



## **The Art of Medical Device Project Management. Don't Let Success "Slip through the Cracks"**

April 11, 2007

Emerging Enterprise Center at Foley Hoag

### ■ **Program Description**

Effective project management will "keep things from falling through the cracks," by utilizing proven tools and techniques. Project Management can play an important and valuable role in medical device development. Effective project management combined with a predictable and measurable product development process can transform medical technology into a successful medical device product.

Medical device development is normally a complex process, involving participation from all disciplines within an organization, and at the same time must be accomplished within the regulatory requirements set forth by the FDA. Project management is a formal discipline that many organizations have adopted to address these development challenges. A project manager leading a medical device development project faces many unique challenges including compliance with complex regulatory requirements such as the FDA, QSR and ISO 13485 design controls.

### ■ **Moderator**

**John Sasso**, Project Manager and Electrical Functional Manager, Haemonetics

### ■ **Panelists**

**Larry Goff**, Director of System Engineering, Farm Design, Inc.

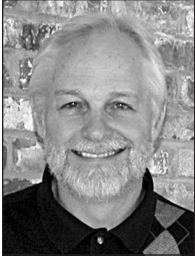
**John Sasso**, Project Manager and Electrical Functional Manager, Haemonetics

**Stephen Teta**, Director of Engineering Services, Instrumentation Laboratory

### ■ **Agenda**

6:00 - 6:30	Networking and light dinner
6:30 - 6:35	MDG announcements
6:35 - 6:45	John Sasso introduction of topic and panelists
6:45 - 7:05	Larry Goff presentation
7:05 - 7:25	Stephen Tetapresentation
7:25 - 7:35	John Sasso presentation
7:35 - 8:10	Panel discussion
8:15	Adjourn

## ■ Biographies



**Larry Goff**

**Larry Goff** has 30 years experience in new product development and engineering management including analog semiconductor, data acquisition systems and medical devices. The most recent 15 years have focused on the development of a variety of medical instruments such as fetal monitors, patient monitors, human heart transport systems, kidney assist devices, airway humidifiers and blood glucose monitors. Areas of expertise include project management, system engineering, user interface design, system architecture development and design controls for complex medical devices and disposable components. He was educated in electrical engineering at Oregon Institute of Technology, San Jose State University and Southern Methodist University. Multiple design patents have been filed for various technologies used in transporting human hearts.



**John Sasso**

**John A. Sasso** has over 15 years experience in high technology companies, including five years executive management in the medical device industry and 10 years' experience in product development, both in engineering and leadership positions. He has managed and grew profitable a U.S. cardiology device distributor from inception to \$28 million annual revenues and 50-plus employees, representing over 65 percent of worldwide business revenue. Mr. Sasso has integrated project management methodology (tools, process definitions and performance metrics) into a company in transition from a single-product line to multiple product and market participation. John received both his BSEE and MSEE from Tufts University and earned his MBA from Bentley College (graduating as class valedictorian). He has been a member of the Project Management Institute for the past 10 years. He has earned numerous awards, including the Professor E. William Dandes Award for Graduate Academic Excellence and the rank of Eagle Scout, and is co-author of "A New Approach to Learning: Strategic Alliances and High Technology," published in *T.H.E. Journal* (October 1997). Mr. Sasso is currently employed by Haemonetics Corp. as a project manager and electrical functional manager in the Life Cycle Management group.



**Stephen Teta Jr.**

**Stephen R. Teta Jr.** is a seasoned product development professional with extensive experience developing medical and commercial instrumentation. He has managed the development of complex instruments involving electronics, mechanisms, complex algorithms, embedded software controls and sophisticated application software. His expertise and experience covers systems engineering, project management, high reliability design, product test and validation and volume production. Mr. Teta is currently director of engineering services for Instrumentation Laboratory. Most recently he was senior manager, electrical engineering for Varian Semiconductor Equipment Associates and director of engineering for Photovac, Inc. Prior to that he was VP, engineering programs, DR systems for Hologic, Inc. developing digital x-ray systems for general radiographic applications. Prior to that he was VP, engineering operations and quality assurance at Amicas, Inc. with responsibility for software development, quality assurance and regulatory affairs for their Web-based medical image management and distribution product and director of engineering at Hologic developing X-ray and ultrasound bone densitometers for diagnosing and treating osteoporosis. Mr. Teta holds bachelor's and master's degrees in electrical engineering from Northeastern University and an MBA from Bentley College.

## ■ MDG Mission

MDG's Mission is to contribute to the continuing development of medical devices and other medical technologies by enhancing the professional development of its members, fostering and supporting entrepreneurial thinking, serving as a forum for exploration of new business opportunities, and promoting best practices in enterprise management.

## ■ MDG Officers, 2006-2007

President	Martin Sklar, Director, Business Development, AlvaMed, LLC
President-Elect	Lisa Sasso, President/CEO, Medical Development Partners & Sasso Solutions
Secretary	Joyce College, Clinical Marketing Consultant
Treasurer	Jim Goell, Ph.D., Product Development Consultant
Board	Jerry Shapiro, Ph.D., President and CEO, Fem-Medical LLC
Board	Ed Berger, Ph.D., Larchmont Strategic Advisors
Board	Bruce Horwitz, President, TechRoadmap Inc.
Board	Judy Isaacson, Director, Vital Now!
Board	David Zlotek, President/CEO, NeuroTech, LLC

## ■ MDG Committee Chairs, 2006-2007

Programming Chair	John Merhige	jmerhige@pluromed.com
Membership Chair	Brian Shoemaker	bshoemaker@shoebarrassoc.com
Marketing Chair	Judy Isaacson	judy@vitalnow.net
Networking Chair	Mariangela Powley	mpowley@janikmedical.com
Sponsorship Chair	Mel Prenovitz	mel@melpren.com
Outreach Chair	Alan Kivnik	akivnik@corummedical.com
Operations Chair	David Miller	davidgmiller1@msn.com

## ■ April Forum Co-Champions:

**Stephen Teta**, Director of Engineering Services, Instrumentation Laboratory

**Prem Ganapathy**, Research Engineer, Tyco Healthcare

**We are always looking for volunteers to help make our forums and networking successful. Please email the chairperson above if you would like to get involved with MDG.**

Educational Opportunities Through MDG

## **Designing Cardiovascular Devices: Begin with the Body in Mind™**

*Presented by Dr. Michael Drues*

This seminar provides an overview of cardiovascular anatomy, physiology and pathophysiology from a medical device perspective. The unique Begin with the Body in Mind™ approach first tries to understand how the body is "designed" to work—then how to design a medical device to work with the body—not against it! Multiple examples of cardiovascular devices and procedural videos are presented in an interactive format.

**Course fee: \$495 plus book cost**

**\$100 deposit due now to reserve your spot. Pay online with credit card. Balance due by first course.**

**New course dates: Thursday evenings, May 10, 24, 31 & June 7**

*For additional information, visit [www.meddevgroup.org](http://www.meddevgroup.org) to secure your space for this exciting course!*

# Medical Development Group

## 2006/2007 Program Calendar

### ■ Forum Meetings

<b>2006</b>	Sept. 6	Strategic Partnerships and Alliances: Assessing, Developing and Managing Relationships
	Oct. 4	Anticipating and Responding to Changing Market Conditions Successfully
	Nov. 1	Seeing the Light—New Advances in Diagnostic Imaging Using Optics and Light
	Dec. 13	The Challenges of Medical Device Startups: Lessons Learned Along the Way
<b>2007</b>	Jan. 10	Beyond FDA—Considerations in Clinical Trial Design & Conduct
	Feb. 7	Distribution Options for Medical Device Companies
	March 7	Integrative Medicine: Thinking Outside the Box

### ▶ All remaining Forums this season will be at Foley Hoag's Emerging Enterprise Center in Waltham.

April 11	Medical Device Project Management. Don't Let Success "Slip through the Cracks"
May 2	Medical Device Software: Don't Let the Bits Byte
June 6	Physician/Clinician Relationships: Making Them Work for You

### ■ Networking Meetings (Pizzeria Uno, Newton Corner, and other locations)

<b>2006</b>	July 19	Medical Technologies: State of the Industry
	Aug. 16	Leadership & Team Building: Developing Intrapreneurial Skills
	Sept. 20	Delivering Care Outside the Hospital as Boomers Turn 60
	Oct. 18	Market Research: Improving Your Product and Market Decisions
	Nov. 15	Medicare: The Changing Rules of Reimbursement ( <i>Location: Silicon Valley Bank</i> )
Dec. 20	Does Size Really Matter: Small vs. Larger Companies	
<b>2007</b>	Jan. 17	Medical Device Outsourcing ( <i>Location: Silicon Valley Bank</i> )
	Feb. 21	Working the Angles: How to Get Good Press
	March 21	Your Intellectual Property: How Much is it Worth?
	April 18	Risk Management (ISO 14971): A Review
	May 16	Strategies for Pre-Clinical Development
	June 20	Post Market Surveillance: What to Expect
	July 18	Working with Academia
	Aug. 15	Finding a Position in the Medical Device Industry

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**If you are interested in sponsorship opportunities,**  
**please contact Mel Prenovitz at [mel@melpren.com](mailto:mel@melpren.com) or 617-738-6599**  
**or David Kaufman at [david\\_kaufman@hotmail.com](mailto:david_kaufman@hotmail.com) or 617-345-6789.**  
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### ■ Upcoming Events

#### **April 18 Networking: *Risk Management (ISO 14971): A Review***

Risk management has become an integral aspect of the medical device development process over the past decade, but industry is still on the learning curve. Risk management is more than risk analysis — it is a comprehensive approach to making sensible decisions. This presentation will review the elements of risk management and how these elements can be used to improve both the product and the process.

#### **May 2 Forum: *Medical Device Software: Don't Let the Bits Byte***

Developing medical device software is a rigorous and sometimes complex process that requires a disciplined approach and compliance to a myriad of standards and regulations. This program will include a brief introduction to this process and then our panelists will share their experience and insights.

Please pre-register for MDG events.  
For more information, visit [www.MedDevGroup.org](http://www.MedDevGroup.org).