

***eNews Update from ASQ Golden Gate Section  
ASQ0618, P.O. Box 360985, Milpitas, CA 95036-0985***



**Please note our new Web address:** <http://www.asqgoldengate.org>

### **Upcoming Events**

**Friday, November 7, 2008, 8:00am – 4:00pm** - RAPS-San Francisco presents a one day symposium on "Creating a Globally Harmonized Quality System to Achieve Global Compliance." For more information or to register, [click here](#).

**Thursday, November 20, 2008** – Risk-based Validation, Presented by Wai Wong, Pharmatech Associates

With the issuance of the FDA's guidance documents defining a more scientifically driven product development and quality paradigm, the philosophy and approach to validation must be revisited. New programs within the FDA such as Process Analytical Technology (PAT) and the Pharmaceutical Quality Assessment System require a much more intensive scientific argument as a premise to validation. One possible solution is to adopt the principles classically utilized within operational excellence approaches such as six-sigma to lay the foundation for a more effective approach to validation and process stability. This presentation will discuss the principles classically employed within validation and process development and describe a new approach that embraces the basic elements of Risk Management and Quality by Design as defined within ICH Q8 and 9 and the ASTM E55 guidance as part of a new approach to Validation. If you have found validation to be a bottleneck in your organization or found difficulties as a quality or validation professional being asked to do more with less, this presentation will help with the establishment of a defensible validation approach

The event will start at 5:30pm and end at 8:00pm. Location: Scott's Restaurant, Jack London Square, Oakland. Dinner will be served. To register for this event:

<http://www.acteva.com/booking.cfm?bevaid=169871>

### **Program Chair**

We enjoyed event the presentation on October 14 at Scott's Restaurant in Oakland. Our guest speaker, Ingrid Gudenas, provided us with the latest breakthroughs in communication skills to enhance interactions in the workplace and in our own lives.

Our goal this year is to provide interesting topics that bring real value to our members. We also plan to provide networking time at each event so that we can get to know each other better and benefit from our collective experience.

Please contact me with ideas for events, topics and locations at [events@goldengate.org](mailto:events@goldengate.org). We have commitments from Bayer and Abbott Labs to host meetings later this year and would welcome the opportunity to have meetings/events at other company locations. It's a great opportunity to showcase your company and provide your fellow employees an onsite learning event.

Our planned schedule:

October 14, 2008 – Scott's  
November 20, 2008 – Scott's  
January 15, 2009  
February 19, 2009

March 19, 2009  
April 16, 2009 – Bayer  
May 21, 2009 - Abbott

### **ASQ Golden Gate Season Pass Still Available!**

This year the Golden Gate Section is offering two options for our season pass. Both offer a great value for the cost. The first pass provides access to any 4 scheduled dinner or networking events for \$99.00. The other pass provides access to all scheduled dinner or networking events for \$150.00. Neither pass provides access to seminars or workshops; however, by prior arrangement, you may use two events on your pass and bring a guest along. To sign up for either season pass, please go to: <http://acteva.com/booking.cfm?bevalD=163758>

### **ASQ - Silicon Valley Events**

Information about upcoming events and member services provided by the ASQ Silicon Valley section can be found at: <http://www.asq-silicon-valley.org/>

### **ASQ – San Francisco Events**

Information about upcoming events and member services provided by the ASQ San Francisco section can be found at: <http://www.asq-sf.com/>

### **ASQ – San Francisco/Bay Area Joint Events Calendar**

A combined calendar of upcoming events for the San Francisco, Silicon Valley and Golden Gate Sections can be found on Yahoo's Upcoming.org. To find out what's events are being sponsored by ASQ Sections around the Bay Area, go to: <http://upcoming.yahoo.com/group/5069/>

## **SF/ Bay Area Networking Group available on LinkedIn**

LinkedIn is an online network of more than 25 million experienced professionals from around the world, representing 150 industries. The San Francisco/Bay Area ASQ Sections, including the SF, Silicon Valley and Golden Gate sections, have established a LinkedIn group, ASQ - SF/Bay Area Network - Sections 0604, 0613, and 0618. This provides a means for our members to enhance local professional networking opportunities. We welcome any ASQ member from a San Francisco Bay Area section.

All Golden Gate section members, as of August 2008, have been pre-approved as members of the group. To join the ASQ SF/Bay Area networking group, submit your request through the following URL: <http://www.linkedin.com/e/gis/146713>.

## **Certification News**

The Golden Gate Section hosted the October 18th ASQ Certification Examination at the Dublin San Ramon Services District, 7051 Dublin Blvd., Dublin CA 94568.

Ellen Hill was the Chief Proctor for the exam.

If you sat for this certification exam, whether at this location or another, we wish you the best of luck!

Our Education Chair, Blaine Glandt, may be able to direct you towards exam preparation classes or materials. Please email him at [education@asqgoldengate.org](mailto:education@asqgoldengate.org). For more information, see our [certification page](#) on the Golden Gate Section Website.

On December 6, 2008, the following certification exams will be offered:

[Calibration Technician](#)

[Quality Auditor](#)

[Quality Engineer](#)

[Quality Improvement Associate](#)

[Quality Process Analyst](#)

[Six Sigma Green Belt](#)

[Software Quality Engineer](#)

Complete information on the ASQ certification process can be obtained on <http://www.asq.org/training-and-certification.html>.

## **Recertification Process**

Recertification CPU documentation is available at Golden Gate meetings and sponsored events. Please contact Jim Kohnen at [jim483@aol.com](mailto:jim483@aol.com) with questions about recertification.

## **ASQ Courses Offered by Silicon Valley Section**

Silicon Valley offers a comprehensive selection of technical, certification exam preparation, and biomedical courses. Certification Courses assume participants have had experience in the field they are preparing for and are directed specifically to certification test preparation.

You can find detailed information about the Silicon Valley course offerings at: <http://www.asq-silicon-valley.org/content/view/19/36/>

## Membership Chair

How can you, as an individual member of ASQ, support our section?

Be an internal champion! When an interesting section topic or event is coming up, you might forward or the section email or Web link to colleagues, or post the flyer or screen print in a central location at work or school. Encourage colleagues who might be interested in an event, but who are not members of ASQ, to join you at a meeting. Share information about our section, and send a personalized invite to come check out the event. This opportunity could lead to further interest in the benefits of ASQ and our Golden Gate Section. New members are the lifeblood of every volunteer organization, and your championship would be helping to keep our organization strong.

## Chairman's corner

Risk is a topic we are all too familiar with these days in light of happenings in the global markets. The financial crisis has prompted banking institutions, financial experts, investors, governments and citizens alike to take a look at how we manage risk in the financial sectors as well as with our personal investment accounts. We are living a case study about risk and the lack of adequate & appropriate management oversight and mitigation.

We hear politicians suggesting we need new tools to deal with this economic morass and that a new approach is warranted...and certainly we must not forget homeowners and small business owners and the "Voice of the Customer".

For quality professionals, regardless of industry, risk has always been a topic of interest. It is an ever more serious topic as we consider implications of FDA guidelines; the increasing cost and time it takes to test, and the serious implications if risk is not identified and/or managed properly.

Join us on November 20 to learn about a risk based approach to validation the theme for our dinner meeting at Scott's Seafood at Jack London Square. Wai Wong - Vice President General Manager of **Pharmatech Associates, Inc.**, Golden Gate Section Chair-elect, will discuss the principles classically employed within validation and process development and describe a *new approach* that embraces the basic elements of Risk Management and Quality by Design.

**Special Note:** When I wrote last month at this same time, we had 22 members on the combined Silicon Valley/SF/Golden Gate sections SF/Bay Area network on LinkedIn. Today we have 42. That's fantastic! Let's start some discussions on topics such as communication and risk, and whatever else is top of mind. Submit your questions and we can start a chat to share ideas and thoughts.

Katherine Raymond  
ASQ Golden Gate Section Chair

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