



Biomedical Division

Southern California Discussion Group

in association with San Gabriel Valley Section 702

***The Southern California Discussion Group of the ASQ Biomedical Division Presents:
An Industry Roundtable Discussion***

Wednesday, June 17, 2009 5:30pm to 8:30pm

Topic: “Quality Planning: in support of compliance with ISO 13485 and 21 CFR 820/cGMP (FDA) requirements”

This session will cover the following aspects of Quality planning:

- Establishing measurable and consistent quality objectives
- Structuring the quality management system to assure objectives are met
- Company preparations for a FDA inspection
- Establishing a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured.
- Most helpful records in planning

NOTE: Sufficient time will be allotted for Open Discussion and Q&A

Discussion Leader: Diane G. Kulisek

Diane Kulisek has over 30 years of practical experience within the Quality profession. She is Director of Quality for Moore Industries-International, Inc. and is President of CAPAtrak, LLC, a consulting firm. She has held key management positions within the consumer products, aerospace, and biomedical industries. A former Vice President of QA and Regulatory Affairs at Spectrum Laboratories, her career has also included 8 years within the Gillette Company and 9 years within Rockwell International, culminating with her role as Associate Product Manager for Avionics & Controls on NASA's Space Shuttle Main Engine Program. Her education includes a Bachelor's Degree in Biology, a Graduate Certificate in Program Management and a Master of Science in Engineering Management from CSUN. A Lean Six Sigma Green Belt, Diane is currently Chair of the Quality Advocacy Committee for the San Fernando Valley Section of ASQ, and National Chair for the Food, Drug and Cosmetic Division of ASQ. She is recognized by ASQ as a Certified Manager of Quality/Organizational Excellence and as a Certified Quality Engineer.

Location: Biosense Webster (15715 Arrow Highway, Irwindale, CA 91706)

Food: Sandwich (turkey/beef/veg), chips, and beverages provided.



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To Register: <http://www.acteva.com/booking.cfm?bevaid=184709> at Acteva.com.

**Members \$20-
Non-members \$30-
(.3 R.U.s Awarded)**

*To encourage interaction, **seating is limited** to the first 40 registrants, so sign up soon!*

For more information, contact: Event Coordinator Marina Guevrekian at (626) 303-7902 ext. 2381
or e-mail mguevrekian@staar.com