



## Combination Products—The Future of Medicine

May 3, 2006  
Silicon Valley Bank

### ■ Program Description

This exciting seminar addresses this topic from two very important perspectives. The first is a presentation on “Drafting Good Manufacturing Practice Guidance” offered by Mina Gerber. Ms. Gerber will review the first glance of the FDA regulatory strategy (found in the draft guidance) as well as discussing the agency’s expectations and practical ways to meet them.

Then Michael Drues, Ph.D. will discuss, “Why devices alone do not work.” No matter how well devices are designed they can only do so much to address the many clinical problems and issues that exist today. In order to address the clinical problems of the future, medical devices will be used in combination with drugs and biologics. Several examples of combination products that are currently on the market, under development or on the drawing board will be presented in an interactive way along with a discussion of what has been successful and what improvements can be made.

### ■ Agenda

- |   |                  |
|---|------------------|
| • Networking, Food and Drink            | 6:00 - 6:30 p.m. |
| • Welcome, MDG Introduction             | 6:30 - 6:40 p.m. |
| • Upcoming MDG Forums & Events          |                  |
| • Recognition of Sponsors               |                  |
| • Introduction of Panelists             | 6:40 - 6:45 p.m. |
| • Topic Review by Moderator & Panelists | 6:45 - 8:10 p.m. |
| • Questions & Panel Discussion          | 8:10 - 8:25 p.m. |
| • Wrap-up                               | 8:25 - 8:30 p.m. |

### ■ Moderator

**Lisa Sasso**, President & CEO, Medical Development Partners, LLC & Principal, Sasso Solutions

### ■ Panelists

**Mina Gerber**, President, NiSa Consultants, Inc.

**Michael Drues, Ph.D.**, President, Vascular Sciences, Grafton, Mass.

#### SPONSORS

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## ■ Biographies



**Mina Gerber**

**Mina Gerber** is a founder of NiSa Consultants, Inc., and an instructor at the Northeastern University. Since 1997 NiSa Consultants provides a variety of services to drug/biologic developers and medical device/medicinal product manufacturers including the release of products, execution of external and internal audits programs, troubleshooting of QSR and CGMP compliance issues, establishing stability programs, organization of training curriculum and preparation for domestic and international authority inspections. Mina received her M.S. degree from Northeastern University, and has an equivalent of M.S. in technology/chemical engineering from the Printing Academy in Lvov, Ukraine. She has significant experience in complicated issues of GCP, GLP and CGMP compliance. Before becoming president of NiSa Consultants, Mina was director of quality assurance and regulatory affairs at Unisyn Technologies, manager of quality assurance at Biogen, manager of quality assurance at MedChem Products, and supervisor of quality control laboratory at Fisons Corporation. Mina is also a member of Regulatory Affairs Professional Society (RAPS), and Parental Drug Association (PDA).



**Mike Drues**

**Michael Drues, Ph.D.**, is president of Vascular Sciences in Grafton, Mass. Vascular Sciences offers a full range of consulting services to medical device, pharmaceutical and biotechnology companies including: prototype design, product development, testing and evaluation, animal and clinical trials, business development, strategic planning, technology assessment and regulatory affairs. Michael received his B.S., M.S., and Ph.D. degrees in biomedical engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the FDA. Michael is an adjunct professor of medicine & biotechnology at Northeastern University, Steven's Institute of Technology (Hoboken, N.J.), Boston College, University of Wisconsin-Madison and University of California-Irvine. He regularly teaches both undergraduate and graduate courses in pathophysiology, biotechnology, regulatory affairs and clinical trials. Michael conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the European Patent Office and the FDA. Current offerings include Designing Cardiovascular Devices, Designing Neurovascular Devices, Designing Peripheral Vascular Devices, Designing Gastrointestinal and Urinary Devices, Minimally Invasive Technologies, Combination Products, Overview of Biotechnology and Regulatory Affairs.



**Lisa Sasso**

**Lisa Sasso** is the principal of Sasso Solutions, a medical device consulting company that helps “start-up’s start up” and which connects doctors, engineers and companies in a collaborative way with the ultimate goal of new product development and commercialization. She is president and CEO of Medical Development Partners, LLC, a company that she co-founded in 2005. This innovative medical device company validates new concepts and helps bring them to market. Lisa was the U.S. founder and past president/CEO of Radi Medical Systems, Inc., a high-tech medical device distributor of several innovative cardiology products. Lisa’s vision and strategic direction were responsible for the company’s explosive growth, with annual triple digit revenue since Radi’s inception in 1998 and profitability for five out of six years. By understanding the impact of new technology and the philosophic change required of customers, Lisa was able to market the company and products directly to physicians, hospital staff and hospital administration. She has an M.B.A. in management from Bentley College, Graduate School of Business, and a B.B.A. in marketing and a B.A. degree in economics from University of Massachusetts at Amherst. In December 2004, she was recognized by the Babson College Center for Women’s Leadership for her efforts and ranked 28 out of 100 women-led businesses in Massachusetts. Lisa currently serves as a board member for two medical education service companies and one non-profit organization, the Medical Development Group.

■ **MDG Mission**

*Founded by entrepreneurs and consultants to foster collaboration and develop new opportunities for medical technology professionals.*

■ **MDG Officers**

- President            Martin Sklar, Director, Business Development, AlvaMed, LLC
- President-Elect    Mark Ettlinger, Chief Technology Officer, Medical Animation & Design
- Secretary            Joyce College, Senior Marketing & Clinical Advisor, Medical Animation & Design
- Treasurer            Bruce Horwitz, President, TechRoadmap Inc.
- Board                 David Barone, Principal, Boston MedTech Advisors, Inc.
- Board                 Sara Dolinsky, Director, Boston MedTech Advisors, Inc.
- Board                 Lisa Sasso, President/CEO, Medical Development Partners, LLC  
& Principal, Sasso Solutions
- Board                 Jerry Shapiro, President and CEO, Fem-Medical, LLC
- Board                 Edward Berger, Principal, Larchmont Strategic Advisors

■ **Committee Chairs**

- |                           |                 |  |
|---------------------------|-----------------|--|
| Programming, Co-Chair     | Lisa Sasso      | <a href="mailto:lisasasso@comcast.net">lisasasso@comcast.net</a>             |
| Programming, Co-Chair     | Jerry Shapiro   | <a href="mailto:shapiro@femiscanusa.com">shapiro@femiscanusa.com</a>         |
| Membership, Chair         | Brian Shoemaker | <a href="mailto:bshoemaker@shoobarassoc.com">bshoemaker@shoobarassoc.com</a> |
| Marketing Chair, Co-Chair | Sara Dolinsky   | <a href="mailto:sdolinsky@bmtadvisors.com">sdolinsky@bmtadvisors.com</a>     |
| Marketing Chair, Co-Chair | Mark Kolnsberg  | <a href="mailto:mkolnsberg@cs.com">mkolnsberg@cs.com</a>                     |
| Sponsorship Chair         | Mel Prenovitz   | <a href="mailto:mel@melpren.com">mel@melpren.com</a>                         |
| Outreach Chair            | Alan Kivnik     | <a href="mailto:kivnik@rcn.com">kivnik@rcn.com</a>                           |

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

**Course: Emerging Trends and Issues in the Medical Device Industry**

Presented by Michael Drues, Ph.D. During this interactive workshop, discussions will focus on trends expected to have a significant impact on the future of the medical device industry. This is the first time that Vascular Sciences is partnering with MDG and Silicon Valley Bank to offer a clinical education course to all members. This course will be held Tuesdays, May 9, 16, 23 & 30 from 4:30–9 p.m. at Silicon Valley Bank, Newton, and will include light dinner and beverages.

**Tonight is your last chance to register and save \$100!**

Register By	MDG Member Price	Non-MDG Member Price
May 3	\$395 (+\$40 for materials)	\$545 (+\$40 for materials)
After May 3	\$495 (+\$40 for materials)	\$645 (+\$40 for materials)

This is an exceptional value. Local graduate schools offer courses covering similar topics and materials for more than three times the cost. The target registration is 20-25 people and will close at that number. We reserve the right to cancel the course if a course minimum is not reached.

*If you have questions about this course or want to learn more, contact:*  
Lisa Sasso, Sasso Solutions at [lisasasso@comcast.net](mailto:lisasasso@comcast.net) or 617-388-7489.

# Medical Development Group

## 2005/2006 Program Calendar

### ■ Forum Panels (Silicon Valley Bank, Newton Lower Falls)

<b>2005</b>	September 7	Home Health Care
	October 6	Anticipating the Future of Medical Devices
	November 2	Medical Needs: From the Physician's View
	December 7	Product Design: New Platforms for Development
<b>2006</b>	January 11	Assessing Markets and Competition
	February 1	Corporate Strategy and Organization
	March 8	Financing a Medical Device Company
	April 5	Reimbursement: Shaping Medical Technology Enterprise Strategy
	May 3	Combination Products: The Future of Medicine
	June 7	<b>Human Factors and Patient Safety</b>

### ■ Networking Meetings (Pizzeria Uno, Newton Corner)

<b>2005</b>	July 20	Medical Device Approval Requirements
	August 17	Networking for Consulting
	September 21	Risk Management (FMEA, Design & Product)
	October 19	Contracts (Employee and Consulting)
	November 16	Testing for Early Design Development
	December 21	Impact of Software in Medical Devices
<b>2006</b>	January 18	Power Networking
	February 15	Transitioning to the Medical Technology Fields
	March 15	CE Marking and Design Control Strategies
	April 26	Outsourcing: Design and Manufacturing
	May 17	<b>Outreach: What Can MDG Do For You?</b>
	June 21	<b>1st Annual MDG Networking Party</b>

If you are interested in sponsorship opportunities,  
please contact Mel Prenovitz at [mel@melpren.com](mailto:mel@melpren.com) or at 617-738-6599

### ■ Upcoming Events

#### May 8 MDG Program Planning Meeting

After an exciting year, we are ready to plan our 2006-2007 programming season. We encourage you to be involved as event champion, speaker, moderator or committee chair. Please RSVP by Friday, May 5 to [programs@meddevgroup.org](mailto:programs@meddevgroup.org). A light dinner will be served. Reservoir Place, Padanarum Room, 1601 Trapelo Road, Waltham, 6-8 p.m.

**May 9 Special 4-Session Course: Emerging Trends and Issues in the Medical Device Industry:** Presented by Michael Drues, Ph.D., this course will be offered on Tuesdays, May 9, 16, 23 & 30, from 4:30-9 p.m. at Silicon Valley Bank. (Complete details on Page 3.)

#### May 17 Networking Meeting: What Can MDG Do For You?

Come and learn about the many ways MDG can help you succeed. Bring your ideas to this interactive session for making MDG a premier medical organization for industry professionals. E-mail your success stories of key introductions, new job opportunities or new company start-ups to [programs@meddevgroup.org](mailto:programs@meddevgroup.org).

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