

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

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## **KEYNOTE SPEAKERS**



Ann Farrell, BSN, RN, Principal & Senior Consultant, Farrell Associates



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



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



## 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

## **ABOUT THE CONFERENCE ORGANIZER**

The Center for Business Innovation (TCBI) organizes conferences and exhibitions for the U.S. and international markets. TCBI is an independent company that is well-positioned to provide objective, balanced information and analysis on a wide range of topics. TCBI currently focuses on organizing programs that offer detailed and practical instruction on clinical, technological, financial, strategic and regulatory aspects of healthcare. These programs are carefully designed to meet the information needs of executives, clinicians and IT staff from hospitals, managed care organizations, physician groups, long-term care facilities, postacute care providers, pharmaceutical/biotechnology companies, medical device companies, information technology vendors and other organizations in the rapidly evolving healthcare industry. For additional information, please visit www.tcbi.org.

## **SPONSORSHIP AND EXHIBITION OPPORTUNITIES**

Sponsorship and exhibition are effective ways to promote your products and services to key decision makers at healthcare provider organizations as well as technology companies. Benefits include space to exhibit at the Conference, passes for staff and clients / potential clients, an advance listing of attendees and exposure on the Conference website. For additional information, please contact TCBI: Tel: (310) 265-2570 Email: info@tcbi.org



## 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



## SECOND ANNUAL MEDICAL DEVICE CONNECTIVITY CONFERENCE AGENDA

# DAY ONE: TUESDAY SEPTEMBER 28, 2010

#### 7:00 REGISTRATION / SPONSOR / EXHIBITOR SHOWCASE & CONTINENTAL BREAKFAST SPONSORED BY: capsule

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

#### 8:15 KEYNOTE ADDRESS: EMERGING PROBLEMS AND RISING AWARENESS OF MEDICAL DEVICE SYSTEMS ON ENTERPRISE NETWORKS

Medical device connectivity is continuing the transition from stand alone or physically separate systems to becoming part of the enterprise IT infrastructure. EMR adoption and the looming 2015 Meaningful Use roadmap milestone for medical device interoperability are hastening this transition. To better gauge the current status of awareness in hospitals of these changes and the reactions and attitudes of those feeling the effects of these changes, a series of focus groups with hospital CIOs and other IT managers was held in several major metro areas in the US. Underwritten by a non-profit private institute, the results of this market research shall be presented. After briefly defining the current market landscape, levels of awareness of key issues will be reviewed. Attitudes regarding wireless medical devices, and the role of device and infrastructure manufacturers will be discussed, along with perceptions about potential solutions to the challenges faced by health care providers. The presentation will close with a discussion of potential solutions and a possible industry wide approach to the challenges presented by the emergence of a growing number of networked medical device systems.

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, Virtua 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), 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, and speculate on 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.

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

#### 9:45 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS SPONSORED BY: capsule)

#### 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 Heath 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** 

#### 11:00 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 attendees' 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 Systems 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 Brian McAlpine, Director Strategic Products, Capsule Tech. Inc.

Jim Welch, VP Patient Safety Initiative, Masimo

#### 12:00 SPONSOR / EXHIBITOR SHOWCASE & LUNCHEON

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

#### **TRACK A - PROVIDERS**

#### 1:15A 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. Niemier 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 Tech, Inc.

#### 2:00A LOOKING BEYOND CONNECTIVITY IN HOSPITALS TO HOME HEALTH AND MOBILITY

The challenges of device connectivity and data integration within the walls of a hospital – in high acuity and low acuity locations – may not be completely solved but these are known environments and solutions are available. The conversation today in healthcare is now focused on the next frontier – home health and mobility. Providing the same level of rigor for data capture, monitoring, and integration as demanded within the hospital environment will be the next challenge to solve – and it is not trivial. Providers will want a way to ensure the seamless, secure, and standardized integration of data from these new environments. This presentation will present both a platform and an approach for achieving this desired continuum from the highest acuity suites to mobile and home venues.

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

#### 2:45A 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, VP Patient Safety Initiative, Masimo** 

#### 3:30 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS SPONSORED BY: capsul

#### 4:00A 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

#### 4:45A 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 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, Cochair ISO/IEC 80001 Joint Working Group 5:30 DAY ONE CONCLUDES; SPONSOR/EXHIBITOR SHOWCASE & NETWORKING RECEPTION

#### TRACK B – MANUFACTURERS

#### 1:15B 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

#### 2:00B 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

#### 2:45B WI-FI ALLIANCE HEALTHCARE TASK GROUP

A formidable challenge facing healthcare is the planning, design, deployment and management of Wi-Fi networks to support wireless medical device systems within the broader hospital enterprise Wi-Fi environment. In an effort to advance the industry with regards to these challenges, the Wi-Fi Alliance has established a task group focusing on Wi-Fi healthcare deployments that support coexistence between wireless medical devices and non medical devices. This presentation will introduce the challenges this group is intended to tackle, mechanisms or best practices for successful converged Wi-Fi networks, and describe progress to date.

Phil Raymond, Wireless Architect, Philips Healthcare, Patient Monitoring Systems

#### 3:30 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS SPONSORED BY: capsul

#### 4:00B 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** 

Bridget Moorman, CCE, President, BMoorman Consulting, LLC

#### 4:45B 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 5:30 DAY ONE CONCLUDES; SPONSOR/EXHIBITOR SHOWCASE & NETWORKING RECEPTION

#### TRACK C – REGULATORY

#### 1:15C 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

#### 2:00C 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.

Scott Thiel, Regulatory Affairs Program Manager, Roche Diagnostics & Member, Continua FDA Workgroup

#### 2:45C 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.

#### 3:30 SPONSOR / EXHIBITOR SHOWCASE & REFRESHMENTS SPONSORED BY: capsule)

#### 4:00C 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** 

#### 4:45C 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 a discussion of various approaches to intended use, testing and hazard analysis as they relate to interoperability.

#### **Moderator:**

Tim Gee, Connectologist & 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 Tech, Inc.

Michael Robkin, Principal, Anakena Solutions Scott Thiel, Regulatory Affairs Program Manager, Roche Diagnostics & Member, Continua FDA Workgroup

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

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

#### **5:30** *DAY ONE CONCLUDES;*

SPONSOR/EXHIBITOR SHOWCASE & NETWORKING RECEPTION



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## SECOND ANNUAL MEDICAL DEVICE CONNECTIVITY CONFERENCE AGENDA

# DAY TWO: WEDNESDAY SEPTEMBER 29, 2010

#### 7:30 SPONSOR / EXHIBITOR SHOWCASE & CONTINENTAL BREAKFAST SPONSORED

BY: SUMMIT

Choose from Track A, B, C or D

TRACK A – PROVIDERS

#### 8:00A CHAIRPERSON'S OPENING REMARKS Monty Petrich, Consulting Architect, GTRI

#### 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.

L. Michael Fraai, Director of Biomedical Engineering, Brigham and Women's Hospital Ilir 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 SPONSORED

## BY: SUMMIT

#### 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, Inc.

#### 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 & Senior Consultant, Farrell Associates

#### Panelists:

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

Anna Ferguson, Regional Sales Director, Amcom Software

Ilir Kullolli, MS, Clinical Engineer, Perioperative Information Management System, Biomedical Engineering Department, Brigham and Women's Hospital

Brent Maranzan, Business Coordinator, Perioperative Services, Thunder Bay Regional Health Sciences Center, ON, CA

Susan Niemeier, RN, BSN, MHA, Chief Nursing Officer, Capsule Tech, Inc.

Russell Vest, Senior Director of Business Development, ExteNet Systems, Inc.

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

#### TRACK B – MANUFACTURERS

8:00B 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 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 SPONSORED BY:

#### 10:30B WIRELESS POSSIBILITIES & NEW DISTRIBUTION CHANNELS FOR MEDICAL DEVICES

Qualcomm Incorporated is the world leader in nextgeneration 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

#### 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 busses 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, Product Management, ExteNet Systems, Inc.

Don Jones, Vice President Business Development, Health & Life Sciences, Qualcomm Sudheer Matta, Product Manager, Wireless Networking Business Unit, Cisco Systems Shahid Shah, CEO, Netspective Communications LLC Gunnar Trommer, PhD, Vice President Marketing & Customer Service, Sotera Wireless

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

#### TRACK C – REGULATORY

#### 8:00C 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, Senior Principal Architect, Enterprise Systems, Mindray North America

#### 9:15C APPLYING 80001 TO DIGITAL OPERATING ROOMS AND ENDOSCOPY

Abstract: EC 80001-1 is an international, voluntary standard being developed by the ISO/TC 215-IEC/SC 62A Joint Working Group (JWG) 7. This new standard is entitled Application of Risk Management for IT-Networks Incorporating Medical Devices-Part 1: Roles, Responsibilities and Activities, and is expected to be ratified in late 2010. The standard focuses on the highlevel actions that a healthcare facility should undertake when connecting medical devices to the hospital IT network. It aims to preserve and balance the following key properties of such an incorporated network: (1) Safety; (2) Effectiveness; and (3) Data and system security. IEC 80001-1 applies to wired or wireless networks that include at least one medical device; it refers to these as "medical IT networks." The standard deals only with the broad risk management processes that hospitals need to address (e.g., definitions, specification of responsibilities, documentation requirements). It does not provide any network or system performance expectations or design criteria.

With the pending release of IEC 80001, the Kaiser Permanente (KP) Clinical Technology team used Digital Operating Room (DOR) and related Endoscopic equipment technology acquisition and implementation projects to trial the application of this new standard. The presentation will analyze KP's DOR-Endo work from an IEC 80001-1 perspective to present perceived Risks and planned Risk Management activities, addressing the requirements of IEC 80001-1.

Tom Judd, National Project Director, Kaiser Permanente Clinical Technology Ken Survillas, Deployment Manager, Southern California, Kaiser Permanente Clinical Technology

10:00	SPONSOR / EXHIBITOR SHOWCASE &
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#### **10:30C** PANEL DISCUSSION: REGULATORY CHANGES DRIVEN BY CONNECTIVITY

Medical devices incorporating connectivity or interoperability features often benefit from a change regulatory approach. The panel will discuss their experience in identifying changes wrought by the addition of connectivity features, and how those changes impacted product development projects and overall product success. **Moderator:** 

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

Ken Fuchs, Senior Principal Architect, Enterprise Systems, Mindray North America Tim Gee, Connectologist & Principal, Medical Connectivity Consulting Peter Kelley, Director Quality Assurance & Regulatory Affairs, Capsule Tech, Inc. Scott Thiel, Regulatory Affairs Program Manager, Roche Diagnostics & Member, Continua FDA Workgroup

#### 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 & Principal, Medical** 

Connectivity Consulting

#### 12:00C CLOSING PANEL DISCUSSION

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

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

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 Peter Kelley, Director Quality Assurance & Regulatory Affairs, Capsule Tech, Inc. Michael Robkin, Principal, Anakena Solutions Scott Thiel, Regulatory Affairs Program Manager, Roche Diagnostics & Member, Continua FDA Workgroup

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

#### Track D - SCHEDULED VENDOR MEETINGS

Meetings to be scheduled with sponsors/exhibitors at the conference. Conference attendees will have the option to schedule meetings with sponsors/exhibitors for indepth solution demonstrations or consultative discussions about their unique needs and situation. Appointments are available from 8:00 am to 12:00 noon and the appointment times correspond with the session times in the other three educational tracks. From 12 noon to 1:00 pm, attendees will have the option of attending one of the other educational tracks: Tracks A, B, or C. For additional information on vendor meetings, please contact TCBI: Tel: (310) 265-2570 Email: info@tcbi.org

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

#### OPTIONAL POST-CONFERENCE WORKSHOP ONE DISTRIBUTED ANTENNA SYSTEMS: DESIGN CONSIDERATIONS FOR 2010 AND BEYOND IN HEALTHCARE

Workshop Hours: 2:00-6:00 pm

This workshop will focus on strategies for achieving seamless connectivity in a clinical setting using distributed antenna system technology to provide both WLAN and commercial network service in an unobtrusive and transparent fashion.

The use of wirelessly-enabled medical devices is continuing to expand in clinical care settings. Their adoption is driven by the need to simplify workflows, improve the quality of care and patient safety, and provide standards-based, real time data and information. In conjunction with this, care delivery organizations are expanding their use of telehealth and telemedicine practices for patient monitoring, alerts, notifications, and intervention techniques, improving access to care. Further, clinicians are increasingly using mobile devices for continuity of care and electronic medical record (EMR) applications. Enabling broadband technologies such as Long Term Evolution (LTE) and MIMO used in 802.11n WLAN provide the basis for interoperability between formerly heterogeneous networks. In this context, the utilization of distributed antenna systems (DAS) provides the basis for "bridging the gap" between commercial networks and a care delivery organization's private network(s).

Indeed, while WLAN has traditionally been used to provide data and voice (i.e., VoIP) services within a clinical facility, sophisticated smartphones require availability of integrated data and voice services from commercial wireless providers. Accordingly, designing robust in-building wireless networks that support commercial wireless transcends the "4-walls" of a care delivery facility, and is arguably a de-facto requirement for an integrated health data network. Use cases include patient and

physician portals, as well as movement of data to support the afore-mentioned telemedicine and telehealth applications. Specific workshop topics include different DAS network solutions to accommodate both WLAN and commercial wireless, and the challenges associated with implementing such solutions. A review will be made of the underlying solutions to include passive designs and fiber fed active based designs. This will include the past and current use model of 802.11a/b/g, 802.11n, voice over IP, MIMO, and WMTS with the technical and financial caveats. Considerations will also be given to the design requirements from DAS manufacturers when combining wireless communications systems onto a DAS. The session will end with this and your questions and comments.

#### **Workshop Instructor:**

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

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.

#### 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, Connectologist & Principal, Medical Connectivity Consulting Shahid Shah, CEO, Netspective Communications LLC

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), and also participates in industry initiatives.

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.

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#### About Capsule

For more than 13 years, Capsule has been the world's leading, award-winning provider of solutions for medical device connectivity. The company has established market leadership through its FDA 510(k) cleared software and medical grade hardware products, its unique expertise in device protocols and firmware, and through its strong partnerships with major medical device manufacturers and HIS companies. Capsule's solutions are proven, with over 617 installations at leading health care facilities worldwide and its technology is secure, with the largest installed device driver library. Furthermore, Capsule is continually recognized as the leader in the industry receiving the Frost & Sullivan Global Technology Leadership Award as well as the Deloitte Technology Fast 50 and Fast 500 EMEA Awards. And, with the introduction of the Capsule Neuron<sup>™</sup> platform and Enterprise Connectivity Solution, Capsule will continue to be the leader, by working with our partners to develop and implement solutions that meet the short and long term patient safety needs of hospitals today. For more information about Capsule, visit the company's Web site at http://www.capsuletech.com.

#### About Capsule's Enterprise Connectivity Solution™

Capsule's Enterprise Connectivity Solution is the only solution that will truly adapt to the environment it operates in. Its design gives hospitals the option to deploy connectivity throughout the enterprise so that all departments, not just high acuity, can enjoy the value that device integration has to offer. And it completely integrates with existing or planned caregiver work processes and allows a facility to leverage existing technologies.

#### About the Capsule Neuron<sup>™</sup> platform

The Capsule Neuron is Capsule's Next Generation Bedside Platform for managing device connectivity. It is a touch screen device equipped with its own docking station that provides a universal view and status of connectivity for all devices connected to a patient, including devices that are connected locally to a Capsule Neuron docking station and devices that are networked via the hospitals' wired or wireless LAN. And the Capsule Neuron provides the basis for an expanding set of solutions to enable improved bedside workflow and enhanced patient safety.

Contact: Cloyce Dickerson, Regional Vice President Tel: (916) 718-2781 Email: cloyced@capsuletech.com

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Medical device makers are beginning to discover what mobile computer makers know: when you need secure and reliable Wi-Fi connectivity, you turn to Summit Data Communications.

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To ensure secure, reliable Wi-Fi connectivity in hospitals, Summit solutions include hardware and software innovations:

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- Software innovations provide reliable connectivity, fast roaming, robust security, full Cisco Compatible Extensions (CCX) support, and centralized configuration and management.

A Summit solution includes much more than hardware and software. It also includes:

- Certifications: Regulatory certifications allow for operation worldwide. Wi-Fi certification demonstrates interoperability with popular Wi-Fi infrastructures. CCX certification is proof of interoperability with Cisco infrastructure and support for Cisco Wi-Fi innovations.
- Integration services: Summit works closely with your technical team to ensure that a Summit solution works reliably on your device.
- Technical support: Whenever a Wi-Fi issue arises in the field, Summit assists your support team to ensure a speedy resolution.

To learn more about Summit Wi-Fi solutions for medical devices, visit www.summit4med.com. There you'll find white papers, webinars, product information, and other resources. And be sure to stop by the Summit table in the Exhibitor Showcase.

Contact: Hannah Wheaton, Summit Data Communications 526 South Main Street, Suite 805, Akron, Ohio 44311 Tel: (330) 434-7929 x102 Email: hwheaton@summitdatacom.com

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iSirona offers a truly simplified approach to medical device integration. Flexible enough for both high-acuity and low-acuity environments, iSirona's technology provides decision makers with fast, reliable access to the data they need. iSirona offers a vendor-neutral software solution that integrates patient data from any device and delivers that data to any clinical information system. iSirona leverages existing technology investments – such as workstations-on-wheels and in-room PCs – and does not require costly hardware at the patient bedside.

iSirona's approach is so straightforward that implementation can be completed in a matter of weeks. And because the software is often embedded into an already familiar CIS, it is intuitive and easy to use.

Contact: Peter Witonsky, President 2211 Hwy 77, Suite 101 Panama City, FL 32444 Email: peter.witonsky@isirona.com Tel: (850) 303-0575



Nuvon connects, integrates, and manages any device to any system anywhere - Point of Care, Anywhere

Medical device data integration and interoperability are critical next steps in the path to a better healthcare system. Today there is no way to integrate data from the many different devices currently used throughout the healthcare system. Nuvon changes the game for the access, use, and utility of patient care data from these disparate medical devices providing critical clinical input to the healthcare decision support infrastructure and easing the workflow requirements of clinicians. Real-time, high quality patient care data enable enhanced clinical applications that deliver better outcomes, improved safety, and eventually lower cost. And, Nuvon helps clinicians and care givers provide better care for their patients with Point of Care ... Anywhere solutions.

Nuvon delivers the missing link - a totally interoperable and integrated device data infrastructure that provides patient care data from medical devices to any system, anywhere, at the point of care in real time. With its next generation VEGA real time grid architecture, Nuvon provides a web-based platform for diverse equipment, protocols, and systems to communicate seamlessly, intelligently, and ubiquitously using any communications standard. Combining scalability, reliability, availability, auditability, integration, automation, security, and user control tools, the Nuvon VEGA platform delivers a complete device data utility layer to support any device data connectivity, integration, and interoperability challenge within the healthcare enterprise. For more information, contact Mark Hallman, Director of Sales, at mhallman@nuvon.com



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### Medical Connectivity Consulting

#### www.medicalconnectivity.com

Medical Connectivity Consulting serves medical device and health care IT manufacturers, and health care provider organizations. Founded in 2004, the company provides insight, strategy development, planning and execution targeting workflow automation through the integration of medical devices and information systems, and enabling technologies. Principal Tim Gee delivers most services, supplemented by a network of industry experts. Engagements typically entail top of mind knowledge and experience, analysis and problem solving skills honed over many years, and the provision of additional resources for specific projects or tasks. Services for manufacturers span product development, regulatory strategy, sales, marketing and operations. Provider services include technology management and planning, process reengineering, and traditional vendor selection. Medical Connectivity Consulting consistently delivers high value services, saving clients both time and money.

#### Contact:

Tim Gee, Connectologist & Principal Tel: (503) 481-2370 Email: tim@medicalconnectivity.com Website: www.medicalconnectivity.com

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Qualcomm Incorporated (www.qualcomm.com) is the world leader in nextgeneration mobile technologies and the world's largest manufacturer of chipsets for the wireless industry. Qualcomm innovations are enabling ultra-personal mobile devices; shaping relevant, next-generation mobile experiences; and inspiring transformative new business models and services. Dedicated to accelerating mobile growth and progress worldwide, Qualcomm is transforming the way people live, learn, work and play. Headquartered in San Diego, California, Qualcomm is included in the S&P 500 Index and is a FORTUNE 500® company traded on the NASDAQ Stock Market® under the ticker symbol QCOM.

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Contact: Keith Sugawara Email: ksugawara@silexamerica.com

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The American College of Clinical Engineering (ACCE) was founded in 1991 with the commitment to enhance the profession of clinical engineering. With members in the United States and abroad, the ACCE is recognized internationally as a leading professional society for clinical engineers with a mission to:

- Establish a standard of competence and to promote excellence in clinical engineering practice.
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- •Represent the professional interests of clinical engineers.

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AAMI, a nonprofit organization founded in 1967, is a unique alliance of nearly 6,000 members from around the world united by one mission - to increase the understanding and beneficial use of medical instrumentation through effective standards and education. AAMI's membership is comprised of physicians, clinical and biomedical engineers and technicians, nurses, hospital administrators, educators and researchers, medical device manufacturers, distributors, government representatives, and other healthcare professionals interested in advancing medical device safety and innovation.



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The Healthcare Technology Foundation is a non-profit IRS 501(c)(3) charitable organization. Its mission is to improve healthcare delivery outcomes by promoting the development, application and support of safe and effective healthcare technologies. Major initiatives of the Foundation have included clinical alarm safety, the development of patient oriented technology safety brochures, the promotion of clinical engineering excellence through training and recognition programs, and the support of clinical engineering certification through the Healthcare Technology Certification Commission. The Foundation is also a federally registered Patient Safety Organization. www.thehtf.org

Contact: William Hyman email: w-hyman@tamu.edu

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The RFID in Healthcare Consortium advocates the safe and effective use of wireless



## Gary & Mary West Wireless Health Institute



based technologies in healthcare, assisted living, and nursing homing facilities. Our members are concerned with issues and solutions that pertain to the successful use of RFID, RTLS, and wireless technologies for patient care and safety. Consortium efforts include: delivering educational programs, support for standards, development of benchmark specifications, best practices, and sponsorship of educational events for all interested parties in the healthcare sector. Please join us. www.rfidinhealthcare.org.

#### www.westwirelesshealth.org

www.rfidinhealthcare.org

The West Wireless Health Institute (www.westwirelesshealth.org) is one of the first medical research organizations in the world supporting the exploration and application of wireless technologies to advance infrastructure independent health care. Founded in March 2009 by the Gary and Mary West Foundation, the nonprofit Institute is dedicated to innovating, validating, advocating for, investing in and commercializing the use of wireless technologies to transform medicine. Its mission is to lower health care costs by accelerating the availability of wireless medical technology. The Institute is based in San Diego, California, the global center for health care innovation.

#### www.wi-fi.org

The Wi-Fi Alliance is a global non-profit industry association of hundreds of leading companies devoted to the proliferation of Wi-Fi technology across devices and market segments. With technology development, market building, and regulatory programs, the Wi-Fi Alliance has enabled widespread adoption of Wi-Fi worldwide.

The Wi-Fi CERTIFIED<sup>™</sup> program was launched in March 2000. It provides a widelyrecognized designation of interoperability and quality, and it helps to ensure that Wi-Fi enabled products deliver the best user experience. The Wi-Fi Alliance has completed more than 7,000 product certifications to date, encouraging the expanded use of Wi-Fi products and services in new and established markets.

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#### Phone Registration Hours: 9 am to 4 pm Pacific Time

For information on registration fees, please see the next page (back cover of brochure)

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Organizations sending three or more registrants to the conference may qualify for an additional group discount. Please note, however, that category two registrants already receiving \$200 in other discounts do not qualify for the additional group discount unless there are four or more registrants from the same organization. Whether a registrant receives a group discount will depend on other discounts already received, the number of individuals from the registrant's organization that are attending the conference, and the category of registration. Please contact TCBI for details. Ph: 310-265-0621 Email: info@tcbi.org

#### PAYMENTS

Payments must be made in U.S. dollars by Visa, Mastercard, Discover, American Express, company check (drawn on a US bank), or by wire transfer. Please make checks payable to The Center for Business Innovation and send to: TCBI, 944 Indian Peak Rd., Suite 120, Rolling Hills Estates, CA 90274. In the memo area of the check, please write the name of the registrant and the conference code **C122**. For information about wire transfers, please contact TCBI: Tel: (310) 265-0621, Email: info@tcbi.org.

#### HOTEL INFORMATION

**Hyatt Regency Mission Bay Spa and Marina, 1441 Quivira Road, San Diego, CA 92109.** To make hotel reservations, please call the Hyatt Regency Mission Bay Spa and Marina Reservations Department at (888) 421-1442. Please mention "TCBI" to receive the preferred single or double occupancy rate of \$159 plus tax for conference attendees. In order to secure the preferred group rate, reservations must be made by September 6, 2010. After that date, the preferred group rate may not be available (please check with the hotel). Please note that the \$159 rate applies only for the nights of September 27th and 28th. However, the hotel may offer the same rate for other nights based on availability. To avoid a cancellation fee, cancellations must be made 72 hours before reservation date. To make your hotel reservations online, please go to www.tcbi.org, click on the link for the Second Annual Medical Device Connectivity Conference and then click on the Hotel Accommodations link.

#### **CANCELLATION POLICY**

For cancellations received in writing:

Four weeks or more prior to the event	Full Refund or Credit Voucher	
Between two weeks and four weeks prior to the event	\$200 Cancellation Fee or Full Credit Voucher	
Two weeks or less prior to the event	No Refund; Full Credit Voucher Will Be Issued	

Credit vouchers may be applied toward any future TCBI event within one calendar year.

If TCBI decides to cancel any portion of this event, the organizers are not responsible for covering airfare, hotel or any other costs. Speakers, networking events and the agenda are subject to change without notice. This cancellation policy applies only to delegate registrations, not sponsorships.

#### SUBSTITUTIONS

Registrant substitutions may be made up to the day of the event.

#### FREE PRESS PASSES AVAILABLE

To find out if you qualify for a free press pass, which is usually offered to full-time journalists, please email info@tcbi.org or call (310) 265-0621.

#### **Conference Registration Form**

Name:					
Job Title:					
Organization:					
Address/Suite/Floor#:					
City:	State: Zip: _				
Telephone:	Fax:				
Email:					
I accept the Cancellation Policy on the previous page. (signature required to process registration):					
Method of Payment (please check one) American Express IVisa Company Check Wire Transfer	□ MasterCard	Discover			
Credit Card #:	Exp. Date:				
Name Appearing on Credit Card:					
Mailing Address for Credit Card:					
Signature:					

To be added to our mailing list, please email info@tcbi.org

#### Second Annual Medical Device Connectivity Conference & Exhibition, Sept. 28-29, 2010, San Diego **Registration Options:** PRICE Category One Registration (Conference Only) \$1295 Category One Registration (Conference Plus Post-Conference Workshop-choose a workshop below) \$1695 U Workshop One: Distributed Antenna Systems: Design Considerations for 2010 and Beyond in Healthcare UWorkshop Two: Open Source Software as a Cost-Effective Quick-to-Market Development Strategy for Medical Device Manufacturers Category one registration fee applies to IT vendors, medical device companies and members of the financial community. Category Two Registration (Conference Only) \$ 695 Category Two Registration (Conference Plus Post-Conference Workshop-choose a workshop below) \$ 995 U Workshop One: Distributed Antenna Systems: Design Considerations for 2010 and Beyond in Healthcare UWorkshop Two: Open Source Software as a Cost-Effective Quick-to-Market Development Strategy for Medical Device Manufacturers Category two registration fee applies to healthcare providers and payers, including hospitals, healthcare systems, physician groups and health plans. The category two fee also applies to academic institutions and government agencies. I qualify for the \$100 earlybird discount (registration and payment must be made by September 16, 2010). I am a member of ACCE, AAMI, INCOSE, RFID in Healthcare Consortium and/or the Wi-Fi Alliance and qualify for a \$100 supporting organization discount on the applicable registration fee above. Please underline the organization through which you are receiving the discount. □ I am a board member of the Healthcare Technology Foundation and qualify for a \$100 supporting organization discount on the applicable registration fee above. Supporting organization discounts cannot be combined with each other; however, the supporting organization discount can be combined with the earlybird discount. Send Completed Registration Form With Payment (if Applicable) To: Total: The Center for Business Innovation 944 Indian Peak Road, Suite 120, Rolling Hills Estates, CA 90274 Phone: (310) 265-0621 Fax: (310) 265-2963 Email: info@tcbi.org To register by phone, please call (310) 265-0621 Register online at www.tcbi.org

#### Phone Registration Hours: 9 am to 4 pm Pacific Time

To register by fax or mail, please fill out a copy of this page for each registrant and send to TCBI.

You may fax this form to (310) 265-2963