



Topic: “Standards and Compliance Driven Delivery of Medical Devices”

Presenter: Irv Badr, IBM Go-to-Market Manager – Energy, Utilities, and Communications Sector

Date: Thursday, February 16, 2012

**Agenda: 6:00-6:30 p.m. CST – Dinner (\$5 Member / \$8 Nonmember) & Networking
6:30-6:45 p.m. CST – Introductions & Announcements
6:45-8:00 p.m. CST – Presentation and Q&A**

- Locations:**
- 1. Schaumburg, IL – IBM, 10 N. Martingale Dr., Schaumburg, IL 60173 (2nd Floor Conference Room)**
 - 2. Milwaukee, WI – Astronautics, 4115 N. Teutonia Ave., Milwaukee, WI 53209 (Board Room)**
 - 3. Madison, WI – Bjorksten | bit 7, 7 Fen Oak Ct., Madison, WI 53718 (Mendota Conference Room)**

Abstract

This presentation is about systems engineering for medical devices. Through systems engineering, the pre-market certification (510K submission) and compliance filing for complex, software-intensive medical devices can be accelerated. Using a model-based verification and validation (V&V) process at system level, much of the V&V can be performed upstream, significantly improving the Time-to-Market for medical products.

About Our Speaker

Irv Badr has nearly twenty years of experience in developing software architecture and marketing complex systems. He works at IBM's Chicago office, as a Go-To-Market Manager focusing on Energy, Utilities, and Communication Service Providers in Rational Software division. Irv was chief systems architect for a complex, multi-processor medical device, and has worked as lead software engineer in medical robotics industry. He received an M.B.A. from Northwestern University and a B.S. in electrical engineering and physiology from the University Of Illinois. In addition to his role at IBM, Irv serves as Adjunct Professor of Technology Management at the Loyola University Graduate School of Business in Chicago. He has written many papers on medical devices from an FDA compliance perspective combined with Agile development methods.

Questions?: For more information, go to <http://www.incose.org/Chicagoland/>.