



Evolving Risk-Based Regulatory Requirements

4 March 2011

Registration Deadline: Payment MUST be received no later than **Friday, 25 February 2011**. Space is limited and may fill prior to deadline; advance registration is strongly recommended.

Send Full Payment:

By mail: RAPS c/o SunTrust Bank
Lockbox Dept., PO Box 79546,
Baltimore, MD 21279-0546

By fax: +1 301 770 2924 (**credit card only**)

Online Information: Visit www.raps.org
Click on "Member Center" in the upper left-hand column, and then click on "Chapters." You will find listings of upcoming chapter events along the right-hand column.

Cancellations: Not accepted; substitutions welcomed with advance notification. Applicable fees apply to substitute registrant.

Questions: Call RAPS Solutions Center at +1 301 770 2920, ext. 200.

RAPS reserves the right to cancel this program at its sole discretion, whereupon all registration fees are refunded. RAPS will not be responsible for travel or other costs incurred due to cancellation.

Registration Contact: Wesley Carr, +1 301 770 2920, ext. 231; wcarr@raps.org

Overview: Join your quality and regulatory colleagues from the ASQ Northern California Biomedical Discussion Group and the RAPS San Francisco Bay Area Chapter for a lively and informative one-day workshop addressing evolving risk-based regulatory requirements in three specific key quality and regulatory areas:

- IEC 60601-1 3rd edition primary, collateral, and particular standards including essential performance, risk management integration, and the impact of changes on industry
- Usability and Human Factors verification, validation, and regulatory requirements
- Clinical evaluation and investigation regulatory requirements

Quality, regulatory and other industry professionals currently working in these areas will leave the program with an expanded and practical understanding of the challenges and opportunities that lie ahead.

Speakers: Geetha Rao, PhD, vice president, risk management and strategy, Triple Ring Technologies, Inc.
Leo Eisner, PE, principal consultant, Eisner Safety Consultants
Ibim Tariah, technical director, BSI Healthcare
Craig J. Coombs, RAC, president, Coombs Medical Device Consulting, Inc.
Juergen Stettin, president and CEO, PROSYSTEM AG

Date/Time: **Friday, 4 March 2011**

7:45 am	Registration Opens
7:45–8:30 am	Registration Check-In, and Continental Breakfast
8:30–12:00 pm	AM Presentations
12:00–1:00 pm	Luncheon and Networking
1:00–4:30 pm	PM Presentations and Q/A Period

Location: Crowne Plaza Mid-Peninsula, 1221 Chess Drive, Foster City, CA 94404
For directions, call +1 650 570 5700.

Local Contacts: Walter Crompton, +1 415 484 1688, geronimo@astound.net
Michelle Ragozzino, PhD. +1 408 861 3861, mragozzino@ucsc-extension.edu

Registration Fees: RAPS and ASQ Member \$175 (Member ID _____) Nonmember \$200 **1121431**

Update the following address in my indicated member record: Business Home

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