



Human Factors: The Challenge of Designing Medical Products for Patient Safety

June 7, 2006
Silicon Valley Bank

■ Program Description

Every year, a significant number of patients die or suffer further injury because the medical equipment used to treat them is poorly designed, resulting in missed diagnoses, incorrect treatments and unnecessary hospital stays. As many as 195,000 people could be dying in U.S. hospitals every year because of preventable medication errors commonly known as “death by decimals” that are due to human errors in programming drug infusion pumps.

The critical importance of considering the “human factor” in the design of medical equipment will be the focus of this forum. This panel discussion will provide information on ergonomic considerations and other factors. The program will cover three key areas to review when designing medical products: process analysis and tactical considerations, cost benefit analysis and regulatory issues.

■ 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

Marc Drucker, MBA, IDSA, President, Newlogic Design, Newton, MA

■ Panelists

Beth Loring, CHFP, Director, Design & Usability Center, Bentley College, Waltham, MA

Michael Wiklund, Founder and President, Wiklund Research & Design, Concord, MA

Michael Mendelson, D.D.S., M.S. Biomed. Eng., Captain, USPHS Human Factors Engineering Team, Food and Drug Administration, Rockville, MD

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■ Biographies



Beth Loring

Beth Loring has 20 years of experience consulting on product design and usability. She has expertise in user needs assessment, graphical user interface design, usability evaluation methods and ergonomics. She has designed and conducted usability tests of consumer electronics, web sites, delivery services and medical devices for clients including Abbott, Baxter Healthcare, Bayer, Critikon, Eli Lilly, Hewlett-Packard, IDEXX, Roche and Sarns. Beth has been a visiting faculty member in Bentley's information design and corporate communications department since 2001. Beth holds an M.S. in engineering design from Tufts University and is a certified human factors professional. She has published numerous papers on usability and is co-author of a case study in "Understanding Your Users: A Practical Guide to User Requirements" by Catherine Courage and Kathy Baxter (Morgan Kaufmann, 2005). She has received design awards from IDEA/Business Week and ID Magazine. Beth is past chair of both the New England Chapter of the Human Factors and Ergonomics Society and BostonCHI.



Michael Wiklund

Michael Wiklund is a frequent contributor to Medical Device & Diagnostic Industry magazine and a member of its editorial advisory board. He is founder and president of Wiklund Research & Design, a human factors consulting firm that specializes in making medical devices safe, effective, usable and appealing. Recent consulting projects have involved the design and evaluation of dialysis, patient monitoring and cardiac therapy equipment, as well as several surgical devices. A certified professional human factors engineer, he is also involved in the development of human factors standards for medical devices, serving on IEC's and AAMI's human factors committees. He received his M.S. Degree in engineering design (human factors) from Tufts University in 1984. A certified human factors professional who holds a professional engineers license in industrial design, Michael is author/editor of two books on medical device design and a co-editor of an upcoming encyclopedic handbook on human factors in medical device design.



Michael Mendelson

Capt. Michael Mendelson (U.S. Public Health Service) is a biomedical engineer with the Human Factors Engineering Team at the Center for Devices and Radiological Health at the Food and Drug Administration in Rockville, Md. He also is a staff dentist at the Dental Readiness Clinic of the National Naval Medical Center, Bethesda, Md. Before joining the FDA's Dental Devices Branch at CDRH's Office of Device Evaluation as a scientific reviewer in 1994, Michael was in private practice. While earning his engineering degree, he performed dental implant research at Rensselaer Polytechnic Institute as a National Institute of Dental Research postdoctoral fellow. He joined the Human Factors Engineering Branch in 1995, where he remains today. He served a tour as a captain in the U.S. Air Force Dental Corps from 1978-81. He received a B.A. in biology from the State University of New York at Binghamton in 1973, a D.D.S. degree from the University of Maryland in 1977, and an M.S. degree in biomedical engineering from Rensselaer Polytechnic Institute in 1991.



Marc Drucker

During his more than 15 years in product design and management, **Marc Drucker** has received more than 10 design and utility patents and several design awards. Prior to founding Newlogic, a full-service product development and innovation firm, Marc was president of Gad Shaanan Design (San Diego and Montreal) and a senior manager at TIAX (formerly Arthur D. Little). He led research, strategy, design, and engineering groups in the development of medical, consumer and telecommunications products. Recent projects have included mobile healthcare devices, patient monitors, hospital furniture, and glucometers. He is active in the Industrial Designers Society of America (IDSA) and has been a contributor to BusinessWeek, Innovation Magazine and US News & World Report. Drucker received his bachelor's degree in industrial design from Art Center College in Pasadena, Calif. and his MBA from Babson College in Wellesley.

■ **MDG Mission**

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

■ **MDG Officers**

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■ **Committee Chairs**

Programming, Co-Chair	Lisa Sasso	lisasasso@comcast.net
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Membership, Chair	Brian Shoemaker	bshoemaker@shoebarrassoc.com
Marketing Chair, Co-Chair	Sara Dolinsky	sdolinsky@bmtadvisors.com
Marketing Chair, Co-Chair	Mark Kolnsberg	mkolnsberg@cs.com
Sponsorship Chair	Mel Prenovitz	mel@melpren.com
Outreach Chair	Alan Kivnik	kivnik@rcn.com

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.

Medical Development Group

2005/2006 Program Calendar

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

2005	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
2006	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	Human Factors and Patient Safety

■ Networking Meetings (Pizzeria Uno, Newton Corner)

2005	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
2006	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	Outreach: What Can MDG Do For You?
	June 21	1st Annual MDG Networking Party (at Silicon Valley Bank)

**If you are interested in sponsorship opportunities,
please contact Mel Prenovitz at mel@melpren.com or at 617-738-6599**

■ Upcoming Events

June 21 1st Annual MDG Networking Party at Silicon Valley Bank

Celebrating 5 Years of Success at MDG

Join us for food, great networking and and a keynote address, "*Trends in Bio-Medical Business Financing,*" featuring Tom Davies, senior relationship manager for the Northeast Life Science Practice, Silicon Valley Bank. Watch your MDG Announcements for more details.

Please pre-register for Forum Panels
For more information, visit www.MedDevGroup.org