Keep It Agile – Keep It Legal

Wednesday
June 3, 2015
5:30 – 8:30 PM
Constant Contact Headquarters
Waltham, MA

Meeting Agenda:
5:30 - 6:15
Arrival, Networking & Dinner
6:15 - 6:30
Announcements & Introductions
6:30 - 8:00
Speakers and Q&A
8:00 - 8:30
More Networking

Program Description
Regulated industries and medical device companies in particular, have been reluctant to adopt these techniques. Often, Agile processes do not seem to fit neatly into medical device quality management systems.

In Agile processes, risk management is addressed in a ‘learn while doing’ mode, rather than aiming to plan everything in advance. By building quality into each step and investing in Agile program structure, the development professional can act quickly on what is learned and the project can move forward more smoothly with fewer setbacks.

This strategy can be accomplished without any compromise to the high standards required in the medical device industry.

Attendees to the June 3rd forum will learn how to reap the benefits of the Agile process while remaining compliant.

Agile project management and technical practices have helped many businesses be more competitive. Projects are often delivered more quickly, with less cost and higher quality.

Many management teams and development professionals believe the Agile process only works in industrial and consumer settings and do not know it can bring the same advantages to medical device projects.

The Agile Process is Efficient!
“Implementing Agile unit tests let us finish our medical device project two weeks ahead of the original schedule.”
“The first time we used Agile methods on a project, our defect list never exceeded two open items.”
“My team used to spend a third of their time debugging - debug time went to near zero with Agile.”

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Upcoming Events

Wed June 10  7:30 AM to 9:30 AM
SIG - CEO: Growth Strategy III – Scalability Issues (Constant Contact)

Wed June 17  5:30 – 8:30 PM
MDG Networking Event (Constant Contact)

Thurs July 16   6:45 – 10:00 PM
Boston Harbor Cruise (Rowes Wharf, Boston)

Wed Sept 9   5:30 – 8:30 PM
Diabetes Today: Discipline, Devices & Development (Constant Contact)
**Panelists**

**Mike Attili**  
President at Amaxo, Inc.  
Mike Attili will provide an overview of traditional waterfall and iterative development methods and describe the Agile development process and how it contrasts with traditional methods. He will describe AAMI TIR-45:2012, which has become an FDA “accepted consensus standard”, and how to apply it to medical device software development.  
Mike is President of Amaxo, Inc., a software consulting company specializing in applications for the biotechnology, pharmaceutical, and medical device industries. He has over 25 years of experience in software design, development, testing, validation, and release engineering.  
Mike has worked on systems ranging from deeply embedded microcontrollers to highly scalable cloud computing infrastructure and applications including IV infusion pumps, cardiac monitors, high-speed DNA sequencing, and infectious disease diagnostics.  
Mike has been applying Agile practices to medical device development since 2004. He is an active member of the Association for the Advancement of Medical Instrumentation (AAMI) software working group, was a contributor to AAMI TIR45:2012 on the use of agile practices in the development of medical device software, and is currently working on the draft for TIR47 on health software quality management.  
Mike holds a Bachelor and a Master of Science in Physics from M.I.T., though he rarely gets a chance to do real physics anymore.

**Nancy Van Schooenderwoert**  
President and Managing Director of Agile Development Practice at Lean-Agile Partners  
Although there are important differences between hardware development and software development, Agile principles are being used to speed hardware development while raising quality. Nancy will present some real examples from real teams to show that the biggest effect of Agile methods is that speed and quality are no longer opposites.  
The speed of Agile organizations calls for very different internal wiring above the team level: Cross-functional autonomous teams need managers who create shared understanding rather than issue commands. They need managers who know that fostering transparency and collaboration leads to a better kind of control than anything achievable through old-style hierarchy. Engineers also need to understand some of the issues senior managers have with Agile’s perceived disorganization and unpredictability, and Nancy will show how to structure Agile development programs to satisfy senior management’s needs to keep schedules and budgets under control.  
Nancy does Agile Enterprise coaching- everything from launching new agile technical teams to advising executives on how to take Agile and Lean principles far beyond software development in their drive to deliver more customer value faster.  
She works with large and small companies. Nancy pioneered agile practices for embedded software development beginning in 1998. Her background in electronics and software development for avionics, factory automation, medical, and defense systems brings a unique perspective to her coaching practice.  
Nancy holds a Scrum Master certification, has edited a column for the Agile Times, and served on the IEEE1648 committee to define a standard for customers of agile teams. She has been a regular presenter at various Agile-related conferences since 2003. Her work in applying Agile methods to embedded systems has been referenced by Jim Shore and Mary Poppendieck in their books. She is a founder and past president of Agile New England, Boston’s largest Agile professional group.

**Co-Champions**

**Eric Poole**  
Medical Device Software Development and Regulatory Consultant at RKT Technologies, Inc.  
Eric brings 42 years’ experience in the industry including 24 years’ experience in medical device software including technical development and regulatory guidance to every project he engages. His clients have engaged Eric for everything from requirements analysis and system specification, to high level design and architecture, to implementation and validation, to technical leadership, to review and verification of the software development process.

**Jeff Karg**  
Director, Program Development at TechEn, Inc.  
TechEn provides electronic and software product development services with complex project experience ranging from continuous blood glucose monitoring patches to portable bone densitometers to NIRS brain mapping/imaging. Jeff oversees project engagements by consistently aligning client needs with TechEn’s suite of services and capabilities. He is responsible for developing program plans that deliver on client expectations and is a member of the TechEn team overseeing project quality.
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)

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<td>Intellectual Property Approaches To Safeguard Value</td>
<td>Rob Adelson, Roy Coleman, Stanley Chalvire</td>
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<td>Optical Cancer Detection: 20 years of Lessons Learned and 20 Years Of Future Promise</td>
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<td>Devices And Combination Products For Neurodegenerative Disease</td>
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<td>Mar 4</td>
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<td>The Surgical Suite Responds to the New Business Model of Healthcare</td>
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### Member News
MDG welcomes these new members:  
Ingrid Centurion  
Ritu Chadha  
Peter Chantiles  
Mike Chase  
Steven Conover  
Rafael Diana  
Sean DiStefano  
Mark Hersum  
Joseph Kvedar  
Dan Lausten  
Sergio Lopez  
Ken Micciche  
Rob Mulligan  
Catherine Petrozzino  
Eric Schattschneider  
Nicole Shugrue  
Teri Stokes  
Jeffrey Thumm  
Delia Vetter

In addition, we welcome back those who have renewed their MDG membership:

- Katherine Belk  
- David Buzzeo  
- Joyce C. Chiu  
- Keith Kowal  
- Mariana Matus Garcia  
- James O’Connor  
- George Romanski  
- Jack Swig

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Explore the NEW MDG Boston website at [www.mdgboston.org](http://www.mdgboston.org)

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### 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.