

## Medical Development Group 2006/2007 Program Calendar



- **Forum Meetings** (Silicon Valley Bank, 1 Newton Executive Park, 2221 Washington St., Newton)
  - 2006 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
  - 2007 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
  - April 11 Medical Device Project Management: Challenges & Strategies for Development
  - May 2 Medical Device Software: Assessing Safety and Efficacy
  - June 6 Physician/Clinician Relationships: Making Them Work for You

- **Networking Meetings** (Pizzeria Uno, Newton Corner, and other locations)
  - 2006 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 (*Location: Silicon Valley Bank*)
  - Dec. 20 Does Size Really Matter: Small vs. Larger Companies
  - 2007 Jan. 17 Medical Device Outsourcing (*Location: Silicon Valley Bank*)
  - Feb. 21 Garnering and Managing Media Attention
  - 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

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.

### ■ Upcoming Events

#### January 17 Forum: *Medical Device Outsourcing*

While the medical device industry has been late to the game in the use of outsourcing, it has been making up for lost time in the last few years. This trend looks to continue — and even accelerate — as many leading medical device OEMs such as J&J, Medtronic and Boston Scientific, have made strategic decisions to increasingly outsource manufacturing and development. In light of this, a highly fragmented supplier base is consolidating and aligning to serve established OEMs and startups in a more sophisticated manner. This forum brings together OEMs and vendors to discuss best practices and current trends in outsourcing.

#### February 7 Forum: *Distribution Options for Medical Device Companies*

What are the various options available to device companies to bring their products to market, including a direct sales forces, distributors, partnerships, etc? How to reach users in the hospitals and office.

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

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## Beyond FDA: Considerations in Clinical Trial Design and Conduct

January 10, 2007  
Silicon Valley Bank

### ■ Program Description

Clinical trials involve much more than collecting data required by the FDA. Required protections for human subjects enrolled in trials, and opportunities to leverage trial data for coverage and reimbursement purposes, need to be incorporated into the design and management of device clinical trials — both in the U.S. and internationally. An exceptional panel of experts will provide a unique and valuable perspective on how to deal with these issues in the most effective and timely way.

### ■ Moderator

**Edward E. Berger, PhD**, President, Larchmont Strategic Advisors

### ■ Panelists

**Edward Greg Koski, MD, PhD**, Senior Scientist, Institute for Health Policy; Associate Professor, Department of Anesthesiology and Critical Care, Massachusetts General Hospital and Harvard Medical School

**Helen Colquhoun, MD**, CEO and President, Pleiad Devices

**William R. Taylor, MD, MPH**, Associate Regional Administrator for New England and Director, Division of Quality Improvement, Centers for Medicare & Medicaid Services

**Michael Fisher, PhD**, Life Sciences Sector Specialist, UK Trade and Investment, British Consulate, Boston, MA

### ■ Agenda

- 6:00 - 6:30 Networking and light dinner
- 6:30 - 6:35 MDG announcements
- 6:35 - 6:45 Moderator's introduction of topic and panelists
- 6:45 - 7:00 Edward Greg Koski presentation
- 7:00 - 7:15 Helen Colquhoun presentation
- 7:15 - 7:30 William Taylor presentation
- 7:30 - 7:45 Michael Fisher presentation
- 7:45 - 8:15 Moderated panel discussion / Q&A
- 8:15 - 8:20 Wrap-up

## ■ Biographies



**Edward Koski**

**Edward Greg Koski, MD, PhD**, senior scientist, Institute for Health Policy and associate professor, Department of Anesthesiology and Critical Care, Massachusetts General Hospital and Harvard Medical School, was the first director of the federal Office for Human Research Protections within the Department of Health and Human Services. He is the leading international expert on the rights of human subjects enrolled in clinical trials. Prior to going to Washington, he was the Director of Human Research Affairs, Partners HealthCare System at Massachusetts General Hospital and Harvard Medical School. He was a member of the first graduating class of the Harvard-Massachusetts Institute of Technology program in health sciences and technology.



**Helen Colquhoun**

**Helen Colquhoun, MD**, is founder, CEO and president of Pleiad Devices, a leading international contract research organization with offices in London, England and Cambridge, Mass. A physician with 16 years experience in the pharmaceutical, biotechnology, and medical device industries. Dr. Colquhoun's expertise includes international clinical study design and management, strategic regulatory affairs including negotiations on claims and clinical study designs, drug and device safety monitoring, combination product development (drug delivery, drug-device combinations and biologics) and assessment of commercialization opportunities.



**William Taylor**

**William R. Taylor, MD, MPH**, is a physician in the Boston regional office of the Centers for Medicare & Medicaid Services. He is the associate regional administrator and director of the Division of Quality Improvement. Formerly, Dr. Taylor led the Georgia Medicaid agency and worked as an epidemiologist at the Centers for Disease Control and Prevention. At the CDC he worked in public health, international health, cancer prevention and control, and health planning and evaluation. Dr. Taylor practiced as an emergency room physician before pursuing a career in public health, prevention and health care quality. He received his medical degree from Case Western Reserve University, his public health degree from the University of California at Berkeley and completed a fellowship in health economics at the University of Pennsylvania.



**Michael Fisher**

**Michael Fisher, PhD**, is life sciences sector specialist, UK Trade and Investment at the British Consulate in Boston. A chartered chemist and member of the Royal Society of Chemistry of Great Britain, Dr. Fisher is now responsible for advising UKTI's U.S. and Canadian network on life science issues and opportunities for the UK, liaising with UK regulators and also the Departments of Health and Trade & Industry. He has a PhD in HIV Protease Inhibition and has produced several scientific publications and one patent from his research.



**Edward Berger**

**Edward Berger, PhD**, founded Larchmont Strategic Advisors in 2005 to help life sciences companies deal with the challenges and opportunities posed by the coverage and reimbursement requirements of public and private payers and a rapidly evolving health care regulatory and policy environment. He has provided reimbursement analysis and strategy development consultation to clients developing new technologies in fields including neural monitoring and neuromodulation, gastrointestinal surgery, severe pulmonary dysfunction and personalized medicine. He previously worked at ABIOMED, Inc., in Danvers, Thermo Cardiosystems, Inc., in Woburn and Fresenius Medical Care in Lexington. From 1969-1980, Dr. Berger held faculty and administrative positions at Boston University, where he earned his doctorate in political science.

## ■ 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, Medical Development Partners & Sasso Solutions, LLC
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@shoobarassoc.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

## ■ January Forum Co-Champions:

**Dr. Robert J. Burger**, Vice President Product Development, PROXEMICS

**Edward E. Berger, PhD**, President, Larchmont Strategic Advisors

**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.**

**Coming Soon:  
The new MDG Web site.  
[www.meddevgroup.org](http://www.meddevgroup.org)**

The screenshot shows the MDG website interface. At the top, there are navigation tabs for "About Us", "Resources", "Membership", "Events", and "Sponsors & Affiliates". Below the tabs is a banner image with the MDG logo and the tagline "The Industry's Professional Network". There are links for "On-Line Calendar" and "Members-only". A section titled "Upcoming Events..." lists several forums and events. Below that is a "News & Announcements" section with several news items. On the right side, there is a "Welcome To Medical Development Group" section with a sub-header "New England's premier organization for individual professionals in the medical device and related fields" and a paragraph describing MDG as a community of individuals committed to the medical device and other medical technology industry segments. At the bottom right, there is a "Get Involved!" section with a bullet point stating "MDG thrives because of the dedication of its volunteer members. Contact our Committee Chairs to see where your unique skills can best help MDG grow."