



*The Center for Business Innovation*

*Presents:*

## **The Second Annual Medical Device Connectivity Conference & Exhibition**

*Connecting Medical Devices to People, Workflow & Information Systems*

**September 28-29, 2010, Hyatt Regency Mission Bay, San Diego, CA**

**Who Should Attend:**

Executives and clinicians at hospitals, healthcare systems, physician groups and health plans, including biomedical engineering, clinical engineering and IT staff

Medical device and IT company executives, including marketing/sales and engineering staff

Management consultants, government officials, academics and the financial community

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**Association for the Advancement of Medical Instrumentation (AAMI)  
American College of Clinical Engineering (ACCE)  
Healthcare Technology Foundation  
International Council of Systems Engineering (INCOSE)  
RFID in Healthcare Consortium  
West Wireless Health Institute  
Wi-Fi Alliance**

## SUPPORTING PUBLICATIONS

**FierceEMR**  
**FierceHealthIT**  
**FierceMobileHealthcare**  
**Healthcare Informatics**  
**MobiHealthNews**  
**Patient Safety & Quality Healthcare**

### ***PROGRAM CHAIRPERSON'S WELCOME***

*The first annual Medical Device Connectivity Conference & Exhibition was held last year at the Joseph B. Martin Conference Center at Harvard Medical School in Boston. If you attended last year's conference, then you know first hand the kind of excitement and passion that attendees, speakers and exhibitors brought to the event.*

*Besides remaining the only event devoted to the topic of medical device connectivity, the conference draws a unique combination of attendees from both healthcare providers and manufacturers. The resulting mix provides a chance to gain insight into end user requirements, new technologies and product plans.*

*This year's conference will offer a unique opportunity to get immersed into every aspect of connectivity, workflow automation and enabling technologies. Like last year, you will find an outstanding agenda with early adopters and innovators in medical device connectivity.*

*The first day's keynotes and panel discussions frame the conference's focus on connectivity. The big issues this year are interoperability, meaningful use and regulatory issues. This year, program tracks will provide a survey of connectivity applications, clinical capabilities and outcomes and explore the gap between regulated vendor-managed systems and the customer-managed and controlled environments in which these systems are used.*

*Thanks to all the conference speakers for their participation and support of the advancement of connectivity, in this conference and beyond. Both their expertise and efforts to share their connectivity experience will create an exceptional conference experience for all attendees.*

*I hope that you will attend this exciting conference and tell your colleagues about this singular opportunity to learn and interact with some of the industry's leading minds in medical device connectivity. Like last year, this conference will explore and frame the issues that will help shape the future of connectivity and next year's Medical Device Connectivity Conference.*

*All the best,*

*Tim Gee, Program Chair  
Principal, Medical Connectivity Consulting*

**For information on speaking, sponsorship/exhibition opportunities and/or registration,  
please contact: Satish Kavirajan, Managing Director, TCBI:  
Ph: 310-265-2570 Email: [sk@tcbi.org](mailto:sk@tcbi.org)**

**SECOND ANNUAL MEDICAL DEVICE CONNECTIVITY CONFERENCE**

**PRELIMINARY AGENDA**

**DAY ONE, TUESDAY, SEPTEMBER 28, 2010**

**7:00 REGISTRATION / SPONSOR / EXHIBITOR SHOWCASE &  
CONTINENTAL BREAKFAST**

**8:00 CHAIRPERSON'S INTRODUCTION & OPENING REMARKS**  
**Tim Gee, Connectologist & Principal, Medical Connectivity Consulting**

**8:30 KEYNOTE ADDRESS: MARKET OVERVIEW, TRENDS AND BARRIERS TO  
ADOPTION**

*Tim Gee is Principal and founder of Medical Connectivity Consulting, specializing in workflow automation through the integration of medical devices with information systems, and enabling technologies. Tim has 25 years of experience with expertise in wireless medical devices, converged medical device/enterprise networks, requirements elicitation, regulatory strategy, connectivity, interoperability, diagnostic and point of care workflows, and patient flow optimization. Tim has served providers and vendors, including: Abbott Point of Care, Ascom, Awarepoint, Baxter Healthcare, Biotronik, Capsule, Cardinal Health, Ekahau, Emergin, GE Healthcare, Hill-Rom, Intel Digital Health, Providence Health, Robert Wood Johnson University Hospital, Spectrum Health, Welch Allyn and others. He is currently an advisor to two startups. Tim speaks frequently at industry conferences and corporate events, national sales meetings and user group meetings. He is on the editorial advisory board of a number of magazines, and publishes the blog Medical Connectivity ([www.medicalconnectivity.com](http://www.medicalconnectivity.com)), and also participates in industry initiatives.*

**Tim Gee, Connectologist & Principal, Medical Connectivity Consulting**

**9:00 KEYNOTE ADDRESS: IS MEDICAL DEVICE CONNECTIVITY REACHING A  
TIPPING POINT?**

The past year has seen much activity in the realm of medical device connectivity and interoperability. Numerous standards efforts have made substantial progress. Government participation is increasingly felt in efforts such as a prototype regulatory submission, groups like HITSP and the recent publication of Meaningful Use criteria. Organizations from outside of health care, such as the International Council on Systems Engineering, with the ability to contribute to some of the challenges facing healthcare, are also coming to the fore. Dr. Goldman will review many of these changes, consider whether these events represent a tipping point in the, and speculate what the near future holds for the adoption of connectivity and interoperability.

*Julian M. Goldman, MD, is Medical Director of Biomedical Engineering for Partners HealthCare System, where he is responsible for developing strategies, identifying technology trends and guiding Partners to stay on the leading edge of infrastructure and patient care technologies to ensure safety, effectiveness and efficiency. Dr. Goldman is also Director of the Program on Interoperability at CIMIT (Center for Integration of Medicine and Innovative Technology), a principal anesthesiologist in the Massachusetts General Hospital "Operating Room of the Future", and founder of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program. He has led the MD PnP program from an initial convening of 85 interested stakeholders in 2004 to a global network of over 700 participants from clinical environments, government agencies, medical device vendors, biomedical and clinical engineering, computer science engineering, and standards organizations. The MD PnP program was recognized with the CIMIT 2007 Edward M. Kennedy award for Healthcare Innovation. Dr. Goldman is the recipient of the 2009 American College of Clinical Engineering Professional Achievement in Technology Award, the Association for the Advancement of Medical Instrumentation (AAMI) Foundation/Institute for Technology in Health Care 2009 Clinical Application Award, and most recently, the International Council on Systems Engineering (INCOSE) 2010 Pioneer Award for leadership in the advancement of the state-of-the-art and practice of systems engineering in the biomedical and healthcare fields.*

**9:45 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS**

- 10:15 KEYNOTE ADDRESS: MEANINGFUL USE REQUIREMENTS FOR CONNECTIVITY**  
This presentation answers the question: what is the role of medical device integration in hospitals' achievement of ARRA HITECH EHR "meaningful use" objectives that will qualify the organization for payments? It presents medical device data in the larger context of the EHR as a critical component of Computerized Provider Order Entry, Medication Administration and Point of Care Clinical Documentation. This session will review the current state of medical device data automation and propose why MDI is a critical strategic initiative.  
*Ann Farrell, BSN, RN is Principal of Farrell Associates, a virtual boutique strategic HIT consulting firm offering business, market and product planning, process improvement and support services. Ann is a nationally recognized Electronic Health Records (EHR) expert and "thought leader", career long evangelist for IT that creates clinician "raving fans", an active HIMSS member and frequent speaker at national, regional and local forums. Prior to consulting, Ann was an RN EMR pioneer at a hospital with first commercial EMR and subsequently served as VP of Product Management and Research & Development for several lead HIT vendors. Ann's current focus is the convergence of Point of Care workflows and technologies with recent emphasis on aligning IT strategy with ARRA HITECH EHR Meaningful Use criteria and timelines.*  
**Ann Farrell, BSN, RN, Principal and Senior Consultant, Farrell Associates**

- 10:45 PANEL DISCUSSION: PICKING WINNERS – WHICH INDUSTRY STANDARDS WILL BE ADOPTED, WHEN AND BY WHOM?**  
Industry standards exist in a world where manufacturers prefer end-to-end proprietary solutions, and buyers prefer open interoperable systems. The preferences of manufacturers and buyers are balanced differently across markets and over time. The panel will answer attendee's questions regarding which standards are being adopted, the rate of adoption, and how this is reflected in commercially available products.  
**Moderator:**  
**Tapan Mehta, Senior Manager, Global Healthcare Solutions, Cisco**  
**Panelists:**  
**Dave Dyell, Chief Executive Officer, iSirona**  
**Ken Fuchs, Senior Principal Architect, Enterprise Systems, Mindray North America**  
**Julian M. Goldman, MD, Director, MD PnP Program & the CIMIT Program on Interoperability & Medical Director, Partners HealthCare Biomedical Engineering**  
**Jim Welch, Vice President, Masimo**

**11:45 SPONSOR / EXHIBITOR SHOWCASE & LUNCHEON**

**Choose From Track A, B or C**

**TRACK A – PROVIDERS**

- 1:00A PATIENT CARE, SAFETY AND WORKFLOW IMPACTS OF MOVING CONNECTIVITY BEYOND CRITICAL CARE TO LOW ACUITY UNITS**  
Medical device connectivity has been used in high acuity areas, such as intensive care units and surgery, for many years. While best practices for medical device connectivity are understood in high acuity areas, clinical and workflow requirements are substantially different in lower acuity units. Ms. Niemeier will explore the unique demands of lower acuity units, and combined with rapidly changing connectivity technologies, explore new evolving best practices.  
**Susan Niemeier, RN, BSN, MHA, Chief Nursing Officer, Capsule Technologie**
- 1:45A MONITORING UNMONITORED PATIENTS: ROI AND KEY CONNECTIVITY ENABLERS**  
The continued prevalence of failure to rescue and the challenges of nursing vigilance have given rise to new medical device systems intended to monitor previously unmonitored patients. Besides the obvious safety issues, cost justification remains a key business issue. While patient monitoring is well understood, differences in patient acuity result in a dramatically different set of requirements. Based on peer reviewed clinical data, this presentation looks at the business case for

monitoring previously unmonitored patients. The connectivity features and capabilities required to improve nursing vigilance and reduce adverse events are also presented.

**Jim Welch, Vice President Patient Safety, Masimo**

**2:30A MEDICAL DEVICE INTEGRATION: CONSIDERING THE CLINICAL PERSPECTIVE**

Although medical device integration most often falls under the jurisdiction of the IT department, the clinical staff ultimately becomes the end users of the technology—and they can provide valuable insights on the front end of the process. This presentation will describe one hospital's successful implementation (completed in just weeks) and the clinician-side involvement that helped drive their success. Considerations specific to connectivity, such as the desire for patient-vs. location-specific device association and the importance of a user-friendly system, will be shared. The presentation will also cover project objectives, vendor selection criteria, implementation challenges and lessons learned.

**Emma Brandon, RN, Director of Clinical Information, Cooper University Hospital**

**3:15 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS**

**3:45A THE IMPACT OF IEC 80001 ON PROVIDER ORGANIZATIONS**

Medical device systems are designed and tested by manufacturers, and cleared by the FDA, to operate on networks by themselves. The reality in customer sites is substantially different, where many medical device systems are attached to enterprise networks where they interact and coexist with other medical device and information systems. The consequences of this disconnect impact can impact the safety and effectiveness of medical devices. The ISO/IEC 80001 standard was conceived to give providers a framework with which to better manage networked medical devices. The ratification of this standard is expected September 26, 2010. Mr. Cooper will provide an overview of this new standard explain why health care providers should implement the standard, and delve into how to prepare your management, staff and vendors for 80001.

**Todd Cooper, President, Breakthrough Solutions, Co-chair ISO/IEC 80001 Joint Working Group**

**4:30A A PLATFORM FOR CONNECTIVITY**

Ms. Pesot will discuss the factors that a hospital or healthcare system should take into consideration when investing in healthcare IT. At a high level, topics discussed will include open platforms, integration of disparate healthcare IT systems, staff adoption, ease of use, device connectivity, bed connectivity and clinical applications. Data included in presentation is drawn directly from clinical and IT focus group feedback conducted over the past year with facilities across the United States (not limited to Hill-Rom customers).

**Whitney Pesot, Director of Product Management, Hill-Rom**

**5:00 DAY ONE CONCLUDES;  
SPONSOR/EXHIBITOR SHOWCASE & NETWORKING RECEPTION**

**Choose From Track A, B or C**

**TRACK B – MANUFACTURERS**

**1:00B DEMYSTIFYING WI-FI**

Wi-Fi is standards-based, but it presents complexities and challenges that are not apparent at first blush. Integrators and IT administrators must select the right infrastructure gear and determine how to deploy it optimally. Device makers must integrate the right feature sets and ensure that their devices work correctly in real-world environments. To make the right decisions about Wi-Fi, you need a foundational understanding of how Wi-Fi works. This presentation provides it, answering questions such as these:

- What is 802.11n, and how does it differ from other 802.11 standards?
- Is the 2.4 GHz band viable for wireless medical devices in hospitals?
- How does Wi-Fi operation at 5 GHz differ from Wi-Fi operation at 2.4 GHz, and how do you optimize each frequency band?
- What is 802.11i (WPA2-Enterprise), and how does it thwart the three main Wi-Fi security threats?

- How does a Wi-Fi client roam from one access point to another, and how can you ensure effective roaming in a hospital?
- How does Wi-Fi location work, and how accurate is it?

**Chris Bolinger, Vice President Sales & Marketing, Summit Data Communications**

**1:45B OPEN EHR MANIFESTSO: OPPORTUNITIES FOR MEDICAL DEVICE COMPANIES**  
Connectivity is inexorably linked with health care information technology, as they increasingly share information in the service of improving patient safety and outcomes, and reducing adverse events. The health care information technology industry is in the midst of a three phase migration, coming from a market dominated by proprietary end to end solutions, the “walled garden” product strategy has evolved as an effort to provide some connectivity and interoperability, but in a controlled manner. Currently the market is evolving to one that will be dominated by open technology platforms. Mr. Kuraitis posits that this evolving strategy offers opportunities and risks for medical device manufacturers. An analogous industry migration (telecom) will be presented. The presentation will next explore the market and technology drivers for open technology platforms and the implications of an open EHR platform, as they relate to medical device manufacturers.

**Vince Kuraitis, JD, MBA, Principal, Better Health Technologies, LLC**

**2:30B WI-FI ALLIANCE MEDICAL DEVICE WORKGROUP**  
A formidable challenge facing health care is the coexistence and effective management of wireless medical device systems within in the broader hospital enterprise environment. In an effort to advance the industry with these challenges, a group of members in the Wi-Fi Alliance have initiated a workgroup. This presentation will introduce the challenges this group is intended to tackle, and describe progress to date.

**Phil Raymond, Network Engineering Technical Lead, Philips Medical Systems**

**3:15 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS**

**3:45B LOOKING BEYOND CONVENTIONAL MEDICAL DEVICES AND MARKETS**  
Qualcomm Incorporated is the world leader in next-generation mobile technologies and the world’s largest manufacturer of chipsets for the wireless industry, and is now revolutionizing Life Sciences by partnering with medical device and health service companies to create innovative health solutions. Don Jones will be discussing the overall wireless health space, including how and why to move from unconnected medical devices to connected wireless medical devices. Mr. Jones will provide insight into making Body Area Network (BAN) technologies a reality, increasing the effectiveness of medical solutions and bringing new capabilities to consumers who want to manage their own health. He will discuss multiple technologies targeting the medical device industry, including ultra low power radios, gateway devices, digital signal processing to reduce noise, and wearable mobile device modules. Mr. Jones will detail how medical device manufacturers can apply the power of wireless to their solutions.

**Don Jones, Vice President Business Development, Health & Life Sciences, Qualcomm**

**4:30B KEY CONSIDERATIONS IN WIRELESS ENABLEMENT**  
Medical device wireless enablement is often a challenge for medical device manufacturers. Because wireless enablement is either new to a manufacturer, or a slow changing feature, many manufacturers are unfamiliar with radio selection criteria, how radios impact medical device design, and the extra steps required to design, test, release and gain regulatory approval for a new radio feature. Best practices are presented describing how wireless enablement impacts medical device product development projects.

**Kelly Oberle, Vice President Product Management, Silex America**

**5:00 DAY ONE CONCLUDES;  
SPONSOR/EXHIBITOR SHOWCASE & NETWORKING RECEPTION**

**Choose From Track A, B or C**

**TRACK C – REGULATORY**

**1:00C CONNECTIVITY REVEALS GAPS IN THE FDA’S REGULATORY FRAMEWORK**

As medical device connectivity technology has advanced, a number of market trends have highlighted areas on the regulatory framework where the needs of industry are unmet or difficult to achieve. Examples of these specific gaps are presented, along with an overview of initiatives underway to mitigate the situation. The presentation will close with a discussion of what health care providers and medical device manufacturers can do to best manage the current regulatory environment.

**Bradley M. Thompson, Esq., Member of the Firm, Epstein Becker & Green**

**1:45C**

**GOALS AND STATUS OF FDA REGULATORY SUBMISSION PROTOTYPE**

A new workgroup made up of industry, providers and the FDA has come together to clarify the application of medical device regulations to interoperable medical devices. This group is creating a prototype regulatory submission that will be used to work through the issues surrounding a prototypical medical device interoperability solution. A description of the project, its purpose, the current status, and its value to defining new regulatory pathways will be presented.

**Invited: Sandy Weininger, PhD., Senior Biomedical Engineer, Office of Science and Engineering Laboratories, Food and Drug Administration or Ken Fuchs, Senior Principal Architect, Enterprise Systems, Mindray North America**

**2:30C**

**FDA REGULATORY SUBMISSION PROTOTYPE USE CASES**

The foundation of the prototype regulatory submission is the use case that underpins the intended use and highlights the challenges inherent in interoperable systems from the perspectives of documentation of clinical guidelines through complex and interoperable control of biomedical devices. The use case describes how biomedical device interoperability addresses specific clinical needs and assists clinical end users in making clinical decisions. The candidate use case driving the prototype submission will be reviewed with an emphasis on how this influences and has revealed key regulatory issues during the course of its development and that of the prototype submission in terms of hazard analysis and design.

**John Zaleski, PhD., Vice President of Clinical Applications and Chief Technology Officer, Nuvon, Inc.**

**3:15**

**SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS**

**3:45C**

**INTEROPERABLE MEDICAL DEVICE SYSTEM ARCHITECTURES**

Certain system architecture requirements can be based on the use cases and technical requirements defined for the FDA prototype regulatory submission. The architectural approaches to interoperability at the technical, user, device, and system level will be discussed within the framework provided by the use cases. Concepts such as Interoperability Scenario and Interaction Protocol will be discussed in terms of the Prototype submission.

**Michael Robkin, Principal, Anakena Solutions**

**4:30C**

**PANEL DISCUSSION: Q&A ON FDA PROTOTYPE REGULATORY SUBMISSION**

Participants in the FDA regulatory submission prototype will answer questions regarding the workgroup and medical device interoperability. Potential topics include: the scope of connectivity and interoperability applications to be covered by the submission, how other manufacturers can learn from the submission, and discuss various approaches to intended use, testing and hazard analysis as they relate to interoperability.

**Moderator: Tim Gee, Connectologist and Principal, Medical Connectivity Consulting**

**Panelists:**

**Julian M. Goldman, MD, Director, MD PnP Program & the CIMIT Program on Interoperability & Medical Director, Partners HealthCare Biomedical Engineering**

**Peter Kelley, Director Quality Assurance Regulatory Affairs, Capsule Technologie**

**Michael Robkin, Principal, Anakena Solutions**

**Bradley M. Thompson, Esq., Member of the Firm, Epstein Becker & Green**

**Invited: Sandy Weininger, PhD., Senior Biomedical Engineer, Office of Science and Engineering Laboratories, Food and Drug Administration**

**John Zaleski, PhD., Vice President of Clinical Applications and Chief Technology Officer, Nuvon, Inc.**

**5:00**

**DAY ONE CONCLUDES;  
SPONSOR/EXHIBITOR SHOWCASE & NETWORKING RECEPTION**

**PRELIMINARY AGENDA  
DAY TWO, WEDNESDAY, SEPTEMBER 29, 2010**

**7:30 SPONSOR / EXHIBITOR SHOWCASE & CONTINENTAL BREAKFAST**

**Choose From Track A, B or C**

**TRACK A – PROVIDERS**

- 8:00 CHAIRPERSON’S OPENING REMARKS**  
**Marilyn Hailperin, Associate Partner, Santa Rosa Consulting**
- 8:30A PERIOPERATIVE SYSTEM ACQUISITION AND IMPLEMENTATION FROM A CLINICAL ENGINEERING PERSPECTIVE**  
Complex clinical information systems, incorporating medical devices and applications from multiple vendors is always a challenge. This presentation explores the experience of Brigham and Women’s Hospital, and their successful effort to acquire and implement such a system – mostly in the absence of industry standards that would assure connectivity.  
**Ilij Kullolli, MS, Clinical Engineer, Perioperative Information Management System, Biomedical Engineering Department, Brigham and Women’s Hospital**
- 9:15A OPERATING ROOM AND BED STATUS MANAGEMENT INTEGRATION PROJECTS**  
The underlying rationale for any medical device connectivity or systems integration project is improving workflow. Understanding current workflow is key to improvement. The final workflow must be understood and validated in advance if any improvements are to take place. Besides determining workflow and technical issues, the approach taken with staff during implementation is critical to success. This presentation reviews one hospital’s experience using messaging middleware to automate workflow, delving into the changes made, lessons learned and the financial results.  
**Brent Maranzan, Business Coordinator, Perioperative Services, Thunder Bay Regional Health Sciences Center, ON, CA**
- 10:00 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS**
- 10:30A COMMERCIAL WIRELESS INDOOR NETWORK FOR SIMI VALLEY HOSPITAL**  
The ubiquity of mobile device users, the promise of true electronic medical records, and ‘Meaningful Use’ are driving provider organizations and care givers to embrace mobile technologies more quickly than ever. Yet, especially in healthcare, wireless network technologies must be reliable and secure. They must allow fast access to patient data, while providing voice, texting, video, or medical images in utmost clarity. Southern California’s Simi Valley Hospital, recognized these needs as part of a \$75 million enhancement of their world-class hospital – one of 17 in the Adventist Health system. Today, Simi Valley Hospital’s indoor network provides coverage for multiple wireless carriers with a unique technology. Using the ductwork of the hospital’s heating, ventilating and air conditioning (HVAC) system as the way to distribute radio waves, the hospital gets thorough and affordable coverage, as well as a discreet, efficient installation that featured minimal construction interruptions to hospital operations.  
**Russell Vest, Senior Director of Business Development, ExteNet Systems**
- 11:15A EXTENDING COMMUNICATIONS WITH MOBILE EVENT NOTIFICATION**  
The safety of your patients, staff and guests can be improved by speeding response time. Effective technologies can integrate disparate systems, resulting in efficient communications. Mobile event notification middleware enables staff to respond more quickly to various situations by sending alerts from systems such as nurse call, patient monitoring, fire, and security directly to the right staff member on his or her mobile device. In this presentation, attendees will learn how mobile event notification can simplify communications throughout your organization and speed response to critical situations, and how hospitals are utilizing these types of solutions.  
**Anna Ferguson, Regional Sales Director, Amcom Software**
- 12:00A CLOSING PANEL DISCUSSION**

This closing panel discussion provides attendees with their last opportunity to query presenters with their most difficult and penetrating questions.

**Moderator:**

**Ann Farrell, BSN, RN, Principal and Senior Consultant, Farrell Associates**

**Panelists:**

**To Be Announced, Amcom Software**

**Emma Brandon, RN, Director of Clinical Information, Cooper University Hospital**

**Invited: Linda Chan, IT Systems Integration Manager, Information Services, Virtua Health**

**Invited: Lancaster General Hospital**

**Susan Niemeier, RN, BSN, MHA, Chief Nursing Officer, Capsule Technologe**

**Whitney Pesot, Director of Product Management, Hill-Rom**

**Jim Welch, Vice President Patient Safety, Masimo**

**1:00 CONFERENCE CONCLUDES; LUNCHEON FOR ATTENDEES OF OPTIONAL POST-CONFERENCE WORKSHOPS**

**TRACK B – MANUFACTURERS**

**8:00 CHAIRPERSON’S OPENING REMARKS**  
**Bridget Moorman, CCE, President, BMoorman Consulting, LLC**

**8:30B BEST PRACTICES FOR MEDICAL DEVICE SOFTWARE APPLICATIONS**  
Application development for general purpose computing platforms differs substantially from the development of embedded systems software. Applying best practices from one discipline to the other can incur unnecessary costs, delays in time to market and may occasion regulatory clearance issues. Mr. Shah will apply current software application development strategies and methodologies to medical device connectivity software this is often used to manage patient context, automate workflow, provide alarm notification, and other key medical device system features commonly implemented on general purpose computing platforms.  
**Shahid Shah, CEO, Netspective Communications LLC**

**9:15B TROUBLE AT THE POINT OF CARE – CONVERGENCE OR COLLISION OF IT? A VIEW FROM THE TRENCHES**  
Research has shown that automating nursing workflows is orders of magnitude more complex than physicians and other care providers. Thus, it’s not surprising that the industry has largely failed to provide useful and usable seamless tools for nurses, many of whom work in what researchers describe as “combat like” conditions. This session provides a high level view of the multiple, inextricable processes performed in parallel by nurses at the point of care, showing Medical Device Integration as but one piece of a very complex larger IT picture.  
**Ann Farrell, BSN, RN, Principal and Senior Consultant, Farrell Associates**

**10:00 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS**

**10:30B THE STORM HAS HIT – HEALTHCARE PROVIDER REALITIES AND NEEDS FROM VENDORS**  
The storm has hit the providers: with a brief review of the regulatory and economic issues facing providers, suggestions on how vendors can assist them in their integration efforts will be presented. The healthcare providers will drive vendors to have more standards based product designs or product networking capability, to meet their regulatory requirements and customer expectations. Moreover, the blurring of the lines between medical devices and IT appliances will change who a vendor’s customers are and how that vendor will be managed both in the procurement as well as operational phases of device or system adoption and implementation. Scenarios both within the traditional healthcare environment as well as externally (home-based) will be reviewed.  
**Bridget Moorman, CCE, President, BMoorman Consulting, LLC**

**11:15B THE ROLE OF OPEN SOURCE SOFTWARE IN MEDICAL DEVICE CONNECTIVITY**  
Medical device systems are highly dependent on proprietary intellectual property for maintaining sustainable competitive advantage. By contrast, connectivity is a feature set domain where easy integration with third party systems is a requirement and adopting commonly shared technologies, like industry standard HL7 become competitive advantages. Because the term *proprietary connectivity* is an oxymoron, industry is increasingly looking to open source software. Mirth

Connect is an open source project used by health care providers and manufacturers alike. This presentation provides a primer on the use of open source software, using Mirth Connect as an example. Attendees will learn about the different types of open source software licenses and the commercial implications of each. Different ways to utilize open source will be discussed, ranging from simply downloading source code to leveraging vendor supported training and technical support. A brief review of open source projects will include both horizontal applications like databases, dashboards and enterprise service buses to health care specific applications for electronic master patient indexes and clinical data repository.

**Jeff Peters, Vice President of Operations, Mirth Corporation**

**12:00B CLOSING PANEL DISCUSSION: DOES HEALTHCARE REQUIRE ADDITIONAL, DEDICATED RF SPECTRUM FOR WIRELESS MEDICAL DEVICES?**

The debate about shared versus dedicated wireless spectrum for medical devices has been around since the advent of WMTS, and continues to today. A small group of vendors recently made their case for dedicated spectrum for wireless body area networks. Comments such as, “Wi-Fi spectrum is full,” have again raised the question whether wireless medical devices should run on their own licensed spectrum. This group will look at both sides of the debate, as they take questions from the audience on the current state of wireless medical devices in health care.

**Moderator:**

**Bridget Moorman, CCE, President, BMoorman Consulting, LLC**

**Panelists:**

**Eric Abbott, Director of Product Management, Extenet Systems**

**Ken Fuchs, Senior Principal Engineer, Enterprise Systems, Mindray North America**

**David Hogle, President, Integra Systems**

**Don Jones, Vice President Business Development, Health & Life Sciences, Qualcomm**

**Sudheer Matta, Product Manager, Wireless Networking Business Unit, Cisco**

**Invited: James Moon, Chief Technology Officer, Sotera Wireless**

**Jim Welch, Vice President Patient Safety, Masimo**

**1:00 CONFERENCE CONCLUDES; LUNCHEON FOR ATTENDEES OF OPTIONAL POST-CONFERENCE WORKSHOPS**

**TRACK C – REGULATORY**

**8:00 CHAIRPERSON’S OPENING REMARKS**  
**Bradley M. Thompson, Esq., Member of the Firm, Epstein Becker & Green**

**8:30C IEC 80001 – WHAT TO DO NOW TO PREPARE**  
The voluntary end-user standard, IEC 8001, should be complete by the time of the conference. Shortly thereafter, manufacturers will likely start receiving requests from hospitals for product data to be used by the hospital for risk analysis of their networked medical devices. This presentation will provide an overview of manufacturer’s responsibilities to their customers under IEC 80001, potential pitfalls, and what manufacturers can do to be prepared.  
**Ken Fuchs, Director of Clinical and Systems Engineering, Mindray**

**9:15C MANAGING THE TRANSITION TO BECOMING AN FDA REGULATED MANUFACTURER**  
The prospect of becoming an FDA regulated manufacturer fills most non-regulated companies with trepidation. At the same time, many firms recognize opportunities in health care and want to pursue them. This presentation describes the process undertaken to bring companies into compliance with the FDA’s Quality System regulation. Starting with a brief overview of the FDA Quality System regulation, this session delves into common strategies and approaches companies can take to gain compliance. Best practices and lessons learned are highlighted.  
**Invited: Beth Bierman, Esq., Partner, Morgan Lewis & Bockluis LLP**

**10:00 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS**

**10:30C AN INSIDERS PERSPECTIVE ON 510(k) SUBMISSION FOR COMPLEX MEDICAL DEVICE SYSTEMS INCORPORATING CONNECTIVITY**  
The regulatory approach to medical devices varies greatly based on product characteristics, such as patient risk, intended use, and the technology incorporated into the device. The regulatory burden for products such as implantable pacemakers, patient monitoring systems or catheters can

be dramatically different. This presentation shall delve into the peculiarities of complex medical device systems incorporating connectivity. Examples of the regulatory approach for a number of such products will be discussed and contrasted against more conventional medical devices.

**Invited: Russ Gray, The Anson Group**

**11:15C REGULATORY STRATEGY DEVELOPMENT FOR CONNECTIVITY PRODUCTS**

A medical device's regulatory strategy is the balance between a compelling intended use, device specifications, and risk management. An optimal mix of these factors can greatly minimize mid to long term sustaining engineering costs and reduce immediate time to market. This presentation will demonstrate how to craft a regulatory strategy for a connectivity solution, presenting best practices and examples from industry.

**Tim Gee, Connectologist and Principal, Medical Connectivity Consulting**

**12:00C CLOSING PANEL DISCUSSION:**

Questions from the audience on the current state of wireless medical devices in health care.

**Moderator:**

**Bradley M. Thompson, Esq., Member of the Firm, Epstein Becker & Green**

**Panelists:**

**Julian M. Goldman, MD, Director, MD PnP Program & the CIMIT Program on Interoperability & Medical Director, Partners HealthCare Biomedical Engineering**

**Peter Kelley, Director Quality Assurance Regulatory Affairs, Capsule Technologie**

**Bridget Moorman, CCE, President, BMoorman Consulting, LLC**

**Michael Robkin, Principal, Anakena Solutions**

**Invited: Sandy Weiniger, PhD., Senior Biomedical Engineer, Office of Science and Engineering Laboratories, Food and Drug Administration**

**John Zaleski, PhD., Vice President of Clinical Applications and Chief Technology Officer, Nuvon, Inc.**

**1:00 CONFERENCE CONCLUDES; LUNCHEON FOR ATTENDEES OF OPTIONAL POST-CONFERENCE WORKSHOPS**

**OPTIONAL POST-CONFERENCE WORKSHOP ONE**

**DISTRIBUTED ANTENNA SYSTEMS: DESIGN CONSIDERTIONS FOR 2010 AND BEYOND IN HEALTH CARE**

**Workshop Hours: 2:00-6:00 pm**

Just like the explosion of wireless LANs in hospitals, a similar trend has occurred with mobile phones, broadband adapters for laptops, and Blackberries. A new era has arrived whereby physicians, patients, and their families will demand to use these devices. Since the events of September 11th, the need for in-building public safety communication coverage has become a critical requirement as many jurisdictions adopt coverage requirements including those referenced in the National Fire Prevention Act (NFPA 2009) code.

This workshop will focus on why in-building broadband coverage is required, review potential policies and procedures for the use of mobile devices, and finally an overview of the different designs of distributed antenna systems (DAS).

While there has been concern about the use of broadband devices in the presence of medical devices, it has been shown that there is little or no EMI concern. The fact remains that the implementation of a DAS will greatly reduce this potential.

A variety of business models will be described for wireless carrier coverage. This includes a single carrier model as well as a multi-carrier model. Additionally the requirement of mandated public safety coverage will be also covered. In light of this a variety of ways to finance the DAS infrastructure, from either carrier funding or self-funding, will be discussed.

The different underlying technologies used in DAS will be described to include the needed design and propagation modeling requirements. A review will be made of the underlying solutions to include passive designs and fiber fed active based designs. This will additionally include the past and current use model of 802.11a/b/g, 802.11n, voice over IP and WMTS with the technical and financial caveats.

While the initial marketing of these combined services may sound attractive, at the end of the day, technical requirements like the link budget will determine practicality. Considerations will also be given to the design requirements of the leading wireless LAN manufacturers when combining a wireless LAN onto a DAS.

What does the future hold for DAS in healthcare and what are some the prevailing solutions on the horizon? The session will end with this and your questions and comments.

**Workshop Instructor:**

*Eric Abbott is the Director of Product Management at ExteNet Systems, Inc., the premier provider of sophisticated, open network wireless communication systems for real estate investment trusts healthcare facilities, educational venues, and enterprise campuses. Mr. Abbott has more than 20 years of experience in the commercialization of new products and solutions in the communications industry with significant understanding of optimal methodologies and best practices to achieve interoperable networks in a variety of settings. Prior to joining ExteNet Systems, Inc., Mr. Abbott served as Senior Product Manager for Motorola, Inc. There, he led the development of advanced wireless communication products and systems for commercial carriers, public safety agencies, and enterprise customers. His background also includes medical informatics, healthcare IT, intellectual property, business strategy, and systems engineering. Mr. Abbott holds degrees in Electrical Engineering from the University of Toronto and the University of Illinois at Urbana-Champaign. He is currently completing his Masters of Medical Informatics degree at Northwestern University and his Master of Business Administration degree at Lake Forest Graduate School of Management.*

**Eric Abbott, Director, Product Management, ExteNet Systems, Inc.**

**OPTIONAL POST-CONFERENCE WORKSHOP TWO  
OPEN SOURCE SOFTWARE AS A COST EFFECTIVE, QUICK-TO-MARKET DEVELOPMENT  
STRATEGY FOR MEDICAL DEVICE MANUFACTURERS**

**Workshop Hours: 2:00-6:00 pm**

Today the universe of medical devices that do not require some connectivity features – not to mention data analysis, review and presentation software – is becoming vanishingly small. Managing device data and serving it up to other systems using standards like HL7 are well understood, but not trivial undertakings. These types of features are most often implemented on general purpose computing platforms as this is a more rapid development environment than embedded systems.

Traditionally, medical device manufacturers developed these applications from scratch, and over a considerable period of time. In a continuing effort to minimize development costs and time to market, manufacturers are starting to adopt an approach utilizing open source software. Open source has long been used for software components in medical devices for simple tasks like parsing data. Increasingly, the trend is to use ever larger systems such as rules engines or databases, and some are building entire systems out of multiple open source projects.

This workshop is for startup manufacturers looking to minimize development costs and time to market for new products, and for established manufacturers considering next generation development approaches for medical device software on general purpose computing platforms.

The workshop will review key applications suitable for implementation with open source software: patient/device context management, device data acquisition and storage, data surveillance, device data review, data analysis, event management (i.e., alarm notification), and health care IT systems integration using HL7.

The impact of open source on product and business strategy is different from conventional embedded systems. The key factors impacting strategy, and best practices or utilizing open source software will be described.

Requirements gathering is critical to successful projects, and differs from requirements gathering for conventional embedded systems. Best practices for requirements gathering and requirements for IT

systems integration for common use cases such as patient demographics, results reporting, and orders are described. Deploying regulated medical devices on general purpose computing platforms also includes a new set of requirements that differ from embedded systems devices.

Regulatory requirements and strategy for open source based regulated products differs from conventional embedded systems software development. The workshop will review regulatory best practices, relevant FDA guidance documents, for product development projects incorporating open source software.

Attendees will receive an extensive survey of common open source projects that may be suitable for their specific medical device projects. Categories of applications include databases, rules engines, enterprise service buses, dashboards and more. How to survey open source projects and important selection criteria, selection and systems integration will be discussed.

Sample project frameworks and time lines, noting key development phases of an open source based project will be presented. Attendees may suggest sample applications to be discussed and outlined for the workshop. Suggested applications include data integration for paperless charting and other EMR integrations, patient monitoring central stations, diagnostic modalities and virtualized medical device architectures.

#### **Workshop Instructors:**

*Tim Gee is Principal and founder of Medical Connectivity Consulting, specializing in workflow automation through the integration of medical devices with information systems, and enabling technologies. Tim has 25 years of experience with expertise in wireless medical devices, converged medical device/enterprise networks, requirements elicitation, regulatory strategy, connectivity, interoperability, diagnostic and point of care workflows, and patient flow optimization. Tim has served providers and vendors, including: Abbott Point of Care, Ascom, Awarepoint, Baxter Healthcare, Biotronik, Capsule, Cardinal Health, Ekahau, Emergin, GE Healthcare, Hill-Rom, Intel Digital Health, Providence Health, Robert Wood Johnson University Hospital, Spectrum Health, Welch Allyn and others. He is currently an advisor to two startups. Tim speaks frequently at industry conferences and corporate events, national sales meetings and user group meetings. He is on the editorial advisory board of a number of magazines, and publishes the blog Medical Connectivity ([www.medicalconnectivity.com](http://www.medicalconnectivity.com)), and also participates in industry initiatives.*

#### **Tim Gee, Connectologist and Principal, Medical Connectivity Consulting**

*Shahid N. Shah is the CEO of Netspective Communications, a software consultancy whose actionable advice and disciplined approach delivers custom software for in-house, outsourced, or offshore solutions. For the past 15 years Shahid has held the positions of CTO, VP of Technology, Chief Software Architect, or Enterprise Architect at large enterprises. His technology expertise includes service-oriented and event-drive architectures, Java/JEE, .NET, and agile development and his healthcare focus starts with an emphasis on e-health, EMRs, data integration, and legacy modernization. Shahid's an expert at discovering practical technology solutions to real-world business initiatives, especially in the government, healthcare and financial services industries. His expertise includes standards development, enterprise architecture analysis and design, interoperability planning, legacy modernization, and related work. He's worked at NIH on standards, Executive Office of the President (White House) and OMB on helping define the needs for standards, and at various commercial healthcare firms like CardinalHealth and COMSYS. In addition to working with C-Suite executives he continues to help engineering teams with architecture and development advice. He is an influential thought leader and a winner of Federal Computer Week's coveted "Fed 100" award given to IT experts that have made a big impact in the government and runs three successful blogs. At <http://shahid.shah.org> he writes about architecture issues, at <http://www.healthcareguy.com> he provides valuable insights on how to apply technology in health care, at <http://www.federalarchitect.com> he advises senior federal technologists, and at <http://www.hitsphere.com> he gives a glimpse of the health-care IT blogosphere as an aggregator.*

#### **Shahid Shah, CEO, Netspective Communications LLC**