



The ASQ Golden Gate Section and ABBOTT



Invite you to participate in a Panel Discussion

" New Developments in Biomedical Technology "

Thursday, April 17, 2008 - 5:30 to 8:30 pm

Abbott Diabetes Care 1360 South Loop Road, Alameda, CA 94502

Topics of interest are as follows:

- State of the Medical Device Industry
- Technical & Process Innovations that impact the field
- Regulatory Changes that impact the industry/ FDA topic (TBD)
- Operational Excellence - Forging Cross Functional Partnerships with R&D and Operations

State of the Medical Device industry with Dr. Sudhi Gautam: The medical device industry is one of the fastest growing high technology sectors in the 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 is the current technical, business, regulatory, quality, process, and market trends that will shape the medical device sector in 2008?

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 that are providing the driving force for the industry, the potential ramifications of overseas product development and considerations for the future.

Regulatory Changes that impact the industry with Janet McDonald PhD: 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 Medical 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.

Operational Excellence - Forging Cross Functional Partnerships with R&D and Operations with Tony Whelan: Alignment of operational excellence and quality management is increasingly a top priority for business leaders in the medical device industry. Whelan will facilitate discussion on how technologies aligned with operational excellence programs improve quality and customer satisfaction, ensure regulatory compliance and minimize direct and indirect costs to maximize global competitive advantage.

Question & Answer Session: After these presentations, this insightful panel will address these topics – 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 development 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?*

Tina Mazurkiewicz

Division Vice President/ Quality Assurance and Compliance/ Abbott Diabetes Care
Host/ Panel moderator

Tina Mazurkiewicz is an ASQ Certified Quality Manager. Since joining Abbott Laboratories in 1987, Tina has worked in Technical Product Development, R&D, Operations, Quality and Regulatory diagnostics devices businesses in Chicago, Germany, Boston and Alameda. Under Tina's direction at Abbott Diabetes Care the quality regulatory submissions has improved and the FDA has recognized the company's CoPilot software submission as their new training standard. Tina graduated from Winona State University and holds a Bachelors Degree in Medical Technology.

Tony Whelan

Division Vice President Worldwide Operations/ Abbott Diabetes Care

Tony Whelan has spent more than 34 years in Healthcare manufacturing and held senior roles in Quality and Operations in Glaxo, Serono, Hoechst and Aventis Pharma. He joined Abbott Diabetes Care in September 2003 as Site Director, Witney, UK and assumed his current role of DVP WW Operations in November 2007. Tony received his Bachelors Degree in Chemistry and Psychology from Liverpool John Moores University and also holds a Masters Degree in Pharmaceutical Quality Assurance from Sunderland University/Royal Society of Chemistry.

Dr. Sudhi Gautam

Founder/MedTech Bridge

Dr. 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. Match 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."

Janet McDonald, PhD

Public Affairs Specialist/ FDA

Janet is a Public Affairs Specialist with the San Francisco District of the U.S. Food and Drug Administration, a position that she has held since 1986. She holds a BS degree in Institution Management and Dietetics from Simmons College in Boston, completed Dietetic Internship at the University of California San Francisco Medical Center, and has a PhD degree in Nutritional Sciences from the University of California at Berkeley. In her capacity as Public Affairs Specialist, she serves as the first line of communication between FDA and the general public, including the media. Her principle responsibility is public education in all matters pertaining to FDA. Janet is a member of several professional organizations, including the American Dietetic Association, American Society for Clinical Nutrition, Institute of Food Technologists, and the Western Association of Food and Drug Officials.

Mr. Bikash Chatterjee

President and Chief Technology Officer/ Pharmatech Associates, Inc.

Mr. Chatterjee is a certified ISO 9000 Lead Assessor and Six-Sigma Master Black Belt. He has extensive experience in the design and implementation of quality systems and has successfully implemented risk based systems, six-sigma and lean manufacturing solutions in the biotech, pharmaceutical, cosmetic and food industries for over 15 years. Pharmatech Associates has managed and successfully deployed Lean and Six Sigma initiatives for both large and small pharmaceutical and biotech customers. Mr. Chatterjee holds a B.A. in Biochemistry and a B.S. in Chemical Engineering from the University of California at San Diego.

Agenda: Light appetizers/buffet dinner will be served.

5:30PM – 6:00PM – Welcome/Networking

6:00PM – 6:30PM – Guest seated and food served

6:30PM – 7:30PM – Panel discussion "**New Developments in Biomedical Technology** "

7:30PM - 8:00PM – QA & Wrap Up

Cost: No cost for registered ASQ members and guests of ABBOTT.

Registration: Limit registration is 75

Please send your registration to "ASQ Golden Gate Section" to ASQ0618, P.O. Box 360985, Milpitas, CA 95036-0985 on the internet at: <http://www.acteva.com/booking.cfm?bevalD=152648>. For a better headcount, email darrell.belt.b@bayer.com or/ and BChatterjee@pharmatechassociates.com for reservation.