

Medical Development Group 2010-11 Program Calendar

Clinical Trial Design & Management in an Evolving Regulatory Environment

November 3, 2010
Emerging Enterprise Center at Foley Hoag

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- **Forum Panels** (*Foley Hoag Emerging Enterprise Center, Waltham*)
 - 2010 Sep 13* The FDA, the Internet & Social Media: Regulatory Issues and Evolving Policy
 - Oct 6 Concept to Commercialization: Turning an Idea into a Marketable Product
 - Nov 3 Clinical Trial Design & Management in an Evolving Regulatory Environment
 - Dec 15* Healthcare Reform: Where We Are and What is Still to Come
 - 2011 Jan 5 Accelerating New Technology Adoption and Minimizing Time-to-Revenue
 - Feb 2 Hotbeds of Innovation: Advances in Treatment of Diabetes and Obesity
 - Mar 2 Innovative Business Models for Startups
 - Apr 6 SIGapalooza: Super SIG Night
 - May 4 Reimbursement Wars: Stories from the Front Lines
 - Jun 1 Computer Assisted Diagnostics: Opportunities and Obstacles
*Special SuperNetworking Event

- **Networking Meetings** (*Rebecca's Cafe, 275 Grove Street, Newton*)
 - 2010 Oct 20 Building a World Class Management Team for Your Startup
 - Nov 17 Successful Partnering: Crossing Organizational & Geographic Boundaries
 - 2011 Jan 19 Product Launch Roadmap: What to Do and When to Do It
 - Feb 16 Medical Device Entrepreneurship: Critical Success Factors
 - Mar 16 Enabling Device Innovation: Advances in Engineering Design Tools
 - Apr 27 Going Off-Shore: Opportunities and Pitfalls for Device Enterprises
 - May 18 Sales Force Effectiveness: Strategic Options and Management Principles
 - Jun 15 Essentials of Business Planning
 - Jul 20 Legal and Regulatory Issues in Corporate-Physician Relations
 - Aug 17 Getting into the Medical Device Industry

If you are interested in sponsorship opportunities,
please contact David Kaufman at dkaufman@meddevgroup.org or 617-345-6789.

- **Upcoming Events**

- Nov. 4 MDG Marketing & Sales SIG** *Rewrite-the-Rules Marketing: Four Not-So-Simple Steps to Changing the Standard of Care*
5:30 p.m. at Rebecca's Cafe, 275 Grove Street, Auburndale

- Nov. 10 MDG Medical Software SIG** *Embedded Design and Development for Medical Applications*
5:30 p.m. at Padanarum Room, Reservoir Place, 1601 Trapelo Road, Waltham

- Nov. 17 Networking** *Successful Partnering: Crossing Organizational & Geographic Boundaries*
In this interactive workshop you will gain insights into how to succeed in cross-organizational collaboration. You will leave the workshop with a few powerful communication skills for resolving partnership breakdowns when they occur. The workshop will be highly interactive with frequent opportunities to apply what you have learned to your own partnering situations. You will have several exercises working in small groups to practice new skills and explore how to apply them in your own situations.

- Nov. 18 MDG PD&MO SIG** *Round Table: Rapid Prototyping in the Development Process*
5:30 p.m. at Padanarum Room, Reservoir Place, 1601 Trapelo Road, Waltham

- Dec. 15 Special SuperNetworking Event** *Healthcare Reform: Where We Are and What is Still to Come*
Learn about what health care reform really means from a panel deeply involved with the practicalities of the health care legislative and policy implementation processes. Our experts will discuss what has been implemented and what is still to come, what is real and what is myth, and what still has to happen to realize the quality improvement and cost control goals promised when this legislation was approved by Congress.

Please pre-register for MDG events.
For more information, visit MedDevGroup.org.

- **Program Description**

This event addresses important recent changes in FDA expectations on clinical trial requirements towards regulatory approval. Presentations will cover the fundamentals, benefits and challenges of Bayesian statistics; the clinical/regulatory landscape and challenges that face CAD device manufacturers; potential changes in the FDA 510(k) clearance process; and the impact of Comparative Effectiveness Research and Health Technology Assessments on reimbursement.

- **Moderator**

Nandini Murthy, Principal, Regulatory Consultant, ENEM Consulting LLC

- **Panelists**

Nitin Patel, Ph.D., Chairman and CTO, Cytel, Inc.

John DeLucia, Vice President of RA/QA, iCAD Inc.

Michael Ferguson, Ph.D., Global Director, Clinical Outcomes and Translational Research, Office of Medical and Health Affairs, Philips Healthcare

- **November Event Coordinator**

Olga Taylor, VP Marketing & Business Development, Quartesian

- **Agenda**

- 5:30 Registration, informal networking, buffet dinner
- 6:15 MDG announcements
- 6:40 Opening comments by moderator and introduction of speakers
- 6:50 Speaker presentations
- 7:30 Q&A
- 8:00 Continued networking and dessert

- **MDG Mission**

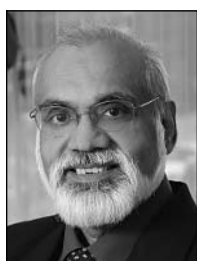
MDG's Mission is to contribute to the continuing development of medical devices and other medical technologies by enhancing the professional development of its members, fostering and supporting entrepreneurial thinking, serving as a forum for exploration of new business opportunities and promoting best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

■ Biographies



Nandini Murthy

Nandini Murthy is principal and founder of ENEM Consulting LLC, a regulatory consulting firm based in Massachusetts. Ms. Murthy has authored several FDA submissions including original PMAs, original IDEs, PMA and IDE supplements and 510(k)s for novel products including implantable therapeutic devices, monitoring tools and diagnostic devices. In addition to her core expertise in regulatory affairs, Ms. Murthy has designed and executed clinical trials and established quality systems to ISO 13485 and FDA quality system requirements. Prior to establishing ENEM Consulting in 2007, Ms. Murthy served as vice president, RA/QA/CA at InfraReDx. She previously served as vice president, RA/QA at Cyberkinetics Neurotechnology Systems. Ms. Murthy has also held regulatory, clinical and quality management positions at Thermo Cardiosystems (now part of Thoratec), Hologic, Aspect Medical (now part of Covidien) and Toxikon.



Nitin Patel

Nitin Patel has a Ph.D. from MIT where he has been a visiting professor for over a decade. He is a fellow of the American Statistical Association and a fellow of the Computer Society of India. He has written over 50 professional papers in leading statistical and computational journals. He has co-authored a book on data mining published by Wiley (now in its second edition). Dr. Patel co-founded Cytel with Cyrus Mehta in 1987 where he is currently chairman and chief technology officer. He has led collaborative research projects with several major pharmaceutical companies on adaptive trial design and implementation. He has been a member of PhRMA and DIA working groups concerned with deploying adaptive trials in practice. He is a co-principal investigator of a collaborative research project on Bayesian software for devices with Gerry Gray, deputy director in the division of Biostatistics at the FDA's Center for Devices and Radiological Health.



John DeLucia

John A. DeLucia is vice president of regulatory affairs & quality assurance at iCAD Inc. where he has responsibility for all regulatory, clinical and quality activities for Class 2 and Class 3 software and computer-assisted detection devices. He has over 25 years of experience in medical devices, in-vitro diagnostics and biomedical research; and has held senior RA/QA positions for C.R Bard, Smiths Medical, ACMI, Genzyme, Pfizer Hospital Products, Z-Tech Medical and EndoMatrix. Mr. DeLucia has a B.S. in political science/biology, Fairfield University; an M.S., microbiology, Quinnipiac College Graduate School; and B.S., quality assurance management, State University of New York. He is an ASQ certified quality engineer, ASQ certified quality auditor; and regulatory affairs certified professional. He was past chair for the ASQ New England Biomedical Discussion Group and currently is an editorial board member for the Medical Device & Diagnostic Industry Journal. He also is a member of the Advisory Health Product Regulation Advisory Board and an instructor at Regis College graduate program in health product regulation.



Michael Ferguson

Michael Ferguson is global director, clinical outcomes and translational research, office of medical and health affairs, Philips Healthcare, where he works with different businesses to develop clinical evidence strategies during product commercialization planning and post launch phases. Prior to joining Philips, he was director of clinical research for Medtronic Spinal and Biologics in Memphis, TN, for six years. Prior to working with Medtronic, he built a clinical research team at Exactech Inc., including clinical trials management, data management and biostatistical analysis services. Dr. Ferguson has more than 10 years experience as a research investigator, including clinical and basic science work and has co-authored more than 25 journal publications. Dr. Ferguson completed his Ph.D. in applied physiology from the University of Florida and has completed additional training in health economics and clinical outcomes research at Harvard University.



Upcoming Programs

Marketing & Sales SIG

Rewrite-the-Rules Marketing:
Four Not-So-Simple Steps to
Changing the Standard of Care

Speaker: Bruce Lehman,
President & CEO, LehmanMillet
Thursday, Nov. 4 at 5:30 p.m.
Rebecca's Café
275 Grove Street, Auburndale

Medical Software SIG

Embedded Design and Development
for Medical Applications
Wednesday, Nov. 10 at 5:30 p.m.
Padanarum Room, Reservoir Place
1601 Trapelo Road, Waltham

PD&MO SIG

Round Table: Rapid Prototyping in
the Development Process
Thursday, Nov. 18 at 5:30 p.m.
Padanarum Room at Reservoir Place
1601 Trapelo Road, Waltham

MDG Member News

News You Can Use

■ New Members

Med Dev Group welcomes all the new members who have joined since the October Forum:

Chris Abele	Rob Gibbons	Peter Vegeto	Nana Yankson
Michael Burka	Daniel Goldberg	Peter Weissman	
Diane Fukuda	Loren Smith	Martin Wells	

In addition, we welcome back those who are returning to MDG:

Jane Coutre	Ken Lawrence	Jim Miraldi	Kurt Rodenhizer
Ian Feldberg	Mark Macedo	Eric Poole	
Javier Jimenez	Bill Mcgrath	Paul Pyzowski	

■ Did You Know?

- ▶ That you can edit any data in your member profile besides the expiration date? This includes your username and password — so if your username is the same as an email address you no longer use, you can change it to something else! Just log in and click the “My Profile” link in the stripe below the MDG banner.
- ▶ That you can insert your own photo, and provide a link to your web site, directly into your online profile?
- ▶ That presentations from past MDG meetings are posted in the members-only area? When you log in, click the “Past Presentations” link — meeting dates and topics are shown, with links to open the posted presentation (converted to PDF form).

■ Member News Announcements

Share your business news with fellow MDG members. We need Member News Announcements! Did you win a patent? Speak at a conference? Secure some funding? Land a new job? Send all your Member News to Sherry Alpert at sherry@alpert-publicrelations.com.

■ MDG Alliances: A Valuable Resource

If you are already a member of MDG, you most likely have heard about the other regional groups that have formed alliances with MDG. MDG members can significantly expand their horizons by tapping into the resources of our alliance members and most often at a significant discount. For example ... “Attend a WPI Venture Forum event and pay as if you were a WPI Venture Forum Member.”

Our alliance partners are on the MDG web site. Visit the ON-LINE CALENDAR tab and see a list of the upcoming events at MDG and our alliance partners. Visit the ALLIANCES tab for a full listing of our alliance partners with a link to their web site and a note about the partner discount which is being offered to MDG members.

But remember, this special benefit is only for MDG members. If you are not already an MDG member, this is another valuable reason to join MDG. If you are an MDG member, this member benefit will broaden your horizons and save you money.* You will also be supporting the efforts of our alliance partners who work hard to bring valuable programs to the community.

Current MDG Alliance Partners

128 Innovation Capital Group (128 ICG)	MIT Enterprise Forum
Babson Life Sciences Club	New Hampshire High Tech Council
BEACON (The Biomedical Engineering Alliance and Consortium)	North Shore Technology Council
C-NET Boston (Boston Consultants Network)	SNEEF (Southern New England Entrepreneurs Forum)
E-NET Boston (IEEE Entrepreneurs Network)	The Capital Network (TCN)
Merrimack Valley Venture Forum (MVVF)	WPI Venture Forum

*You can obtain an MDG membership card as proof of your membership by going to the MEMBERS LOGIN tab and clicking on Membership Card in the grey column on the left.

For additional information and to learn how to become an Alliance Partner, please contact our co-chairs: Alan Kivnik (akivnik@meddevgroup.org) or Lee Jones (ljones@meddevgroup.org).

■ MDG Officers, 2010-2011

President

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■ MDG Board of Directors, 2010-2011

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■ MDG Committee Chairs, 2010-2011

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■ MDG SIG Chairs, 2010-2011

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■ MDG Volunteers, 2010-2011

Sherry Alpert, MDG Member News
Heinz Bachmann, Operations
Joe Civiello, Sponsorships
Roy Coleman, Programming Coordinator
Eric Cunningham, Membership
Gary Duffy, Marketing/PR
Bruce Horwitz, Internet Support
Cathy Lai, Membership Analytics

Craig Lazinsky, Marketing/PR
Bill Munger, Programming Liaison
Peter Novello, Membership
Maria Shonyo, MDG Conference List
Charlie Sweet, Operations
Peter Vegeto, Membership
Jim Vellenga, Operations

MDG runs on volunteers. If you would like to get involved, email the committee chairperson above.