Featuring Thought Leaders and Experts from top medical device manufacturers including:
GE HEALTHCARE, PHILIPS HEALTHCARE, BAXTER, MEDTRONIC, AND MUCH MORE!

20th Software Design for Medical Devices™

October 26 – 28, 2015
Boston Park Plaza

ENHANCE DESIGN FLOWS TO EFFECTIVELY IMPACT PRODUCT LIFE-CYCLES & LAUNCHES

TOP BENEFITS OF ATTENDING:

- Learn how software design can influence design flows to accelerate successful product launches and life-cycles
- Evaluate the regulatory landscape to ensure compliance, therefore avoiding halts in design/launch
- Examine a variety of resources, practice methods, and team dynamics to improve design outcomes
- Learn more about the topics vital to your continued success such as: Development & Trends in Agile-Based Design, Cybersecurity, Mobile Medical, Cloud-Computing, Risk Management, Interoperability, the "Internet of Things", Big Data, and much more

FURTHER YOUR KNOWLEDGE BY REGISTERING FOR OUR 3 INTERACTIVE WORKSHOPS:

WORKSHOP A:
Market Positioning: Deciding Upon a U.S. or E.U. Approach

Better understand the regulations and guidelines under each agency to best position your product offerings

WORKSHOP B:
Class 3: Implantable Devices - Software Life-Cycle Boot Camp

Learn software design considerations for external peripherals of implantable devices

WORKSHOP C:
Agile is More Than Software!

Learn how an Agile approach can drive a smooth and continuous development progress--and can aid in successful product deliveries

FEATURED SPEAKERS:


Paul Cox
Director, Software Engineering
Medtronic


Dharmesh Rupareliya
Principal Quality Assurance Engineer
Edwards Lifesciences


Paul Goode, Ph.D.
Chief Technical Officer
EndoStim, Inc.


Jeet Sarkar
Director, Quality for Information Systems
Baxter International, Inc.


Dr. Celestina Bianco
Director of Quality and Regulatory Affairs
Systelabs


Brian Shoemaker, Ph.D
Principal Consultant
ShoeBar Associates

SUMMIT CHAIR


Phani Bidarahalli
GM & Global Practice Head - Healthcare Engineering
Wipro

"This forum will serve as a platform to exchange best practices, ideas and help drive innovative solutions for medical devices"
– Phani Bidarahalli, Conference Chairman and GM & Global Practice Head - Healthcare Engineering, Wipro

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DID YOU KNOW?

Sources: http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126955.pdf, Drivers Behind the Biomed Software Industry

500 MILLION smartphone users, worldwide, will be using a health care application app by 2015

8% of medical device failures are due to **SOFTWARE FLAWS**

7 out of 10 of the TOP Medical Device Companies are **U.S. BASED**

Dear Colleague:

With innovative and effective software design, medical device manufacturers are able to go-to-market quicker and more successfully---as well as positively affect their product life-cycles, i.e.- with Agile-based design practices and other cost-saving methods. However, due to increased regulatory pressures, ensuring efficient design into product R&D, quality assurance, and other aspects of the product life-cycle can be challenging. By harnessing the appropriate tools to be more effective, medical device manufacturers are able to thrive within this highly competitive marketplace.

IQPC's **20th Software Design for Medical Devices Summit - East** was designed to address the challenges, identify the opportunities and provide perspective on the applicable solutions within the industry, so that medical device manufacturers can be more competitive in today's time-sensitive, regulation-driven marketplace.

The conference is the perfect opportunity to:

- Learn how software design can influence design flows to accelerate successful product launches and life-cycles
- Evaluate the regulatory landscape (FDA & MDD) to ensure compliance on either side of the Atlantic; therefore avoiding halts in design
- Examine a variety of resources, practice methods, and team dynamics to improve design outcomes
- Learn more about the topics vital to your continued success such as: Development & Trends in Agile-Based Design, Cybersecurity, Mobile Medical, Cloud-Computing, Risk Management, Interoperability, the "Internet of Things", Big Data, and much more

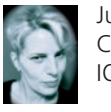
By attending this valuable conference, you will stay up-to-date with the current and future trends in the industry; and in-turn you will be able to better plan, design, and execute the most cost-effective software designs for your medical devices and clients.

IQPC's **20th Software Design for Medical Devices Summit – East** will offer you an exclusive opportunity to network and learn more about the evolving software design landscape through Panel/Roundtable Discussions, Case Studies---and other interactive program formats led by industry Thought Leaders---as well as from your peers and competitors, including Software Designers/Engineers, Risk Management & Regulatory Affairs Managers, Agile Design Consultants, and many more within the Medical Device Manufacturer space.

Don't miss out on this opportunity to learn more about the best practices and future trends shaping software design for the medical device industry.

I look forward to seeing you in October!

Sincerely,



Jules Miller
Conference Director
IQPC

P.S. Take part in our Networking Demo Drive and spend some time with other conference attendees and speakers while visiting our sponsors' booths during the Morning Networking Break on Main Conference Day One of the program. Complete the 'Bingo' form to be entered into the raffle on Day Two -in order to receive a great prize!

Who will be attending the 20th Software Design for Medical Devices Summit – East ?

Vice Presidents, Principals, Directors, Managers, and Consultants of:

- Software Engineering/Architecture
- R&D/Product Development
- Human Factors & Usability
- Quality Assurance
- Safety Engineers
- Design Control
- Systems Analyst
- Software Validation & Verification
- Regulatory Compliance & Affairs

What previous attendees had to say about IQPC's Software Design for Medical Devices Summit Series:

"Great discussions amongst team and during presentation."

- Head of Platform Firmware & Mobile Software, Proteus Digital Health

"It was interesting to hear how other industry professionals approach compliance."

- Software Quality Assurance Manager, Terumo BCT

Sponsorship & Exhibition Opportunities

Event sponsorship is an excellent opportunity for your company to showcase its products and services to senior level, targeted decision makers attending the 20th Software Design for Medical Devices Summit – East. IQPC, Pharma IQ help companies like yours achieve important sales, marketing and branding objectives by setting aside a limited number of event sponsorships – all of which are tailored to assist your organization in creating a platform to maximize its exposure at the event. **For registration information visit www.sdmdconference.com or call +1 (800) 882-8684.**

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8:00 A.M. **Workshop A: Registration & Networking Breakfast**

8:30 A.M.

A WORKSHOP A: Market Positioning: Deciding Upon a U.S. or E.U. Approach

With the varying requirements set forth by the FDA and MDD, deciding upon which market to first tackle on a pre-market submission level poses many questions that must be answered early on in the R&D stage.

In this session we will explore the greatest challenges, as well as benefits of each scenario and dig deep into the technical, workflow, verification and validation, and other matters associated with going to market faster---due to choosing one market over the other as your first market of choice.

Attend this session in order to:

- Obtain further understanding of the regulations and guidelines under each agency
- Define and evaluate the best strategy for your product
- Explore impactful execution practices to go through the selection process to best position your product

Dr. Celestina Bianco
Director of Quality and Regulatory Affairs
Systelabs

10:30 A.M. **Workshop B: Registration**

11:00 A.M.

B WORKSHOP B: Class 3: Implantable Devices – Software Life-Cycle Boot Camp

**Boxed lunch to be served at Workshop B (working lunch)*

Implantable device systems incorporating electronics and software (active implantable medical devices) are becoming ubiquitous in healthcare. Once-novel cardiac pacemakers are becoming commoditized, while spinal cord stimulation for pain management continues to grow, and emerging therapies such as deep brain stimulation are relatively new to the marketplace. While large companies in this area have well-established mechanisms in place to develop, manufacture, and commercialize such products, there are many smaller companies developing the next frontier of active implantable medical device-based therapies. These new therapies address such medical conditions as obesity, acid reflux, heart failure, hypertension, and diabetes, just to name a few.

This workshop will address many of the key requirements that are common to all active implantable medical devices. These include implantable device power management, external device human factors analyses, and requirements from regulatory bodies, such as the FDA or a European notified body. The regulatory requirements are typically more rigorous than non-implantable and non-Class III systems. These requirements impact many aspects of the software design cycle including software architecture, component and tool selection, usability and human factors, and software risk analysis. As such, there is an emphasis towards regulatory considerations for software of active implantable medical device systems while also addressing practical design challenges.

Attend this session in order to:

- Obtain a general overview of implantable stimulator systems, applications, and general system architectures
- Learn firmware techniques to reduce the power consumption of an implantable device
- Learn software design considerations for external peripherals of implantable devices
- Understand software risk analysis considerations for active implantable medical device systems
- Obtain a regulatory body perspective of active implantable medical device systems, particularly the software regulatory requirements

Paul Goode, Ph.D.
Chief Technical Officer
EndoStim, Inc.

Yohannes Iyassu, Ph.D
Principal R&D Engineer
Greatbatch

Gregory Martin, Ph.D, MSEE
Product Expert
British Standards Institute

Claudio Propato
Embedded Systems Architect
Greatbatch, Advanced Technologies Group

1:00 P.M. **Workshop C: Registration**

1:30 P.M.

C WORKSHOP C: Agile is More Than Software!

Trying to understand the "Agile method" as just another software development lifecycle, with specific rules and a fixed outline, is mistaken, and seriously limits the benefits that Agile can bring. Successful Agile implementations include development, operations and business functions right from the outset. Anything less just creates another process island and cross function friction. All functions must participate actively throughout development, since development is recognized to require learning and adapting (and market needs can change rapidly).

Hardware development is as much a learning environment as software; the timeframes of hardware iterations may be different, but iteration and adaptation are still valid. Coordination with rapid software iterations requires discipline, but is definitely possible.

Quality procedures (SOPs) need not impede the iterative, learning process of Agile. Deliverables, rather than the specific sequence of operations, can be the focus, with regular opportunity for reflection and process improvement.

Hazard analysis and risk management benefit from collaboration and iteration. Multiple points of view, with opportunity to learn from experience, catch much more of the safety issues in a design than an alayze-once approach.

We suggest a five-step fluency model as a framework through which companies can understand their progress in becoming Agile across all functions - not just software.

Attend this session in order to:

- Understand the principles of Agile design and implementation — and reap the associated productivity rewards
- Learn how an Agile approach can drive a smooth and continuous development progress — and can aid in successful product deliveries
- Develop a benefits' pros & cons analysis — to then apply to your overall program initiatives
- Gain in-depth examination of key take aways that enhance project deliveries

Brian Shoemaker, Ph.D
Principal Consultant
ShoeBar Associates

Nancy Van Schooenderwoert
President and Managing Partner
Lean-Agile Partners, Inc

4:00 P.M. **End of Workshop Day**

MAIN CONFERENCE: DAY ONE

Tuesday, October 27, 2015

8:00 A.M. **Networking Breakfast & Registration**

9:00 A.M. **Chairperson's Notes**

Phani Bidarahalli
GM & Global Practice Head - Healthcare Engineering
Wipro

9:15 A.M. **FIRESIDE CHAT: FDA Medical Device 510(k) Submission Preparation**

The best kept secret to obtaining regulatory approval is developing templates for technical documentation that perfectly match the FDA's regulatory requirements. The FDA 510(k) process has changed tremendously in the past few years---which in turn have required medical device manufacturers to update their documents and procedures.

In this session, we will:

- Evaluate recent FDA guidance documents to better understand how to be compliant and decrease the likelihood of project delays
- Go over the step-by-step process for preparing a 510 (k) submission to avoid budget and production over runs

Oscar Sanchez
Chief Quality, Regulatory and Compliance Officer
Maquet USA

Ian Welsford, Ph.D
Vice President of Quality Assurance & Regulatory Affairs
Autonomic Technologies, Inc.

10:00 A.M. **CASE STUDY: Cloud Computing: Developing Measurable & Flexible Software Platforms for Connected Medical Devices**

Medical device manufacturers are rapidly designing integrated connectivity capabilities that will mirror enterprise cloud computing and introduce more efficient ways to provide healthcare services. However, developing cloud-connected medical devices bring design challenges, complexities, and risk. With costs top of mind, software platforms must readily adapt to meet the evolving needs of the healthcare industry, taking in account the impact cloud-computing will play in the years to come.

In this session we will discuss:

- How cloud-computing can enhance medical device user deliverable
- The impact cloud will play on the industry, i.e.- data sharing, interconnectability, etc.

Neeraj Mainkar, Ph.D
Senior Director, Product Development
Neuronetics, Inc.

10:45 A.M. **Morning Networking Break & Demo Drive**

11:30 A.M. **PANEL DISCUSSION: Mobile Medical Applications & Incorporating Human Factors Into Design**

With the popularity of mobile medical applications being utilized by medical professionals, and most notably, the general public, incorporating human factors engineering into a product's design strategy not only makes sense, but could very well save lives. Coupling the FDA's guidance on human factors with its guidance on mobile medical apps, poses unique design challenges for developing mobile health apps that are not only easy to use but also safe.

This session will address such matters as:

- Mobile app usability testing and metrics
- FDA regulations and submission guidance
- Usability challenges with smart watches and glasses
- Physician's point of view of what is most needed in respect to mobile medical and data interoperability

Paul Cox
Director, Software Engineering
Medtronic

Nat Sims, MD
Physician Advisor, Biomedical Engineering
Department of Anesthesia, Critical Care and Pain Medicine Massachusetts General Hospital

Gerard Torenvliet
Manager, Human Factors Engineering
Medtronic

12:30 P.M. **Networking Lunch Break**

1:30 P.M. **Software Standards: Friend, Not Foe!**

1 ½ hours of in-depth examination

Designing within complex software systems with strict standards for design and implementation can be challenging. In developing medical device software, if we understand the purpose of the standards, we can use them to our advantage.

- Standards can be bewildering - get over it.
- Quality sounds like a buzzword, but it underlies everything else in our business.
- The development lifecycle gives a framework.
- Risk Management is about how to MANAGE risks, not how to find and remove them.
- Electrical equipment safety inevitably involves software.
- Usability requires us to understand who we're working to help.
- Planned changes will adapt these standards to new challenges.
- Good engineering is our goal; compliance follows.

In this session we will:

- Review the crucial standards which govern medical device software development
- Place the standards together in a landscape of quality and risk management
- Take a peek into the future: revisions, clarifications, and broadened scope

Brian Shoemaker, Ph.D
Principal Consultant
ShoeBar Associates

3:00 P.M. **Avoiding Recalls to Dodge Costly Fees & Loss of Market-Share**

Certainly pre-market FDA evaluation and approval is important, yet just as significant is how well a medical device works when it's used by patients, caregivers, and clinicians. Beyond clinical trials, real-life patient experience may discover unanticipated device risks.

To avoid recalls, a robust post-market surveillance system can provide vigorous and timely benefit-risk profiles for devices so

that providers and patients can make better informed health care decisions.

Developing a strategy that takes in account preventive solutions and determines potential risks and product error into your software design project is essential to avoid product recall.

In this session we will explore:

- Best practice systems to reduce product recall at the product R&D stage
- Systems to track, access, and reduce risk

3:45 P.M. **Afternoon Networking Break**

4:30 P.M. **CASE STUDY: Utilizing Risk Management Continuously Through a Device's Life-Cycle to Avoid, Prevent & Reduce Risk Probability**

First and foremost, software design for medical devices must be safe. Residual risks can be assumed only if the clinical relevance is high, meaning the probability of beneficial effects highly outweigh the probability of harm. The causes that must be investigated include the intrinsic characteristics and features of the medical system, technical problems, software defects, and also misuse or under-use.

Software, either as part of a medical system or a medical device itself, has the ultimate responsibility to protect against hardware faults and incorrect use. Utilizing Risk Management as a continuous process through a device's lifecycle, to avoid, prevent, or reduce the probability of risks in the use of software, and/or to mitigate the severity of the consequences is of utmost importance. A Risk Driven Quality System increases the robustness and provides a framework that guarantees greater safety with reduced additional costs.

In this session we will explore:

- Various risk control methods and systems to ensure product safety
- Benefits of a risk design approach and how to maximize reward returns

Dr. Celestina Bianco
Director of Quality and Regulatory Affairs
Systelabs

5:30 P.M. **Main Conference: Day One Close**

MAIN CONFERENCE: DAY TWO

Wednesday, October 28, 2015

8:15 A.M. **Networking Breakfast & Registration**

9:00 A.M. **Chairperson's Recap**

Phani Bidarahalli
GM & Global Practice Head - Healthcare Engineering
Wipro

9:15 A.M. **CASE STUDY: Firmware Transformation for Revolution CT: An Agile Journey**

Agile is an established development methodology in modern software. However, its adoption for embedded software (firmware) meets unique challenges, in particular in large organizations developing complex products. Studying adoption experience can be extremely helpful in planning a successful Agile transformation for firmware teams.

In this session, we will examine the agile transformation in GE Healthcare's CT firmware team, which included strategies to:

- Enable conversations
- Ensure productivity
- Enable quality

Yan Sorkin
Engineering Director, Embedded Software
GE Healthcare

10:00 A.M. **PANEL DISCUSSION: Successfully Navigate the FDA's Cybersecurity Guidelines to Drive Improved Software Designs**

The FDA's "Content of Pre-Market Submissions for Management of Cybersecurity in Medical Devices" guidance, released in October 2014, has provided medical device manufacturers recommendations on cybersecurity management that should be included in their pre-market submissions. The guidance offers suggestions on how to address such vulnerabilities as malware infections, failure to provide software updates and patches to medical devices and networks, unsecured or uncontrolled distribution of passwords, and off-the-shelf software designed to prevent unauthorized access.

The FDA has strongly suggested manufacturers to put into account cybersecurity during the design and development phase of their medical devices. They have also recommended manufacturers establish a cybersecurity vulnerability and management strategy as part of their overall software validation and risk analysis plans.

In this session we will explore the below matters:

- Pinpoint threats and vulnerabilities, including back door entry into a device's integrated network
- Evaluate the impact of vulnerabilities on device functionality

Claudio Propato
Embedded Systems Architect
Greatbatch - QiG Group

Jeet Sarkar
Director, Quality for Information Systems
Baxter International, Inc.

Chris Fischer
Senior Manager, Systems Software Engineering, Breast and Skeletal Health Solutions
Hologic

Homa Alemzadeh
Graduate Research Assistant, Coordinated Science Laboratory, Department of Electrical and Computer Engineering
University of Illinois at Urbana-Champaign

10:45 A.M. **Morning Networking Break**

11:30 A.M. **PANEL DISCUSSION: Incorporating Human Factors & Usability Into Marketable Medical Devices to Ensure Product Success**

Embracing human factors principles and usability guidelines as part of the software design for medical devices' development process is vital in respect to optimizing product success, lessening user-risk, and increasing performance. Ensuring a collaborative team consisting of research, design, quality engineering, and regulatory experts is crucial to the successful development of safe and user-friendly medical devices' design/production.

In this session we will examine:

- Best strategies to design and engineer innovative medical devices that successfully integrate the needs of diverse users (globally, disabled, etc.)
- Varying product development perspective and design challenges/solutions
- Understanding user-testing methods/metrics to optimize product usability/safety
- FDA regulations on human factors and how to be compliant with these guidances to best ensure safe product delivery/usability

Paul Cox
Director, Software Engineering
Medtronics

Dave Osborn
Senior Manager of Global Regulations & Standards
Philips

Douglas Stanton
Software Engineer 2
Siemens Healthcare Laboratory Diagnostics

12:30 P.M. **Networking Lunch Break**

1:30 P.M. **PANEL DISCUSSION: "The Internet of Things" and its Impact On Software Development for Medical Devices**

The "Internet of Things" is certainly a hot topic in the industry today. With the "Internet of Things" being based on increasing machine-to-machine (M2M) communication built on Cloud-computing and networks of data-gathering sensors, it's easy to understand why there's so much buzz surrounding the topic.

However, what are the benefits of the "Internet of Things" in software development for medical devices, and how can it be applied to your projects?

In this session we will explore the below in Case Study format:

- Software design that optimizes connectivity and data analytics
- Programming efficient data filtering and distribution systems
- M2M delivery execution systems

Chris Fischer
Senior Manager, Systems Software Engineering, Breast and Skeletal Health Solutions
Hologic

Ian Welsford, Ph.D
Vice President of Quality Assurance & Regulatory Affairs
Autonomic Technologies, Inc.

David Arney
Lead Engineer, MD PnP Program
Massachusetts General Hospital

2:30 P.M. **Refresher on FDA Guidance for Software Validation**

Software as an integral part of a medical device or a medical device in itself outsourced or developed in-house, needs to follow the requirements as prescribed in IEC 62304 and FDA's guidance. Risk based approach to the rigor of the practice is acceptable and encouraged by the regulatory bodies.

In this session we will explore in Case Study format:

- How to best interpret the IEC 62304 and FDA's guidance on software V&V
- Validation of product software, tools and equipment, and quality system software
- Risk based approach to software validation
- Case Study examples with comparative analysis

Dharmesh Rupareliya
Principal Quality Assurance Engineer
Edwards Lifesciences

3:15 P.M. **Afternoon Networking Break**

4:00 P.M. **Medical Devices in a Big Data World**

Healthcare and technology are changing exponentially in every way. Miniaturization of sensor technology combined with nearly ubiquitous connectivity is producing massive amounts of raw data. What things should medical devices provide to properly enable analytics? What do advances in HL7, IHE and other standards have to offer medical devices? What kind of methodologies and tooling are IT organizations and hospitals looking to for help in organizing their Big Data?

In this session we will:

- Examine why hospitals are desperately looking to analytics
- Explore case studies on applications of analytics
- Encourage awareness of analytics integration in product design and development

Brian Nantz
Senior Software Engineer
GE Healthcare

4:45 P.M. **Close of Conference - See You Next Year!**

What previous attendees had to say about IQPC's Software Design for Medical Devices Summit Series:

"Good knowledge of Agile methodologies in detail."
-Quality Assurance Engineer, Arthrex

"The chance to network with like-minded Engineers."
- Software Manager, Key Technologies, Inc.

"Very educational and rewarding experience with great emphasis on aligning the behind-market healthcare to current and future practices and technologies."
-Software Engineer, Medtronic

"Good speakers, topics and networking opportunity."
- Senior Software Development Engineer, Arthrex

Pricing & Registration

Pricing for End Users

Package	Standard Price
Main Conference	$2,099
All Access: Main Conference + All 3 Workshops	$3,099
Workshops (individual)	$549

End Users are defined as: Medical Device Manufacturers, Pharmaceutical Companies, Associations & Government (Please ask about our Government discount)

Pricing for Vendors/ Service Providers

Package	Standard Price
Main Conference	$3,099
All Access: Main Conference + All 3 Workshops	$4,099
Workshops (individual)	$549

Vendors/Service Providers are defined as: Software Development Companies, Software Solution Providers, Consultants, Risk Management Companies, Inventory & Supply Chain Management Companies, & PLM/ALM Companies

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535 5th Avenue, 8th Floor
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Boston Park Plaza

50 Park Plaza, Boston, Massachusetts 02116, United States
Website: www.bostonparkplaza.com
Phone: 617-654-1976

The special room rate of $319 has been established to make your reservation process easy. Simply call 1.800.225.2008 and give the group name Software Design for Medical Devices no later than October 5, 2015.

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