

Medical Development Group 2009/2010 Program Calendar



■ Forum Panels (*Foley Hoag Emerging Enterprise Center, Waltham*)

2009	Sep 16	Startup Funding in Hard Times*
	Oct 7	Merging Mindsets: Device-Biotech Combination Products
	Nov 4	Healthcare Reform and its Effect on Medical Technology Usage
	Dec 9	Acquisitions: The Acquirer's Perspective
2010	Jan 6	Women's Health: New Markets, Expanding Opportunities
	Feb 3	The Interoperability Challenge: Getting Devices to Talk to Each Other
	Mar 3	Neonates to Nonagenarians: Critical Unmet Needs of Special Patients
	Apr 7	Biomaterials, Polymers and Engineered Surfaces: What's New for Medical Devices
	May 5	The Future for Home Use Devices
	Jun 2	Nanotechnology and the Future of Medical Devices *Special SuperNetworking Event

■ Networking Meetings (*Rebecca's Cafe, 275 Grove Street, Newton*)

2009	Oct 21	Post-approval Studies: Maximizing the Value of Clinical Experience
	Nov 18	Pre-clinical Device Qualification: Keeping the FDA Happy
2010	Jan 20	Cost-effective Market Research for Startups
	Feb 17	Customer Service for Startups and Beyond: How to Do It Right
	Mar 17	Unlocking the Value in Dormant IP
	Apr 21	The Power of Trade Secrets: When Not to Patent Your Invention
	May 19	Product Liability for Device Manufacturers: Limiting Your Exposure
	Jun 16	The Evolution of Angel Financing: Changing Perspectives, Goals and Requirements
	Jul 21	GNP: Good Networking Practices
	Aug 18	Transitioning into the Medical Device Industry

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**If you are interested in sponsorship opportunities,**  
**please contact David Kaufman at [dkaufman@meddevgroup.org](mailto:dkaufman@meddevgroup.org) or 617-345-6789.**  
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■ Upcoming Events

Oct. 13 MDG & Avnet Educational Series: Safety and Security for Medical Disposables

This evening event will provide an overview of various technologies with a specific focus on RFID as an enabling smart technology.

Oct. 21 Networking: Post-approval Studies: Maximizing the Value of Clinical Experience

An overview of clinical trials at various stages following the submission of an application for a regulatory clearance including trial planning, control, identification of data that has to be reported to the FDA and possible implications for the commercial use of the device.

Nov. 4 Forum: Healthcare Reform and its Effect on Medical Technology Usage

Federal and state policy makers and legislative staff will discuss policies and emerging trends that will affect the development/delivery/review of medical care and medical technology development.

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

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Merging Mindsets: Device-Biotech Combination Products

October 7, 2009
 Emerging Enterprise Center at Foley Hoag

■ Program Description

Some of the most medically important and commercially successful products consist of combinations of devices and pharmaceuticals (e.g., drug-eluting stents). Success in this medical development category requires bringing together diverse perspectives and expertise in engineering, materials, biology, chemistry, pharmacology, regulatory affairs and manufacturing. New technologies are expected to provide more opportunities for such combinations. Three experienced professionals in this area with different perspectives will make presentations that include:

- 1) A survey of drug-device combinations now being marketed and in the pipeline
- 2) Unmet medical needs that could potentially be treated with novel drug-device combinations
- 3) The kinds of critical issues that drug-device development teams must understand and address
- 4) Case history of a successful drug-device product development

■ Moderator

William E. Munger, PhD, Biotechnology Consultant and Entrepreneur, Stow, Mass.

■ Presenters

Jim Embree, Principal/President JAGE Biotechnology Consulting, Wrentham, Mass.

Sam Clark, PhD, Principal, Abantos Biosolutions, Barrington, RI

Frank Bobe, PhD, MBA, President, ENTRA Pharmaceuticals, Boston, Mass.

■ October Event Co-Champions

Robert Ezzell, PhD, RAC, Regulatory Affairs Consultant, Medicept Inc, Ashland, Mass.

William E. Munger, PhD, Biotechnology Consultant and Entrepreneur, Stow, Mass.

■ Agenda

5:30	Registration, informal networking, buffet dinner
6:15	MDG announcements
6:30	Opening comments by moderator and introduction of speakers
6:35	Speaker presentations
7:30	Q&A
8:00	Continued networking and dessert

■ MDG Mission

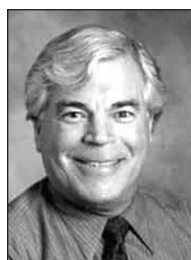
MDG's Mission is to contribute to the continuing development of medical devices and other medical technologies by enhancing the professional development of its members, fostering and supporting entrepreneurial thinking, serving as a forum for exploration of new business opportunities and promoting best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

■ Biographies



Bill Munger

Bill Munger has over 20 years of experience in the biotechnology/pharmaceutical sector, ranging from preclinical discovery to candidate development for small molecules, proteins and gene therapy. He has managed both internal and partnered programs in multiple disease areas (e.g., cardiovascular disease, cancer, inflammation). Since 2008 he has been working on creating a clinical development-focused biotechnology startup company. He previously worked at Curis, Inc., a drug discovery and development company in Cambridge, where he was executive director of technology and program management, responsible for strategic planning, program management and technical due diligence. While at Curis, he created and led a largely external "virtual" team for preparing an IND application for Curis' novel cancer drug candidate, CUDC-101, now in Phase I clinical trials.



Jim Embree

Jim Embree has 30 years of development and manufacturing management experience at development-stage and Fortune 100 companies. His primary technical experience is in product, method and process development and manufacturing; however, he is also well founded in quality system requirements, regulatory and other compliance activities associated with the industry. In addition, he has provided QC oversight; initiated QA and compliance groups; managed design control and quality system development; and managed clinical stage and commercial production. His product experience includes parenteral therapeutics (antibodies and recombinants), combination products, cell therapy products, drug products, and in vitro diagnostics.



Sam Clark

Sam Clark has almost two decades of experience in companies developing and marketing biological and combination products, both in the U.S. and Europe. His primary experience is in the cellular aspect of product, process and method development. These include both primary and secondary cells processed for combination products or for cellular bioassays. He has developed and implemented cellular bioassays and cell production methods for treatment modalities in diabetes, organ failure (renal and hepatic), neurodegenerative disease and oncology.



Frank Bobe

Frank Bobe joined ENTRA Pharmaceuticals in 2008 as the company's first CEO with 20 years of biotechnology and pharmaceutical industry experience, most in senior executive roles. As president and CEO of BioAxone Therapeutic in Montreal, Canada and then CBO and executive vice president of Alseres Pharmaceuticals, Mr. Bobe was responsible for the successful cross-border transaction of BioAxone's clinical spinal cord program, providing the company with a desired exit. Before moving to Montreal in 2003, he was Novartis' representative director and country head of South Korea. Earlier in his career, he held operational management and global corporate leadership positions at Novartis AG, with increasing responsibilities in preclinical research, sales and marketing and general management. Mr. Bobe holds a PhD in bio-organic chemistry from the University of California at Davis and completed a postdoctoral research fellowship in biochemistry in the laboratory of Nobel Laureate Prof. Bruce Merrifield, Rockefeller University, New York. He also holds an MBA from INSEAD in France and a bachelor's of science equivalent from Universität Bielefeld, Germany.

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■ MDG Volunteers, 2009-2010

Sherry Alpert, MDG Member News	Lee Jones, Marketing and Operations
Robert Burger, Programming	Julie Lavallee, Marketing/PR
Joe Civiello, Sponsorships	Maria Shonyo, MDG Conference List
Suzanne d'Amonville, Marketing/PR	Charlie Sweet, Operations
Olivier Giuliani, Website Calendar	Jim Vellenga, Operations
Sharon Herman, Marketing/PR	Paul White, Website

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

■ MDG Alliance Partners

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