and IEEE Consulting Society.

MEETING SCHEDULE

Our 2007 scheduled speakers and topics:(all meetings are on the second Wednesday of each month)

Sep 12 - Mr. Mike Silverman - TBD

Oct 10 - Mr. Fred Schenkelberg - Traits of an Effective Reliability Program

Nov 14 - SPC Panel Discussion (Bring your questions)

and - Annual Speakers Dinner

Dec 13 - No meeting, Happy Holidays

Our 2008 scheduled speakers and topics:(all meetings are on the second Wednesday of each month)

Jan 9 - Mr. Jack Tomsy - Empirical Bayes Acceptance Sampling

Feb 13 -

Mar 12 - Mr. John Kendrick - AHP for Six Sigma Project Selection and Optimization

Apr 9 -
May 14 - DOE Panel Discussion
Jun 11 - Dr. John J. Flaig ^ Sequential Simplex EVOP
Jul 9 -
Aug 13 -
Sep 10 -
Oct 8 - SPC Panel Discussion
Nov 12 -
and - Annual Speakers Dinner
Dec 10 - No meeting, Happy Holidays

MEETING DETAILS: 6:00 to 6:30 pm Introductions and Networking; 6:30 to 7:30 pm Presentation
7:30 to 8:00 pm Question and Answer Session

LOCATION: Applied Materials, Bowers Cafe (aka Campus Cafe), 3090 Bowers Ave., Santa Clara, CA. 95054 (see directions below)

If possible please RSVP by Monday evening if you plan to attend so we can have the badges pre-printed for you. Pizza and soft drinks will be available (\$5.00 for 2 pieces of Pizza and \$1.00 for drinks - water or cola).

For more information contact Rosetrina at: Applied Technology, 1237 Clark Way, San Jose, CA 95125; Tel: (408) 266-5174; Email: <mailto:Inquiry%40e-AT-USA.com>Inquiry@e-AT-USA.com
Website: www.e-AT-USA.com

- ISO Standards Discussion Group will meet September 18, at Linear Technology Corp., 1630 McCarthy Blvd, Milpitas. PLEASE NOTE THIS IS A NEW MEETING LOCATION. , Contact is Dirk Van Putten at (408) 432-1900 , e-mail: dvanputten@linear.com

Topic: EAGLE'S INSIGHT: "Experience Speaks of Lessons Learned". Come learn from the voices of experience about the most common challenges companies have with achieving ISO certification and their efforts in problem solving and continuous improvement. EAGLE Registrations has assembled the real-world experiences of over 50 third-party auditors and business participants for this collaborative presentation. Topics will include:

1. What Auditors see as the top challenges clients have in obtaining and maintaining ISO Certification and the best corrective action plans they have seen to resolve these issues.
2. Also, what Clients and their Business Participants express are their biggest hurdles with ISO certification and their best efforts to overcome these issues.

Speaker: Mr. Burjor Mehta, President/CEO of ISSI & RABQSA Certified Lead Auditor for EAGLE Registrations, Inc. Mr. Mehta oversees ISSI's offerings for customized business strategy consulting, managed services and security solutions for quality management for clients. He has taught "Value-Added Internal Audits", "Problem Solving Tools", and "Managing an ISO Quality System". Burjor is a RABQSA Certified Lead Auditor having audited over 350 companies.

7) ASQ Certification Courses

Below is the course summary for the 2007 Certificate Preparation Classes sponsored by the Silicon Valley Section of ASQ. If you're interested in the course, E-mail Don Evans your contact information ASAP including FIRST/LAST NAME, daytime telephone, Course number interest (C01 – C14,) and class ID. Once the minimum class size is met, Don will provide you with the registration instructions. **Don Evans, Certification Prep Coordinator , DEvans@natus.com 408.718.8189.**

INSTRUCTORS NEEDED: If you are a subject matter expert in one of the Certification areas and/or have experience teaching these courses and want to become an instructor, contact Don Evans at , DEvans@natus.com 408.718.8189 for an instructor application. Don can send you a copy of the SV ASQ Section standards & requirements for instructors.

ASQ Silicon Valley Section 0613 2007 Certification Preparation Class Schedule

Some popular classes are scheduled but subject to cancellation from low enrollment. These classes have committed instructors to support you. Other classes will form on as requested basis. Any forward visibility is helpful, so ask NOW.

CRE: No Schedule; interested persons contact Don Evans

CQI: No Schedule; interested persons contact Don Evans

C01 - Certified Calibration Technician

CCT-WN1 10/18/07 – 11/15/07 – Thursday - 06:00PM – 10:00PM – Southbay – Instructor: Don Evans

C04 – Auditing BIOMEDICAL

CQAB-FA1 8/29/07 – 10/17/07 Wednesday, 6:00PM - 9:30PM. South bay. Instructor: Brian Grigsby

C06 – Quality Engineering

CQE-FA1 09/11/07 – 11/13/07 – Tuesday – 06:00PM – 10:00PM – Southbay – Instructor: Don Evans

CQE-FA2 09/22/07- 11/17/07 – Saturday – 08:00AM – 05:00PM – Southbay – Instructor: Don Evans

Basic requirements for CQE - understanding of basic probability, high school algebra, some statistical work.

CQT

C10 – Quality Technician: No Schedule; interested persons contact Don Evans

CQT-FA1

C12 – Six Sigma Black Belt

CSSBB- FA1 08/22/07 – 10/17/07 Wednesday, 5:30PM – 8:30 PM. Milpitas. Instructor: Govind Ramu

C13 – Six Sigma Green Belt

CSSGB- FA1 08/22/07 – 10/17/07 Wednesday, 5:30PM – 8:30 PM. Southbay. Instructor: Bob Husar

CQA – Certified Quality Auditor - October 11 through November 15, Thursdays class time 6-10pm

Basic requirements - basic understanding of sampling ANSI Z1.4 and ANSI Z1.9

8) Biomedical Courses for 2007 Fall Schedule

The Biomedical course schedule and descriptions will be available on the SV ASQ website <http://www.asq-silicon-valley.org>. Contact Jim Bischof at JBischof01@aol.com to register for all courses and for a copy of the course schedule. Include your name, home and work addresses, home phone, work phone, and e-mail address. For questions about the biomedical classes, contact jbischof01@aol.com.

Please note new class pricing. ASQ members have lower prices than non members. Members must supply member number to get member price. Unemployed persons have lower prices than employed persons. Course payment is due when registering.

To join ASQ phone 1-800-248-1946 or log on to <http://www.asq.org>.

Schedule of Classes – Biomedical Education-New Classes Added FALL 2007

No.	Course Title	# of Classes	Dates	Day	Time	Location and Address	Instructor	Price (See price code below)
604	ISO 9001:2000 QMS Transition (14 hrs total)	2	Sep 13, 20 (Tentative)	Thu	9-12, 1-5	TBD (Call J Bischof if you wish to hold this class at your site)	Marieann Shovlin	NME=\$360 ME= \$285 NMU=\$115 MU=\$105
606	Complaint Handling, Medical Device Reporting (6 hrs total)	1	Sep 21	Fri	9am to 12pm, 1pm to 4pm	TBD (Call J Bischof if you wish to hold this class at your site)	Richard Rush	NME=\$175 ME= \$140 NMU=\$60 MU=\$55
625	Document Control and Records Management in Regulated Environments (8 hours total)		Sep 29	Sat	8-12, 1-5pm	TBD (Call J Bischof if you wish to hold this class at your site)	Deborah Blackmon	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
613A	Basic Statistical Principles Necessary to Understand Part B of this course. (6 hrs total)	1	Oct 2	Tue	9-12, 1-5	TBD (Call J Bischof if you wish to hold this class at your site)	John Zorich	Revise prices NME=\$175 ME= \$140 NMU=\$60 MU=\$55
601	Introduction to the Bio Medical Industry (16 hrs total)	4	Oct 2, 9, 16, 23	Tue	6pm-10pm	TBD (Call J Bischof if you wish to hold this class at your site)	Marieann Shovlin	NME=\$380 ME= \$305 NMU=\$120 MU=\$110
620	Medical Terminology for the Medical Device Professional (8 hours total)	1	Oct 4	Thu	8am to 12pm, 1pm to 5pm	TBD(Call J Bischof if you wish to hold this class at your site)	Dr. Sudhi Gautam	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
613B	Choosing Sample Size for Test & Inspection in QC/QA, Mfg., & Engineering (8 hrs total)	1	Oct 9	Tue	8-12, 1-5	TBD (Call J Bischof if you wish to hold this class at your site)	John Zorich	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
622	Science and Technology of Medical Devices (8 hours total)	1	Oct 11	Thu	10am to 6pm	Girvan Bldg. 3940 Freedom Circle, Santa	Dr. Sudhi Gautam	NME=\$220 ME= \$175 NMU=\$80 MU=\$70

						Clara		
618	ISO 13485:2003 – Implementation and Transitioning of the QMS for Medical Device Organizations (16 hours total)	2	Oct 13, 20	Sat	8-12, 1-5	TBD (Call J Bischof if you wish to hold this class at your site)	Marieann Shovlin	NME=\$380 ME= \$305 NMU=\$120 MU=\$110
602	Quality System Regulation (QSR) for Medical Devices (13.5 hrs total)	2	Oct 15, 17, 22 6:30 to 10pm Oct 24 6:30 to 9:30pm	Mon, Wed		TBD (Call J Bischof if you wish to hold this class at your site)	Bill Hufford	NME=340 ME= \$270 NMU=\$110 MU=\$100
627	Medical Devices: State of the Industry 2007 (8 hours total)	1	Oct 18	Thur	9:30 to 12:30, 1:00 to 6pm	Girvan Bldg. 3940 Freedom Circle, Santa Clara	Dr. Sudhi Gautam	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
614	ISO Quality Management System Implementation (8 hours total)	1	Oct 25	Thu	8am-12pm, 1pm - 5pm	TBD (Call J Bischof if you wish to hold this class at your site)	Marieann Shovlin	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
616	Auditing (FDA, Notified Body, Internal) (4 hours total)	1	Nov 3	Thu	6pm to 10pm	TBD (Call J Bischof if you wish to hold this class at your site)	Barry Craner	NME=\$95 ME= \$75 NMU=\$30 MU=\$25
628	Health and Wellness Strategies for Medical Device Professionals (8 hours total)	1	Nov 8	Thur	9:30 to 12:30, 1pm to 6pm	Girvan Bldg. 3940 Freedom Circle, Santa Clara	Dr. Sudhi Gautam	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
612	Design Control Requirements (8 hrs total)	2	Dec 1	Sat	8am-12pm, 1pm to 5pm	TBD (Call J Bischof if you wish to hold this class at your site)	Barry Craner	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
611	Risk Management (8 hours total)	1	Dec 15	Sat	8am to 12pm, 1pm to 5pm	TBD (Call J Bischof if you wish to hold this class at your site)	Barry Craner	NME=\$220 ME= \$175 NMU=\$80 MU=\$70

615	Validation of Computer System Used in Production and/or Quality Systems (12 hours total)	2	Feb 16, 23 2008 (tentative)	Sat	9-12, 1-4	TBD (Call J Bischof if you wish to hold this class at your site)	Tim Stein	NME=\$400 ME= \$330 NMU=\$170 MU=\$160
623	Basic Design of Experiments (16 hours total)	2	TBD	TBD	8am-12pm, 1pm to 5pm	TBD (Call J Bischof if you wish to hold this class at your site)	Soly Paterson	
619	Obtaining the CE Mark, MDD requirements, CMDR, PAL (8 hours total)	1	TBD	TBD	TBD	TBD(Call J Bischof if you wish to hold this class at your site)	TBD	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
610	Electronic Signatures Part 11 (4.5 hrs total)	1	TBD (Not currently scheduled)	TBD	8:30am to 1pm	TBD (Call J Bischof if you wish to hold this class at your site)	Greg Look	NME=\$105 ME= \$85 NMU=\$30 MU=\$25
621	Introduction to Physiology for the Medical Device Professional (16 hours total)	2	TBD (Not currently scheduled)		8am to 12pm, 1pm to 5pm	TBD(Call J Bischof if you wish to hold this class at your site)	Dr. Sudhi Gautam	NME=\$380 ME= \$305 NMU=\$120 MU=\$110
603	Preparing and submitting 510k's, PMA's (4 hrs total)	1	TBD	Fri	8-12	TBD (Call J Bischof if you wish to hold this class at your site)	Mike Crompton	NME=\$95 ME= \$75 NMU=\$30 MU=\$25
C04	Certified Quality Auditor-Biomedical Exam Preparation Course (28 hrs total)	8	TBD	Wednesdays	6:00pm to 9:30pm	Contact Brian Grigsby at 408-741-8773 X317	Brian Grigsby	Contact Brian Grigsby at 408-741-8773 X317
607	Sterilization Validation for the Medical Device Industry (8 hours total)	1	TBD	Wed	8am to 12pm, 1pm to 5pm	TBD (Call J Bischof if you wish to hold this class at your site)	Dr. Iliia Jimenez	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
608	Overview of Lean Manufacturing (8 hrs total)	1	TBD	Thu	8-12, 1-5	100 N Winchester Blvd. Santa Clara. 3rd floor	Paul Jahanian	NME=\$220 ME= \$175 NMU=\$80 MU=\$70

						conference room (Tentative)		
605	Process Validation (8 hrs total)	1	TBD	Tue	8-12, 1-5	TBD (Call J Bischof if you wish to hold this class at your site)	Dr. Wayne Schrier	NME=\$220 ME= \$175 NMU=\$80 MU=\$70
624	Value Stream Mapping (8 hrs total)	1	TBD	Thu	8am-12pm, 1pm to 5pm	TBD (Call J Bischof if you wish to hold this class at your site)	Paul Jahanian	NME=\$220 ME= \$175 NMU=\$80 MU=\$70

Price coding is as follows:

- NME = Non member employed price
- ME = Member employed price
- NMU = Non member unemployed price
- MU = Member unemployed price

There is a 10% discount for each of three or more people from the same company for the same class.

Please contact Jim Bischof (Ph: 408-972-8852, jbischof01@aol.com) for more information on other local ASQ activities, other Sources of training in quality, regulatory affairs, and related areas, and help for job seekers.

In Closing, remember to sign up for the September 19, 2007 Dinner Meeting at <http://www.asq-silicon-valley.org> - and join us in our continuing celebration of our 42nd Anniversary - 42 Years of Quality!

“If we want to see more of the good news than the bad, we will have to do it for ourselves. It is no good waiting for an unidentified “they” to fix our world for us.”

Charles Handy

Please send inputs and comments to SV ASQ E-News Editor, m.shovlin@comcast.net