Working Together – Keeping Informed

October SPECIAL EVENT

Thursday
Oct 30, 2014
11:30 am – 5 PM
Constant Contact Headquarters
Waltham, MA

Program Description
The Medical Development Group (MDG) is collaborating with the FDA New England District Office in presenting a half day seminar that will address the following:

- **Doing Business in a Regulated Industry**
  Preparing for an FDA Review together with presentations from FDA Investigators on QSIT Inspections, Complaint Handling and What You Need to Know about Recalls

- **Meeting FDA Guidelines in Implementing UDI (Unique Device Identification)**
  which will be in effect for Class III products beginning on Sept. 24, 2014, with Class II and Class I implementations required over the next several years. In addition, there will be a discussion of the benefits of using botanical DNA in the future as a more effective alternative to bar coding.

- **Addressing the growing problem of Medical Device Counterfeit Parts**
  Several case studies showing medical device counterfeit part detection techniques will be reviewed as well as the impact on customer satisfaction and financial savings will be quantified.

The FDA Review Session will be conducted by FDA Management and Investigators from the New England district offices. The Counterfeiting and UDI sessions will use experts from MDG.

The seminar is targeted at medical device and life sciences companies in the New England area. Space is limited so early registration is strongly recommended.

Agenda
11:30 AM - 12:30 PM
REGISTRATION, LUNCH AND NETWORKING
12:30 – 12:45 PM
Welcome Address & Workshop Overview
12:45 – 1:15 PM
Doing Business in a Regulated Industry – Moderator - Mary Yebba (FDA) and Maura Rooney (FDA)
1:15 – 1:45 PM
QSIT Inspections, An Investigator’s Perspective – (FDA CSO)
1:45 – 2:15 PM
Complaint Handling - (FDA CSO)
2:15 – 3:00 PM
What You Need to Know about Recalls – (FDA CSO)
3:00 – 3:15 PM    Break
3:15 – 4:00 PM
Implementing UDI to meet FDA requirements - Jonathan C. Bretz (President - RSQM Associates) and Larry McIntosh (Applied DNA Sciences)
4:00 – 4:45 PM
Locating Counterfeit Medical Devices - Richard Nadeau (President – eComp) and Albert Cruz (Hologic)
4:45 – 5:00 PM    Final Questions & Wrap-up
Mary Yebba, FDA
Public Affairs Specialist for New England District Office
Mary Yebba has worked for the Food and Drug Administration for over 20 years. She started out at FDA’s Winchester Engineering and Analytical Center laboratory where she worked as a drug chemist for 7 years. She then transferred to FDA’s State Program Branch where she worked as a Milk and Retail Food Specialist until October of 2003. In October of 2003 Mary accepted her current position as the Public Affairs Specialist for FDA’s New England District Office in Stoneham, Massachusetts.

Maura Rooney, FDA
Supervisory Consumer Safety Officer for New England District
Maura has been with the FDA for five years. Prior to joining FDA, she worked for more than 10 years in the medical device industry. In her current role, she is responsible for supervising a team of investigators who inspect medical device manufacturers in New England and in countries worldwide. She has a MS in Mechanical Engineering from Worcester Polytechnic Institute.

Jonathan C. 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.

Albert Cruz
Senior Product Quality Engineer III, Hologic
Al’s primary role at Hologic is to develop, modify, apply, and maintain quality plans and protocols for processing materials and products. Al monitors overall quality performance of assigned products and recommends quality improvements initiatives to management. He supports new product development by leading the activities for performing Risk Management and supporting design assurance and operation activities. Al is IPC-A-610 certified, TQM certified instructor, Six Sigma certified, Supplier Quality Assurance certified and Counterfeit part certified.
Al developed a failure analysis lab at Hologic that has helped discover counterfeit parts. He has a B.S.E.E. from New York Institute of Technology, 12 years experience in the medical field and 25 years experience in failure analysis with electronic components, counterfeit parts and ESD damage.

Richard Nadeau
Founder and President of eComp-Electronic Components
eComp-Electronic Components Inc is a 14 year old company focused on specialty distribution and counterfeit product detection. eComp began in 1996 by solving Raytheon’s procurement, testing and authentication problems for obsolete semiconductors in its Patriot Japan Program, Aegis ship and many other legacy programs.
Other defense contractors have included General Dynamics, Lockheed, the DOD and NAVSEA. eComp is now focusing on the medical device market with programs that include component authentication and DNA marking to provide traceability. Rich began his career at Waters Associates and also worked RCA Corporation and other manufacturer rep companies prior to founding eComp. He has a BS in Electrical and Industrial Management Engineering from Wentworth Institute of Technology.

Larry McIntosh
Director of Sales, Applied DNA Sciences
Larry McIntosh has 20 years of sales experience in the microprocessor, semiconductors and other electronic-driven industries, and possesses a wealth of B2B experience in selling technology-enabled services and products. He started his career as a police officer in White Plains, NY.
Larry will substantially elevate APDN’s sales efforts, particularly as the Company begins to enter the fields of DNA marking of mission critical products to prevent counterfeit and diversion activities and working to continue to expand APDN’s reach within the government, security and commercial sectors for these applications. Mr. McIntosh received a Bachelor of Arts degree in Economics and Psychology from Fairfield University.

Hank Allard
Principal of Edge Rep Solutions
Focuses on providing OEM embedded systems, M2M (Machine to Machine) and Home Health care products, services and solutions to Medical Device Manufacturers and health care providers

Richard “Dick” O’Brien
Founder of Nagoghill Partners
A business development consultant, working with clients in medical device and related life sciences fields as well as serving technology/scientific organizations.
MDG Boston

We would like to thank the hundreds of volunteers who help to make this organization a success.

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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:
Lawrence C. Pieper
Mark Emery
Meenajshi Pandey
Rodolfo Archbold
Jack Besczak
Tun Liu
Gang Li
Yan Liu
Nancy Teasdale
Kristian DiMatteo
Denny Lo
Arthur Leary
John Rosala
Jennifer Kamerman

In addition, we welcome back those who have renewed their MDG membership:
Sean Phillips
Jennifer Anderson
John Merhige
Ian Mcrury
David Bonneau
John Vittal
Jerrold Shapiro
Bruce Horwitz
John Gillespie
Alan Kivnik
Charisse Sebastian
Joyce College

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.