

This message is sent by the Silicon Valley Section of the American Society for Quality as a benefit of your membership.

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](mailto: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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**- Silicon Valley ASQ Leadership Meeting for November will be held Wednesday, November 7. Please join us Wednesday, November 7, 2007, at 100 N. Winchester Blvd., San Jose. Contact [Chandru Idnani at cidnani@yahoo.com](mailto:ChandruIdnani@cidnani@yahoo.com) to RSVP.**

**Share your voice - participate in your Section planning and activity implementation throughout the year!**

**1) Upcoming Special Events & News**

**- ASQ International Team Excellence Awards** - Deborah Blackmon, Section 613 Vice Chair, will be judging a preliminary round of the ASQ International Team Excellence Award on Nov 8-9 in Denver, CO. Participating in the Team Excellence process is a superb way to promote business effectiveness and demonstrate commitment to quality and learn more about formal team practices. The Award Criteria detail and scoring guidelines can be obtained from the ASQ website for use in self assessment and improvement. <http://www.asq.org>. The Team Excellence Award recipients will be announced on May 2, 2008 at the ASQ World Conference on Quality and Improvement in Houston TX after a final round of live competition between the quality team preliminary finalists.

**- CONGRATULATIONS to Dr. H. James Harrington**, one of our members, on being awarded the Simon Collier Quality Award! The award will be made at the Nov. 14, 2007 meeting of the Los Angeles ASQ Section. Additional information and reservations can be obtained at <http://www.asq-la.org>. All are invited to hear his talk on the Five Pillars for Excellence. Dr. Harrington will be the SV ASQ Dinner Meeting speaker in March 19, 2008.

**- An OFFER for the ASQ Membership: Come get a free 1 ½ hour session with Ingrid Gudenas, one of today's leading experts on the subject of communication skills.** At the June ASQ dinner meeting, Ingrid gave a talk on communication that was very well received and she has been asked back in 2008. She has agreed to offer a free, no obligation communication evaluations to this hard working group. This offer will not be available indefinitely, so call us now to reserve your time!

You will get

- ❖ An evaluation of your skills by an expert in the subject!
- ❖ A detailed look at the 18 skills you need to handle difficult people and situations.
- ❖ An answer for what you can do right now that can drastically improve your ability as a communicator.

Write to [cris@trainingsuccess.com](mailto:cris@trainingsuccess.com) or call 510-797-6806 right now to schedule an appt with Ingrid. We look forward to meeting you!

**- BioDevice Group Meetings:** Networking meetings are held on the 1st, 3rd, and 4th Tuesdays of each month for unemployed biomedical professionals, or people wishing to get into the biomedical industry. Meetings are

held at 8:30am at the Sunnyvale Employment Development Campus at 505 West Olive Ave., Room 510, Sunnyvale. Go to <http://www.biodevicegroup.org> for more information.

**2) November Dinner Meeting Information: New Developments in Biomedical Technology, November 28, 2007, 5:30 – 8:30, at the Embassy Suites Hotel, Milpitas, CA, map below.**

ASQ Silicon Valley Section, in collaboration with ASQ Golden Gate Section and the Northern California Biomedical Discussion Group invite you to participate in a Panel Discussion: **New Developments in Biomedical Technology.**

**Topics include:**

1) **State of the Medical Device industry** – with an introduction by panel moderator Sudhi Gautam:

The medical device industry is one of the fastest growing high technology sectors in USA . Innovation in the medical device industry continues at an accelerating pace and a number of important trends are taking root, ranging from integrated combination devices that deliver drugs to stem-cell therapies. What are the current technical, business, regulatory, quality, process and market trends that will shape the medical device sector in 2008?

2) **Technical & Process Innovations that impact the field** with Bikash Chatterjee:

Innovation has been the corner stone of biomedical product development. This presentation will explore some of the latest innovations which are providing the driving force for the industry, the potential ramifications of overseas product development and considerations for the future.

3) **New Product Advancements in the field** with Richard Rush:

As changes in regulation, technology, business climate, and healthcare financing unfold, Quality professionals must continue to adapt to the changing environment and bring new knowledge and skills to the workplace. Find out where venture capitalists are spending their investment dollars, the clinical areas that are being affected, and how you can advance your skills to improve your marketability and job satisfaction.

4) **Regulatory Changes that impact the industry** with Gary Seeger:

There are a number of regulatory changes that impact the medical device industry. This section will present a very brief summary of some of the more significant regulatory changes that will impact the industry including the new FDA medical device user fees and annual electronic establishment registration, the updated ISO 14971 risk standard, the updated IEC 60601-1 electrical safety standard, the updated Medical Device Directive, the Medical Vigilance reporting changes, the China medical device registration process, and the Japanese notified body inspections of medical device manufacturing facilities for new product license approvals in Japan.

**Question & Answer Session:**

After these presentations, this insightful panel will address these questions – plus yours:

*Where are the Medical Device VCs investing their dollars?*

*What are the new markets within the Medical Device Sector?*

*How new technologies affecting how medical devices are being developed?*

*What are the new Regulatory challenges? How is FDA helping or retarding innovation in the industry?*

*What new clinical developments is likely to affect the Medical Device world?*

*What are the Technical & Process Innovations that impact the field?*

*What new knowledge has to be acquired by medical device industry professionals to stay abreast of the new changes and improve marketability?*

**Agenda:**

**5:30: Brief business session**

**5:45: Sumptuous buffet dinner**

**6:30 – 8:30 New Developments in Biomedical Technology Panel**

**Register at: <http://www.asq-silicon-valley.org/>**

**Location and Directions: Embassy Suites Hotel**, 901 East Calaveras Blvd., Milpitas, CA 95035. Directions: <http://www.google.com/maps?f=d&saddr=&daddr=901+E+Calaveras+Blvd+Milpitas,+CA+95035&cd=1&ie=UTF8&z=16&om=1>

Dinner cost: \$35 employed; \$20 unemployed.

**Panel Bios:**

**Dr. Sudhi Gautam** is a surgeon-turned-biomedical engineer who after eight years of surgical practice saw the impact that engineering technology could have in addressing clinically unmet needs. This motivated him to pursue a Ph.D. in Engineering at the Indian Institute of Technology, Bombay and post-doctoral research at University of Michigan , Ann Arbor . In 2005, he founded MedTech Bridge , a consulting and training startup whose mission is to

expedite biomedical innovation and enhance corporate productivity. Medtech Bridge helps hi-tech and non-medical companies to enter biomedical markets by conceptualizing new innovative biomedical products leveraging their own core technologies and strengths. It helps early stage companies get off the ground by developing strategies and doing technology assessments, due diligence and evaluating competitive attractiveness of opportunities to make investment decisions."

**Mr. Bikash Chatterjee** has 21 years experience in the Pharmaceutical, Bio Sciences, Medical Device and Diagnostic areas. He has held senior management positions in operating companies for over a decade. He has successfully brought multiple drug platforms through the drug development process to market. He has broad experience in the development and implementation of strategic initiatives for the Development, Quality and Operations environment and in establishing the necessary infrastructure to support a regulated product. He has significant experience in engineering, automation, and process development of discrete and continuous processes. Mr. Chatterjee is recognized as an industry expert in computer validation and Part 11 Compliance and in the establishment of the computer validation lifecycle and GAMP 4 requirements. His experience encompasses all elements of solid, semi-solid and parenteral manufacturing, cell culture and purification processing. He has built and validated multiple manufacturing, and support facilities, is versed in CMC and regulatory requirements for FDA and European filings, including PAI activities, as well as, support activities for new product introductions.

**Mr. Richard Rush** of Quality Management Consulting is a quality consultant who works with small, growing and changing businesses. Quality Management Consulting designs customized Quality Systems, assesses companies for performance improvement, and trains employees in quality leadership skills. A former Vice President at Guidant Corporation, Richard has held leadership positions at other internationally respected companies such as Alcon Laboratories, and Coherent, Incorporated. He has a Masters degree in Business Administration (UC Berkeley), a Bachelor of Science degree in General Engineering (UI Urbana) and advanced coursework from Universities of Iowa, Michigan, and Wisconsin.

**Mr. Gary Seeger** is the Vice President of Quality Assurance and Regulatory Affairs at Iridex Corporation in Mountain View, CA. Gary has over 35 years of experience in pharmaceutical and medical device quality assurance and regulatory affairs. He has significant expertise in 510(k) clearances and CE Mark approvals, particularly with therapeutic energy delivery devices and extensive experience in the transfer of products from design to manufacturing. He is a certified quality engineer and certified reliability engineer with the American Society for Quality (ASQ) and serves on the Board of the ASQ Northern California Biomedical Discussion Group. Gary holds a BS in physics from Harvey Mudd College and an MBA from UCLA.

### **3) *Future SV ASQ Dinner Meetings & Events***

**November 28: Panel on New Developments in the Biomedical Industry – Joint Section Meeting with Golden Gate and Northern California Biomedical Discussion Group at the Embassy Suites in Milpitas. Moderated by Dr. Sudhi Gautam with panelists Bikash Chatterjee, Richard Love, Richard Rush, and Gary Seeger. Join us for a dynamite evening!**

**December: No Dinner Meeting – Happy Holidays!**

**January 18, 2008: Maurice Ghysels on “Continuous Improvement Parallels with Industry & 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”**

**June 18, 2008: Ingrid Gudenas on “Assessing Training Effectivity”**

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](mailto: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:

- **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](mailto: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!
- **Nominations will be opening for 2008-2009 SV ASQ Officers in January, 2008. Do you want to earn extra CRU's, participate in an exciting leadership opportunity, and help build the future quality community of practice? Contact Marieann Shovlin at [m.shovlin@Comcast.net](mailto:m.shovlin@Comcast.net)**

For more information about any of these critical positions, please contact [m.shovlin@Comcast.net](mailto:m.shovlin@Comcast.net) and/or attend the **Silicon Valley ASQ Leadership Meeting, the first Wednesday of the month, 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:**

Mohamed A. Absourlseoud, CQA, CQE; Kevin Debella, CQE; Michael L. Knaebel, CQM;  
Prior Certifications: Haney Abdelwahed, CQE, CSQE; Barrett Craner, CQA, CQE, CRE, CQA-Bio; John R. Crepeau, CQE, CRE; Manthos Economou, CQE, CRE, CQM/CSSBB; Ed Fincke, CQM; H. James Harrington, CQE, CRE; Suvarna Jalundhwala, CQA; Jay King, CSQE; Charlotte Roberta Smith, CSQE; 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; Jess Jiminez, CQA; Rafi K. Khawaja, CSQE; Derrick Kidani, CSSBB; John Martsof, CQE; Romeo Mayo, CQE; Carlos Mena, CQE; Damon Moreland, CQE; Lanny Ng, CQA, CRE, CSSBB; Dami Patel, CQM; Kenneth W. Paxton, CQA, CQE; Hortensia Pinon, CQE; Saeko Reignierd, CQA, CQE; Krina Shah, CQE; Kamaljit K. Sigel, CQA; Winifred J. Sloan, CQA; Richard Spano, CQA, CQE, CQA-Bio; Kelly S. Stone, CQE; John Taber, CSQE; Terry L. Taylor, CRE; Nazareno Timbol, CQE, CQM; Robert W. Trietley, Jr., CQA; Neil Vanden Brook, CQE; Janice Walker, CQE

#### 6) **Section Special Interest Meetings**

**- SSQA MONTHLY MEETING:** Tuesday, November 14, 2007, 6:30 - 8:15 pm, **HP Cupertino** (directions below)

**TOPIC:** TBA

**NEW MEETING LOCATION:** Hewlett-Packard, Building 48, Oak Room

**19483 Pruneridge Ave** (near corner of Wolfe Rd, just off I-280), **Cupertino, CA 95014**

SSQA meetings are now held on HP's Cupertino campus at 19483 Pruneridge Ave in Building 48. HP's campus (bounded by Pruneridge, Wolfe, Homestead and Tantau) offers terrific freeway access to nearby I-280 (just 1 block away) and Hwy-85. A map of HP's Cupertino campus is posted on the SSQA home page. The Oak Room (our new home) is a comfortable 100-seat facility.

**SSQA:** The Silicon Valley Software Quality Association (SSQA) meets monthly to discuss topics of interest to software quality engineers, testers, and developers. SSQA meetings are FREE, open to the public, and held on the second Tuesday of each month at 6:30 pm on HP's Cupertino campus. No RSVP is necessary. See <http://www.ssqa-sv.org> for more details. SSQA is also the Software Quality Discussion Forum of the Silicon Valley section of the American Society for Quality (ASQ); event attendance thus qualifies for RUs towards recertification by ASQ and other professional societies.

<<http://www.ssqa-sv.org>><http://www.ssqa-sv.org>

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

### CELEBRATING 20 YEARS OF SSQA!

**- The Statistics Discussion Group cordially invites you to attend an outstanding FREE presentation: Traits of an Effective Reliability Program with Mr. Fred Schenkelberg**

**Abstract:** Having the privilege to interview a cross-section of more than 70 product development teams to understand their reliability program has led to a few observations. Only a rare few have mature, cost effective and efficient reliability programs.

A clear understanding of your organization's reliability program along with a clear vision of what is possible is the crucial first step to making systematic program improvements. This presentation explores the key traits which separate good from great reliability programs. Marketing, product volume, complexity and organizational structure do

not tend to matter however a proactive approach, statistical thinking, fact based decision making and integrated reliability tools do tend to make a difference. This paper outlines how to assess your organization and provides highlights of key traits of good and simply great reliability programs.

**Speaker Biography:** Fred joined the ranks of independent consultants to focus on reliability engineering in 2004. He currently works with wide variety of clients using reliability assessments as a starting point to develop detailed reliability plans and programs. Also, he uses his reliability engineering and statistical knowledge to design and conduct accelerated life tests. Fred previously worked at HP starting in Vancouver, WA. He later joined HP's ESTC division in Palo Alto, CA where he co-founded the HP Product Reliability Team. In that role, Fred was responsible for the consulting, training, and community building aspects of HP's Product Reliability Program. He was also responsible for research and development on selected product reliability management topics at HP.

Fred has a Bachelors of Science in Physics from the United States Military Academy and a Masters of Science in Statistics from Stanford University. Fred is an active member of the RAMS Management Committee and is currently the IEEE Reliability Society Santa Clara Valley Chapter Vice President and ASQ Reliability Division Treasurer.

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

Nov 14 - Mr. Fred Schenkelberg - Traits of an Effective Reliability Program 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 - Dr. Hong Liu -

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

Apr 9 - Mr. Ed Russell - TBD

May 14 - DOE Panel Discussion (bring your questions)

Jun 11 - Dr. John Flaig ^ Sequential Simplex EVOP

**MEETING 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).

**- The ISO Standards Discussion Group** meets the third Tuesday of every other month. November 20, 2007, the topic is QC 80000 and RoHS with Stan Salot.

The meetings are from 6 - 8 PM and are held at Linear Technology Corp. 1630 McCarthy Blvd, Milptas, CA 95018. Dirk van Putten (dvanputten@linear.com) leads this group.

**Speaker Bio:** Mr. Salot is an acknowledged expert in business and quality process management and is active in U.S. and international industry standards bodies. He serves as President of the Electronic Component Certification

Corporation, the U.S. representative of the International Electrotechnical Commission Quality Assessment System for Electronic Components (IECQ), and is an officer of the board for the Electronic Component Certification Board (ECCB). Mr. Salot served as the chairman of the work group that authored and implemented the international specification, QC 080000 IECQ HSPM, for hazardous substance process management for the electronics and electrical industries.

Stan has served as Chairman of the Users Advisory Group for the ECCB. He is an active member of the American Society for Quality where he served two terms as Santa Clara Valley Section Chairman, was the founder and chairman of the Silicon Valley ASQ ISO 9000 Users Task Group. Stan co-founded the Santa Clara Valley Software Quality Association. Stan has served as a member of the Advisory Board at the University of California Santa Cruz, the American Electronics Association, NorCal Quality Council and was a member of the American Management Association for many years.

**MEETING SCHEDULE:**

**November 20, 2007 - Stan Salot, QC 080000 and RoHS**

**January 15, 2008 - Joseph Tsiakals, Vice Chair of US Technical Advisory Group to ISO, Discussing new revision of ISO 9004**

**March 18, 2008 - Alka Jarvis, Chair of US Technical Advisory Group to ISO, Discussing changes to ISO 9001**

**7) Silicon Valley ASQ Section #0613 2007 Certification Preparation Course Schedule**

The Course schedule for 2008 is being developed. If you're interested in a particular course, E-mail Don Evans your contact information ASAP including FIRST/LAST NAME, daytime telephone, and Course title. Once the minimum class size is met, Don will provide you with the registration instructions. **Don Evans, Certification Prep Coordinator** , [DEvans@natus.com](mailto: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](mailto: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.

**8) Biomedical Courses for 2007-2008 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](mailto: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](mailto: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)
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

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](mailto: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.

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**In Closing, remember to sign up for the November 28, 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!

**“Success is not the result of spontaneous combustion. You must set yourself on fire.” Reggie Leach**  
**Please send inputs and comments to SV ASQ E-News Editor, [m.shovlin@comcast.net](mailto:m.shovlin@comcast.net)**

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