Medical Devices
Conference

Tools, Technologies, and Strategies to Accelerate Your Time to Market ™

November 5-7, 2012 | San Francisco, CA

CYPIN PRODUCTION
Building Bridges Between U.S. and China BioPharma

Speed up your product's time to market

Any lag in getting products to market is costly on every front from cash expenditures to loss of market share and the evaporation of the first-to-market competitive edge. Designing medical devices that meet the complex safety certification and regulatory requirements are the most common reasons for delays, especially if these requirements are not known in the early stages of design. With the transition to the 3rd Edition of IEC 60601 globally, the approval process is expected to be more challenging and time consuming than ever. Are you ready for the transition? Do you understand the new requirements?

Fortunately the lag can be shortened substantially with a better understanding before the design phase, to include proper regulatory guidance and the use of a pre-submission evaluation process. These measures can increase product safety and prevent costly errors and delays from accidental omission of vital information.

Groundbreaking program highlights includes:

- An exclusive **90-minute Q&A with the FDA,** Underwriter Laboratories, and TÜV
- Critical updates regarding the **3rd Edition of IEC 60601**, **pre-market approval** (PMA), auditing process, documents requirement, and any other questions you have!
- 20+ leaders and expert sessions on the latest and most critical discussion on regulatory compliance, software design and development, improving usability, and much more.

The **Medical Devices Conference** will put you in front of regulatory and Notified Bodies' officials and experts who will provide you with such guidance to speed your time to market and smooth the transition to IEC 60601. There are also workshops and podium presentations in key issues from improving human-to-device interfaces to designing software and managing risks in an FDA regulated medical environment.

With so much at stake, can you really afford to operate without this information? Join us at the Medical Devices Conference and get up to speed now!

To register, call Sam Eid at 917.338.6822 or email sam.eid@cypinproduction.com

Medical Devices Conference

Tools, Technologies, and Strategies to Accelerate Your Time to Market ™

Who Should Attend

The Medical Devices conference is ideal for VP, Director, Manager, and Engineers working in Medical Devices, Pharmaceuticals and Biotech companies from the following departments:

- Regulatory Affairs
- Product Design/ Development
- Software Engineering
- Research and Development
- QA/QC
- Validation and Verification
- Business Development
- Sales & Marketing
- And anyone who wants to speed up their product's time to market!

Prices and Discounts

Pricing	Book and Pay by 8/31/12	Book and Pay by 10/19/12	Standard Price
BEST VALUE **All Access Pass** (1 night FREE + 3-day conference)	**(SAVE $400)** $1,699	**(SAVE $200)** $1,899	$2,099
Conference Only	**(SAVE $400)** $1,299	**(SAVE $200)** $1,499	$1,699
Each Workshop	$499	$499	$499

One night FREE accommodation and COMPLIMENTARY pull-up display!

You will receive **one night *FREE** accommodation at **Sheraton Fisherman's Wharf** when you register for the All Access package!

**You must stay for a minimum of two nights at the hotel to get the third night free.*

When two or more registered as a group, you will receive ****COMPLIMENTARY space to display** one vertical pull-up banner at the networking area! All displays will be accepted on a first-come, first-serve basis.

***This offer only applies to registrations for the All Access or Conference Only packages. Free hotel is NOT included in this offer.*

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Main Conference Day One

Tuesday, November 6, 2012

8:00am	*Continental Breakfast and Registration*
9:00am	*Chairperson's Welcome and Opening Remarks*

510(K) CLEARANCES AND PRE-MARKET APPROVAL

9:15am

SPECIFIC REQUIREMENTS FROM THE FDA REGARDING PREMARKET APPROVAL (PMA), 510(K) CLEARANCE, AND THE THIRD EDITION OF IEC 60601

- Specify 510(k) and PMA requirements
- Get an update on the upcoming transition to the 3rd Edition of IEC 60601
- Learn best practices for preparing regulatory filings for approval of new and modified medical devices and clinical studies.
- Understand different requirements for various classifications, especially Class C and Class D medical devices
- Hear examples of submission weaknesses from the perspective of regulatory body officials.
- Learn how good submission quality can decrease review times - what works, what doesn't.

Richard Chapman, General Engineer, Center for Device and Radiological Health (CDRH), FOOD AND DRUG ADMINISTRATION (FDA)

REGULATORY UPDATES, INDUSTRY STANDARDS, AND COMPLIANCE

10:00am

CRITICAL REQUIREMENTS AND PROCEDURES FOR GETTING THE EUROPEAN CONFORMITY (CE) MARK FOR MEDICAL DEVICES

- Understand and built strategies on how to establish conformity using harmonized standards and understand the conditions of harmonization,
- Expectations of Notified Bodies in using harmonized standards particularly EN ISO 14971:2012 and EN 60601-1:2006 and Am 1 (2012)

- Overview of the proposed changes brought by the revised regulation for medical devices in Europe
- Develop strategies for how to stay current with regulatory developments in Europe

White papers, case studies, and articles for the transition to IEC 60601 3rd edition are available for participants to download

Steve McRoberts, Principal Engineer for Medical Regulatory & Proprietary Compliance, UNDERWRITER LABORATORIES

10:45am	*Morning Networking and Refreshment Break*
11:15am	**MEDICAL DEVICE WEB APPLICATIONS** The web is an appealing pathway for medical device manufacturers to offer creative solutions that will enhance their patient's lives. The web can be used to provide information to a physician, permit configuration of a patient's device remotely, capture data from a device remotely, and much more. But it comes with different problem sets that medical device manufacturers might not have needed to understand till now. This session will cover: • FDA's concerns with Web based systems • Browser Complexities • Possible Hazards • Validation concerns • Configuration issues • The role of the web server • Concerns over cyber security **Erik Hilliard, Project Lead Engineer, STERLING MEDICAL DEVICES**
12:00pm	**DESIGN FOR COMPLIANCE – ACHIEVING REGULATORY COMPLIANCE WITH FEWER HEADACHES** Time to market is essential for success in today's highly competitive medical device market. Working with a partner that has expertise in the regulatory requirements needed for market access can have a

significant positive impact in getting your products to markets faster and saving you money. The earlier in the product development cycle you engage a regulatory compliance partner, the greater the impact can be.

This session will provide practical guidance on:

- When and how to engage a regulatory compliance partner
- Tips to help you designing for compliance
- Developing a regulatory strategy that reduces risk while increasing efficiencies in compliance, manufacturing and logistics
- Early planning for global regulatory approvals

Justin Heyl, Program Manager, INTERTEK CONSULTING SERVICES

QUALITY ASSURANCE, VALIDATION AND VERIFICATION	
12:45pm	*Networking Luncheon*
2:00pm **SPECIAL SPEED NETWORKING**	**5-MINUTE SPEED NETWORKING AND EXPOSITION** *Instructions: Once the session begins, participants will have five minutes to network. At the end of the five minutes, a moderator will ask participants to switch partners. The process will continue until the end of the speed networking session.*
2:30pm	**HANDS-ON TOOLS AND STRATEGIES TO SPEED UP YOUR TIME TO MARKET** • Master tools and strategies to understand your market and customers • Get guidance on your development and test strategies to meet your market deployment plan • Learn how to factor risk and performance-based requirements into your product design, testing and certification to increase R&D efficiency • Gain proficiency and ensure compliance with product preliminary construction review and gap analysis • Evaluate options and determine ways to staff your product design, development, testing, manufacturing and validation efforts with experienced personnel to speed up time to market **Tajudeen Oladele, Consultant-Global Regulatory Compliance, TERUMO CADIOVASCULAR**

3:15pm	**STREAMLINE QUALITY ASSURANCE PROCESS TO ACCELERATE TIME-TO-MARKET** • ***Risk Based Approach:*** Incorporate a simplified, defensible, risk based approach to meeting regulatory compliance, particularly on ISO 14971 and other standards. • ***Critical Thinking:*** Introduce a "critical thinking" approach to validation of automated process. A valuable resource we will use is the TIR36 published by AAMI. Apply the appropriate rigor in the areas that re relevant your project. • ***Simplified Defensible approach***: Learn how to simplify the approach to quality assurance through proven techniques. Avoid unnecessary processes and techniques that hinder the ability for manufacturers to perform their duties. **Participants will receive bonus checklists and templates for the Quality Management System** **Thomas L. Bento, Sr. Regulatory Consultant, CERTIFIED COMPLIANCE SOLUTIONS, INC.**

Mid-Conference Workshop

Tuesday, November 6, 2012

WORKSHOP C: 90-MINUTE EXCLUSIVE Q&A *(Requires separate registration)*	
4:00pm	**90-MINUTE Q&A SESSION WITH THE FDA, UNDERWRITER LABORATORIES, AND THE TUV RHEINLAND** The FDA, Underwriter Laboratories, and TÜV are c-hosting the Q&A session to cover regulatory topics including the transition to the 3rd Edition of IEC 60601; 510(k) pre-marketing submission; pre-market

approval (PMA); and European Conformity (CE) mark for medical devices. This workshop will provide insider tips to streamline approval processes, offer key strategies and insights into the regulatory authorities' priorities, and lift the veil of confusion on how these impact your company submission.

How you will benefit:

- Master the critical regulatory requirements and priorities
- Get a clear understanding of what documents are required for submission
- Prevent post-market problems with effective compliance strategies

What you will learn:

- Critical updates regarding the 3rd Edition of IEC 60601
- How to Determine the level of concern for computerized devices
- How to discern the key components for validation of computerized medical devices
- Critical procedures and standards for the pre-market documentation submission

Your workshop leaders:

Richard Chapman, General Engineer, Center for Device and Radiological Health (CDRH), FOOD AND DRUG ADMINISTRATION (FDA)

Steve McRoberts, Principal Engineer for Medical Regulatory & Proprietary Compliance, UNDERWRITER LABORATORIES

Dale Hallerberg, Technical Manager – Medical Test, TÜV RHEINLAND NORTH AMERICA

Main Conference Day Two

Wednesday, November 7, 2012

8:00am	*Continental Breakfast and Registration*

HUMAN FACTORS ENGINEERING AND ERGONOMICS

9:00am

APPLICATION OF HUMAN FACTORS ENGINEERING TO MEDICAL DEVICES

Proper application of human factors can reduce use errors and result in safe and effective products and facilitate device regulatory approval process. In this talk, we will provide a brief overview of safety record of medical devices, the FDA requirements for human factors engineering during design and development and how application of human factors can produce more safe and effective devices.

- Understand the importance of Human Factors in design
- Application of Human Factors to Medical Devices
- FDA's New Guidelines on Human Factors

Abe Mamaghani, Manager Development R&D, ABBOTT LABORATORIES

9:45am

IMPROVING USABILITY OF HOME MEDICAL DEVICES

- Understand how recent changes in usability-related requirements apply to home healthcare devices
- Learn how to use new technology to learn what really goes on in patients' homes
- How in-home research can speed time to market
- Gain and use tools and strategies to improve safety and ease of use to improve patient compliance

Recommended references and resources are available for participants

Stephen B. Wilcox, Ph.D., Founder and President, DESIGN SCIENCE

10:30am *Morning Refreshment and Networking Break*

SOFTWARE DESIGN AND DEVELOPMENT

11:00am

Dr. Ray is one of the project leads for the infusion pump projects at CDRH, FDA

SECURITY FOR MEDICAL DEVICES: THE NEXT GREAT DESIGN CHALLENGE

In this presentation, Dr. Arnab Ray will provide a brief survey of recent exploits on devices, examine attack pathways by which hackers compromise systems, and advocate a more structured consideration of security as a design-driver so that manufacturers may reduce time to market for devices and prevent costly recalls.

- The current and future landscape of medical device security
- Security and regulatory authorities
- Recommendations for the present (security audits of existing devices) and for the future (security by design)

Arnab Ray, Research Scientist, FRAUNHOFER CENTER FOR EXPERIMENTAL SOFTWARE ENGINEERING

11:45am

RISK MANAGEMENT REQUIREMENTS FOR MEDICAL DEVICES

- Learn how risk management is integrated into the 3rd edition of 60601-1
- Understand the demands of ISO 14971
- Build a design process that includes risk management
- Master risk management documentation for legacy devices

White paper on "Turning the 3rd Edition of IEC 60601-1 to Your Advantage" is available for download

Dale Hallerberg, Technical Manager – Medical Test, TÜV RHEINLAND NORTH AMERICA

12:30pm *Networking Luncheon*

1:30pm

CONSIDERATIONS FOR A SUCCESSFUL IMPLEMENTATION OF AN AGILE SDLC FOR MEDICAL DEVICES

Agile and Lean development methodologies can not only expedite time to market, but also increase quality. With the right customization on your Agile development process you can also meet regulatory

	requirements. This presentation will focus on: • How Agile principles can contribute to quality • Meet IEC 62304 requirements • Get and use tools for collocated and distributed teams • Continuous improvement **Adam Darmstadt, Software Development Manager, BIO-RAD LABORATORIES**
2:30pm	**DESIGNING MEDICAL DEVICES TO MEET THE NEEDS OF THE PATIENTS GLOBALLY** **Sathish Ramkumar, Sr. Development Manager, Software Development, Imaging Clinical Applications and Platforms (ICAP)-NM, PHILIPS HEALTHCARE**
	PROJECT MANAGEMENT, METRICS, AND ESTIMATION
3:15pm	**ACCELERATE YOUR TIME TO MARKET USING CRITICAL CHAIN PROJECT MANAGEMENT** Industry statistics show that traditional development projects finish late, over budget or with compromises in key functionality. New project methodologies are needed to compete in today's tough environment. Critical Chain project management is the biggest innovation in project management methods since the cold war and overcomes many of the shortcomings of traditional methods. Critical Chain methods allow the project manager to identify and optimize the tasks and resources that will bring the project to completion on time. • Analyze traditional estimation and project management • Find the answer to the question "Why do we fail to deliver projects with full scope, on schedule and within budget?" • Solve the problem using Critical Chain Project Management **Ron Rammage, PMP, Software Engineering Manager, ABBOTT MEDICAL OPTICS**
4:00pm	*Closing Remarks from Chairman and End of Conference*

Pre-Conference Workshop

Monday, November 5, 2012

WORKSHOP A (3 HOURS)

11:15am
(Lunch included)

ON BEING NIMBLE: LEAN DEVELOPMENT PRINCIPLES IN MEDICAL DEVICE SOFTWARE DEVELOPMENT

How many times have you heard "You can have your software on time, on budget, or high quality – pick any two" and wished you could break out of the tradeoff? The enemy is not poor practices, inadequate talent, or lack of rigor, but linear / sequential thinking. Recent developments in team organization, design philosophy, and development models have enabled far higher productivity, and lower defect rates, than were ever possible with the "waterfall" mindset.

How you will benefit:

- Understand how to learn the real requirements even as development progresses
- Learn how to demonstrate progress to management, and earn trust
- See how to unlock "freezing" inputs at a project's outset, and get a more robust product faster
- Understand how iterative software development, done right, is inherently safer

What you will learn:

- Key elements needed for nimble, customer-responsive software development
- Tools for tracking iterative software development
- Approaches to ensuring that rigorous, auditable deliverables are produced
- Strategies for tying iterative software development to parallel, concurrent hardware development

Participants will receive a 26-page guidelines and tips on developing software quality procedure

Your workshop leader:

Brian Shoemaker, Principal Consultant, SHOEBAR ASSOCIATES

WORKSHOP B (3 HOURS)

2:30pm

HUMAN FACTORS ENGINEERING AND RISK MANAGEMENT FOR MEDICAL DEVICES DESIGN

Human Factors Engineering (HFE) and usability testing are concerned with ways of designing tools, machines, operations, regulatory compliance, environment or work systems so they are compatible with human capabilities and limitations. Drawing on case studies, this workshop will discuss close collaboration between human factors/ usability requirements according IEC 62366 for Medical Devices as well as independent Risk Management according ISO 14971 as a means to achieve breakthroughs in the design of safe and effective medical devices and to speed up time to market.

How you will benefit:

- Obtain an understanding of "Intended Use" as a key foundation for solid HFE
- Learn specific methods how to separate Risk-Management activities from Usability Engineering tasks for developing usable interfaces, including alarm design
- Implement usability testing throughout the product lifecycle
- Discuss trends in simulated usability environments and share Experiences

What you will learn:

- Differences between "Hazards/Hazardous Situations" and "Use errors"
- Pitfalls associated with the design of medical interfaces and how to avoid them
- The pros and cons of different approaches to rapid prototyping
- How to do usability testing throughout the product life cycle
- How to analyze usability data and incorporate it into hazard analysis
- Valuable contacts for FDA QSR/design control requirements

	• Latest up-dates on IEC 62366-1 (2nd ed.) as well as on FDA Usability Guidance **Your workshop leaders:** **Juergen Stettin M.D., Ph.D. , CEO, PROSYSTEM AG, Hamburg** **Chairman of German Scientific Hospital Organization (WGKT)** **Oliver P. Christ, CEO Healthcare PROSYSTEM AG, Hamburg** **Member of International Standardization Group for IEC 62366**
5:30pm	*End of Pre-Conference Workshop Day*