Combination Products
Diversity in Type and Application

Wednesday
March 4, 2015
5:30 – 8:30 PM
Constant Contact Headquarters
Waltham, MA

What do a drug loaded nanofibrous device, an insulin pump, an antimi-
icrobial coated catheter and a mechanical ribosome a.k.a. DNA repair nanobot all have in common? They are all combination products!

Program Description
Combination products first appeared on the regulatory landscape in the 1970s and since that time have grown into a diverse range of products cutting across the pharmaceutical, biological and device disciplines. From diagnostics to implants, the synergistic effects of combined therapies have altered the practice of healthcare.

This month’s presentation will update the audience on the diverse types of combination products in development or on the market and perhaps more importantly will discuss some of unique challenges and requirements that organizations have encountered when bringing combination products to market.

If you are interested in combination products and want to:
• Demystify today’s PMOA guidance
• Gain valuable lessons learned
• Understand how combination products will be defined in the future

This session is for you!

Upcoming Events
Wed, April 1:  5:30 - 8:30 PM
The Surgical Suite Responds to the New Business Model of Healthcare
(Constant Contact)

Wed April 29:  3:30 – 8:00 PM
SPECIAL EVENT:
Connecting Medical Products to the Internet of Things (IOT)
(Foley Hoag Law Offices
South Boston, MA)

Wed May 6:  5:30 – 8:30 PM
Advancing Women’s Health: Gender Centered Treatments for What Worries Women
(Constant Contact)
Moderator

Jonathan Bretz, OT/L, MBA, RAC
President & Founder, RSQM Associates, LLC.
Jon has worked in the medical device field for nearly 40 years. RSQM Associates provides world class regulatory, quality management, marketing and product development/engineering support and services to its partners as they bring their medical devices to market and beyond. He previously held various senior executive positions at AliMed Inc in marketing/sales, operations, and regulatory affairs. He was responsible for regulatory submission to the FDA, EU and Health Canada and managing the Quality systems. Jon recently completed the Regulatory Affairs Professional Society certificate program in Medical Devices and Pharmaceuticals. He earned his Executive MBA from Anna Maria College and a BS in Occupational Therapy from Tufts-University.

Panelists

Matthew Phaneuf
President and Chief Technical Officer of BioSurfaces, Inc.
Matt received his B.S. degree in biochemistry from the University of Massachusetts at Dartmouth in 1989 and began his research career in the Vascular Surgery Research Laboratory at the Beth Israel Deaconess Medical Center in Boston, serving as the assistant director from 1989 to 2005. While there, he helped to establish the Massachusetts small business research and development company BioMod Surfaces in 1998. In 2003, he co-founded BioSurfaces, Inc. and in 2014 spun out NuVascular Technologies, Inc. and EmergStat Technologies, Inc. He has more than 40 peer-reviewed publications and presentations, holds several patents and has received multiple awards. He is a member of several biomaterial organizations, including Surfaces in Biomaterials Foundation, and an ad hoc reviewer for several journals.

Rosalyn Año
Business Development Manager - Medical Devices, Toxikon Corporation
Rosalyn received a B.S. in Biomedical Engineering from Boston University. She previously worked as a clinical research associate at PAREXEL, utilizing medical imaging endpoint analyses for CNS and Oncology clinical trials. Joining Toxikon in 2008, she assists medical device companies with the development of product safety testing strategies. Her areas of expertise include biocompatibility testing, developing cost effective strategies for testing combination devices, and integrating both Extractable/Leachable programs as well as preclinical efficacy & surgical research studies. She has a track record of controlling study costs through sound risk management techniques, reducing the probability of test failure, and streamlining product development timelines to successfully get high quality and safe products to market.

Michael Drues, Ph.D
President of Vascular Sciences
Vascular Sciences is an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including prototype design, product development, animal testing, regulatory strategy, intelligence & clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment.
Dr. Drues 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 as well as the FDA, Health Canada, the US and European Patent Offices and the Centers for Medicare and Medicaid Services (CMS). He is an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology at several universities and medical schools.

Co-Champions

John O’Gara, Project Manager, Hologic, Inc.
Rich Andrews, SQA Engineer, Avedro
MDG Boston
We would like to thank the hundreds of volunteers who help to make this organization a success.

MDG Officers, 2013-2014
President
Peter Madras
pmadras@mdgboston.org
Secretary
Jerrold M. Shapiro, PhD
jshapiro@mdgboston.org
Treasurer
Peter Fuchs
pfuchs@mdgboston.org

MDG Board of Directors
Paul Hartung
phartung@mdgboston.org
William McIlhargey
wmcilhargey@mdgboston.org
Lisa Sasso
lsasso@mdgboston.org
Ashley Sherman
asherman@mdgboston.org
Anna Xia
axia@mdgboston.org

MDG Special Interest Groups
Diagnostics
John Wyatt
john.wyatt02@gmail.com
Entrepreneurial & Clinical
Roy Coleman
rcoleman@ianidiorio.com
Marketing & Sales SIG
John Knott
johnk@jdtechsales.com
David Hamacher
davidh@getbettersales.com
Medical Software
Eric Poole
eric@rkt-tech.com
Product Development SIG
Michael Aprea, Co-Chair
maprea-sdw@cox.net
Kevin Pelletier, Co-Chair
kpelletier@massmaterials.com

MDG Committee Co-Chairs
Program Central
Ed Dolan, Co-Chair
edolan@mdgboston.org
Joe Berkowitz, Co-Chair Networking
jberkowitz@mdgboston.org
Michael Mills, Co-Chair Networking
MJDMMills@gmail.com
Event Operations
David Ennen
dennen@mdgboston.org
Membership
Paul Hartung
phartung@mdgboston.org
Partners & Alliances
Alan Kivnik
akivnik@mdgboston.org
Sponsorship
Joe Berkowitz
jberkowitz@mdgboston.org
Jon Nugent
jnugent@mdgboston.org
Ashley Sherman
asherman@mdgboston.org
Leaders/Resources
Marie Cloutier (Membership)
marie@mariec.com
Jeff Karg (Program Central)
jeff.karg@techn.com
Sean Phillips (Membership)
sean@rocketsd.com
Tom Rose (Membership)
ftom.rose@gmail.com
Life Science Nation: Dennis Ford, CEO, Jack Fuller,
Bus Dev’t, tcrosby@lifesciencenation.com
FoleyHoag: David Pierson, Partner; Claire M. Lawless

MDG Consultants
CPA
Andrew S. Goloboy
g-cpa.com
Admin Support
Patti Clark
medicaldevicegroup4@gmail.com
Graphic Design
Bill Denison
bill@denisondesigngroup.com

MDG Staff
Director of Operations
William Munger
wmunger@mdgboston.org
MDG Boston 2014-2015 Program Calendar

Forum Panels
(Location: Constant Contact Headquarters, Waltham, unless noted otherwise)

Sept 10 Bringing Bionics To Life
Co-Champions: Kevin Franck, Dan Healey

Oct 1 Intellectual Property Approaches To Safeguard Value
Co-Champions: Rob Adelson, Roy Coleman, Stanley Chalvire

Nov 5 Optical Cancer Detection: 20 years of Lessons Learned
and 20 Years Of Future Promise
Co-Champions: Bob Andrews, Randy Chinnock

Dec 3 The Radical Transformation of Healthcare: The Rise Of Virtual Care Delivery
Co-Champions: Kevin Fickenscher, MD, Shankar Krishnan, MD

Jan 7 Making Medical Technology More Human
Co-Champions: Mike Wiklund, Sean Phillips

Feb 4 Devices And Combination Products For Neurodegenerative Disease
Co-Champions: Paul Hartung, Richard O’Brien

Mar 4 Combination Devices: Diversity In Type And Application
Co-Champions: John O’Gara, Rich Andrews

Apr 1 The Surgical Suite Responds to the New Business Model of Healthcare
Co-Champions: Bill McIlhargey, Melvin Prenovitz

May 6 Advancing Women’s Health:
Gender Centered Treatments for What Worries Women
Co-Champions: Anna Xia, Jerry Shapiro

June 3 Keep It Agile – Keep It Legal
Co-Champions: Eric Poole, Jeff Karg

Member News
MDG welcomes these new members:
Erik Bates
Bill Bullen
Arthur Combs
David Fleischer
Michael Foshey
Lew Harrold
Geoffrey Moodie
Paul Nickelsberg
Izabela Stroe
Phyllis Swartz

In addition, we welcome back those who have renewed their MDG membership:
Daniel Healey
Eric Klem
John Knott
John Sokolowski
Steven Stanford
Charles Sweet
Rosanna Villani
Adam Wallen

About MDG Boston
MDG is the professional association for career building, knowledge acquisition and mutual support for New England medical technology professionals.

MDG sponsors Forums, Networking, SIGs (Special Interest Groups), Workshops and Special Events where diverse industry leaders can share their experience and knowledge as presenters and one-on-one.