

The Southern California Discussion Group of the ASQ Biomedical Division
in association with Temecula/Inland Empire Sections Presents:

Risk Management

Effective Deployment for Strategic Decision Making

An Industry Roundtable Discussion

Thursday, April 19, 2012 5:30pm to 8:30pm

Topic: **Utilizing Risk Management to Drive Business Success**

No longer just another buzzword process, Risk Management has fast become a business necessity driving effective and efficient decision making. Many companies have become adept at applying Risk Management throughout the product development process, but did you know that you could get more out of other Quality Management System processes using the same Risk Management application? Would you like to maximize the effectiveness of your Process Validation system? How about Purchasing and Supplier Controls? How about CAPA? Product Quality? Audits? Good Integration of Risk Management throughout your Quality System can drive a culture of effective and efficient decision making allowing your company to remain nimble and focus resources appropriately.

So how do you get there? Many companies treat Risk Management as its own separate system receiving only minimal benefits from its existence. Maintaining one system across your organization is challenging enough; managing another may make you a patient of your own life saving device! This discussion will show you not only how to use Risk Management for maximum benefit but also how to refine and tie your systems together making them compliant, easy to manage, and useful. *A good Risk Management system helps a business not only comply, but excel.*

Takeaways:

- Refinement of your Risk Management System
- Effective integration of Risk Management throughout your Quality System
- Nimble deployment to drive compliance and business success
- Mistakes and pitfalls

This topic is geared towards the experienced professional and intended to be both advanced and interactive. Please bring your questions, experiences, and other commentary to make this a more valuable experience.

Expert: **Scott Blood, CQE, CQA**

Scott Blood brings more than 15 years of professional experience and leadership in quality, regulatory, operations, and product design for life science companies. He is currently the Senior Director of Quality Assurance at NinePoint Medical, a medical device digital pathology start-up. He also operates his own consulting firm providing services in establishing quality systems, resolving compliance issues, developing sterilization, cleaning, design, and process validations, constructing regulatory strategies for early-stage medical device companies, and representing firms in third party audits including the FDA and Notified Bodies.

Scott sits on the Board of Directors of the Massachusetts Medical Device Industry Council (MassMEDIC) and is a key member of the Biomedical Division of the American Society of Quality (ASQ) leadership team. He is an active committee member of New England ASQ Biomedical Discussion Group and a frequent lecturer on quality, clinical, and regulatory topics relevant to the medical device industry. Scott earned a Bachelors of Science from Wentworth Institute of Technology. He is a Certified Quality Engineer, Certified Quality Auditor, and holds Regulatory Affairs Certification through the Regulatory Affairs Professionals Society.

To Register: <http://www.acteva.com/booking.cfm?bevaaid=229446>

Members \$20-, Non-members \$30-, Walkins \$30- (cash only) if seating is available
Seating is limited to the first 40 registrants, so sign up soon!

Location: **Abbott Vascular** 26531 Ynez Rd., Temecula, CA 92591

Dinner: Dinner and beverages will be provided.

For more information, contact: Lisa Grosskopf at (909) 239-5843 or email lisagrosskopf@yahoo.com

Tony Kalwasinski at (951) 914-2727 or email anthony.kalwasinski@av.abbott.com

As volunteers in a not-for-profit professional organization ASQ Biomedical, SCDG (Southern California Discussion Group) is committed to providing low cost high value events for biomedical professionals and the local community. We are able to keep our costs low by utilizing a registration system that incurs minimal administrative overhead expenses and minimizes excess time and effort spent by our volunteers to bring you these events. Please help us continue providing low cost quality programs to you by using the system that works well for us. If you do not wish to use the registration system to preregister, you may attempt to register at the event, however seating is limited therefore entrance and/or food cannot be guaranteed. Also, due to the nature of the low pricing scheme and the registration system used, we are unable to perform refunds.