Healthcare iQ a division of IQPC presents the 6th Annual

# SD MD Software Design for Medical Devices Europe™

MAXIMISING COMPLIANCE WHILE FOSTERING PROGRESS AND INNOVATION IN THE DEVELOPMENT OF MEDICAL DEVICE SOFTWARE

Pre-Conference Workshops: 22nd February 2016
Main Conference: 23rd February - 24th February 2016
Munich, Germany

## Europe's Only International Forum Dedicated to Medical Device Software Design and Compliance

### Bringing Together 50+ Professionals From Across the Medical Device Industry to:

- Overcome regulatory challenges with a keynote address from the **MHRA** on the new EU medical device regulation proposal
- Drive innovation in product development with case studies from **Siemens** and **GE Healthcare**
- Implement Agile methodologies with interactive agile training from a certified **Agile Coach**
- Receive Human Factor methodology training from **Roche Diagnostics** to improve you products
- Get the latest in quality and regulatory compliance tips, tricks, and lessons learned from **Philips Healthcare**

### Top 4 Reasons to Get Involved in 2016:

1. **NEW!** **Interactive Troubleshooting Session** – Where you have the opportunity to ask experts your most pressing questions
2. **NEW!** **Innovative Insight** - Hear exclusive real life case studies from companies like Miracor Medical, who took an idea from a prototype to a highly successful product
3. **NEW!** **Mob Programming - The Next Leap Forward in Agile Development** - Uncover the unexpected benefits of having a whole team working on the same thing, at the same time, on the same computer
4. **NEW!** **First-hand Regulatory Insight** – Hear from the MHRA and ask a regulator your most pressing questions

### Hear exclusive case studies from over 16 industry leaders, including:

**Rob Higgins**, Head of Regulatory Affairs (Devices), **MHRA**

**Georg Heidenreich**, Head of Medical Computer Science, **SIEMENS**

**Urs Suter**, Usability Engineer, **ROCHE DIAGNOSTICS**

**Martin Haidacher**, Project Manager Software Development and Data Analysis, **MIRACOR MEDICAL SYSTEMS**

**Andrew Smart**, Human Factors Engineer, **NOVARTIS**

**Bob Hunt**, Senior Program Manager, **DRÄGERWERK**

**Jonathan Salmon**, Research Manager, **QUANTUM MDx**

**Olivier Blandin**, Head of Operations, **NAYAMED**

*Plus many more*

**WWW.SDMDEUROPE.COM**

# Welcome

Dear Colleague,

Software design for medical devices is becoming subject to increased regulations, changing standards and evolving best practices. In order to help you keep up with this shifting landscape, Pharma-IQ is proud to present its 6th Annual Software Design for Medical Devices (SDMD) conference!

SDMD 2016 will bring together 50+ professionals from across the medical device industry with the end goal of addressing their regulatory and technical challenges.

**Join us at SDMD 2016 to:**

- Discuss the proposed new European regulatory structure with insight from the MHRA
- Discover what novel practices and tools your peers (and competitors) are using in their software development and validation with case studies from GE, Philips, Siemens, Drägerwerk and more
- Learn how to get the most out of a truly agile workflow in your projects with an innovative demonstration from an Agile Coach on 'mob-programming'
- Develop basic-crypto techniques to increase product security with insight from Philips Healthcare
- Gain a better understanding of the Human Factors engineering process with help from Roche Diagnostics

Bringing together Software Engineers, Quality Assurance and Regulatory Managers, with an inspiring speaker panel and content that really addresses the challenges and issues on everyone's mind right now. This event promises to be a platform for innovation and an incredible networking opportunity.

Look forward to meeting you in February!

**Katherine Gordon**,
Conference Director

**"This is the most useful conference I have attended to date"**

QMS Manager, INFOR, Delegate 2015

**"Very valuable to get both regulatory and software views"**

SW Development Manager, Renishaw, Delegate 2015

**"Very valuable event - State of the art."**

Biocodex, Delegate 2015

## Meet Your 2016 Expert Speakers:

**Rob Higgins**,
Head of Regulatory Affairs (Devices),
**MHRA**



**Dr. Georg Heidenreich**,
Head of Medical Computer Science,
**SIEMENS**

**Brian Shoemaker**,
Principal Consultant,
**SHOEBAR ASSOCIATES**

**Andrew Smart**,
Human Factors Engineer,
**NOVARTIS**

**Nancy Von Schooenderwoert**,
President and Managing Partner Development Practice,
**LEAN-AGILE PARTNERS**

**Urs Suter**,
Usability Engineer,
**ROCHE DIAGNOSTICS**

**Jonathan Salmon**,
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**Olivier Blandin**,
Head of Operations,
**NAYAMED**

**Bob Hunt**,
Senior Program Manager,
**DRÄGERWERK**

**Hagai Livni**,
Global Head of Software Validation,
**CONVIDEN**

**Holger Mikolon**,
Senior Software Architect,
**PHILIPS HEALTHCARE**

**Holger Most**,
Regulatory Affairs Leader,
**GE HEALTHCARE**

**Rost Dorozoh**,
Software Project Engineer,
**ELEKTA**

**György Petö**,
Test Automation Engineer,
**VARIAN**

**Heidi Manijeh Mehrzad**,
Principal Human Factors Specialist,
**BIOTRONIK**

**Sven Grand**,
Software Quality Expert,
**PHILIPS HEALTHCARE**

**Celestina Bianco**,
Quality and Regulatory Affairs Director,
**SYSTELAB TECHNOLOGIES**

**Albert Ferre**,
Project Manager of Software Development,
**SYSTELAB TECHNOLOGIES HEALTHCARE**

**WWW.SDMDEUROPE.COM**

# Pre-Conference Workshops – 22nd February 2016

Get ahead of the rest with these dedicated interactive sessions and get to grips with the most challenging issues in software design for medical devices. These tailored, one on one workshops are targeted to really push the boundaries of knowledge and leave our delegation inspired and informed.

## Workshop A
**09:00-11:30**

## 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 analyse-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-always that enhance project deliveries

**Nancy Von Schooenderwoert**,
President and Managing Partner Development Practice,
**LEAN-AGILE PARTNERS**

**Brian Shoemaker**,
Principal Consultant,
**SHOEBAR ASSOCIATES**

## Workshop B
**11:30 to 14:00**

## Applying Human Factors and Usability Engineering to Optimize Medical Device Design

The value of any medical device can only be measured by its impact on patient outcomes. It seems simple but is often forgotten. This workshop will help you better understand the importance of usability and Human Factors in device design, and how to incorporate these considerations throughout the development process.

**Attend this session in order to:**

- Minimize use-related hazards and risks
- Confirm that these efforts were successful and users can use the device
- Optimize device design by improving safety and efficiency

**Heidi Manijeh Mehrzad**,
Principal Human Factors Specialist,
**BIOTRONIK**

## Workshop C
**14:00 – 16:30**

## Documentation and Records: How Much is Enough and How Much is Too Much?

Throughout the product lifecycle, a significant amount of documentation and records is required by both manufacturer and regulator in order to demonstrate thorough design controls, document controls and audit history. However, guidance on how much documentation is enough can be unclear, leading to companies wasting time by producing too much and sacrificing efficiency. So how much documentation is enough, and how do you know when to stop?

**This workshop will help you:**

- See examples of what data is expected and find out now to know when enough documentation has been produced
- Learn how to stay efficient while producing enough documentation to demonstrate compliance
- Discover how to train staff to get documentation accurate and concise
- Maintain optimum levels of efficiency and product to market time frames while remaining compliant

**Holger Most**,
Manager Regulatory Affairs,
**GE HEALTHCARE**

# Conference Day One:
# Tuesday 23rd February 2016

08:15 Registration and Coffee

08:50 **Pharma IQ Welcome**

09:00 **Chairman's Opening Remarks**
The chair will set the mission statement for the two days ahead, introduce the key themes and highlight the outline of the day. Take this opportunity to get to know your peers and discuss your priorities for the next two days.
Brian Shoemaker, Principal Consultant, **SHOEBAR ASSOCIATES**

## Maintaining Compliance throughout the Regulation Evolution

09:15 **KEYNOTE ADDRESS: The New Medical Device Regulation Proposal: Everything You Need to Know to Stay Compliant**
KEYNOTE ADDRESS:
- Be prepared for upcoming changes by learning what the new proposal means for your company
- Get ideas ahead of time to prepare for new regulations
- Have your chance to ask questions and get answers from a regulator to avoid issues for your company down the track

Rob Higgins, Head of Regulatory Affairs (Devices,) **MHRA**

10:00 **How To Comply With IEC 80001 As A Medical Device Manufacturer**
- Learn about the practical effects of IEC 80001
- Discover how large manufacturers are complying with IEC 80001
- Learn how your company can achieve regulation compliance without sacrificing process efficiency

Georg Heidenreich, Director Healthcare IT Standards, **SIEMENS HEALTHCARE**

10:45 Networking Coffee Break

11:15 **Increase Product-Cycle Efficiency Through Automated Design Processes**
CASE STUDY
- Enable your engineers to assess the thoroughness of system testing by automatically recording which parts of the application are stimulated by each system test
- Discover the advantages of automated software testing compared to manual software testing
- Learn about code driven testing, graphical user interface testing and API driven

Hagai Livni, Global Head of Software Validation, **CONVIDEN**

## Understanding the Importance of Usability and Human Factors

12:00 **Improving Your Product by Maximizing Usability through Human Factor Methodologies**
- Discover how maximising usability can improve your medical device design
- Learn how to improve Human Factors process in your company from a leading expert
- Develop a leading edge on competitors by producing better, easier-to-use products

Andrew Smart, Human Factors Engineer, **NOVARTIS**

12:45 Networking Lunch

13:45 **Understanding the Advantages of Implementing Human Factors into the Development Cycle**
- Discover the value of user research in developing a product that customers enjoy using
- Develop Human Factors tools and techniques and learn when to include them into the development cycle
- Learn best practices methods based on recent FDA submissions where usability engineering was part of the process

Urs Suter, Usability Engineer, **ROCHE DIAGNOSTICS**

14:30 **PANEL DISCUSSION: Human Factors and Usability considerations in Software Design for Medical Devices**

This discussion will focus on generating the best strategies to produce innovative medical devices that effectively integrate the diverse needs of all product users. Gain an understanding of the different user-testing methods and work out which is the best fit for your organization.
PANELISTS:
Heidi Manijeh Mehrzad, Principal Human Factors Specialist, **BIOTRONIK**
Urs Suter, Usability Engineer, **ROCHE DIAGNOSTICS**
Andrew Smart, Human Factors Engineer, **NOVARTIS**

15:15 Networking Coffee Break

15:45 **Theory and Practice of Effective Bug Fixing for Successful Software Teams**
- Learn how to take a tailored, risk-based approach to information security
- Discover how Philips Healthcare are protecting their vital information
- Acquire practical take-home skills for effective bug-fixing in your software systems

Sven Grand, Software Quality Expert, **PHILIPS HEALTHCARE**

16:30 **Balancing the Scales: How Much Documentation is Enough?**
- Learn how to produce enough documentation to stay compliant with regulations and avoid penalisation
- Uncover the secret to maintaining efficiency while producing enough documentation
- Discover how to train staff to get documentation accurate and concise in a time efficient way

Celestina Bianco, Quality and Regulatory Affairs Director, **SYSTELAB TECHNOLOGIES** and Albert Ferre, Project Manager of Software Development, **SYSTELAB TECHNOLOGIES**

17:15 **Chairman's Summary of Day One**

> **"Stimulating discussions"**
>
> Consultant Clinical Scientist, NHS, **Delegate 2015**

# Conference Day Two:
# Wednesday 24th February 2016

08:30 Registration and Welcome Coffee

09:00 **Chairman's Recap of Day One**

09:15 **KEYNOTE ADDRESS: Innovative Thinking in Software Design for Medical Devices - A Case Study**

KEYNOTE ADDRESS:

- Hear from an SME about how they used innovative thinking to take an idea and turn it into a successful company
- Discover how QuantuMDx developed a handheld DNA sequencer to diagnose disease and identify drug resistance in under 20 minutes for a few dollars by the patient's side
- Learn about how Q-POC could prevent pandemics via rapid identification of novel pathogens in the field and a cloud-based monitoring system
- Gain insight into software development for a handheld point-of-care diagnostic device

**Jonathan Salmon, Research Manager, QUANTUM MDx**

10:00 **Interactive Troubleshooting Session**

One of the best aspects of a conference is the knowledge of its delegates. Is there a particular challenge you are facing that another delegate might already have a solution for? Have you recently overcome a challenge are willing to share you achievement?

This session allows you to write down you post pressing question, and see who in the room already has the answer. Likewise, it will give you the opportunity to share your experiences with peers.

10:45 Networking Coffee Break

## Minimising Risk and Increasing Security

11:15 **Applying Risk Management to Medical Device Software**

- Hear about ISO 14971 from a medical device software perspective
- Learn about a safety driven software development life-cycle
- Develop risk analysis techniques, and methods of failure analysis

**Rostyslav Dorozh, Software Project Engineer, ELEKTA**

12:00 **Digital Signing of Software on Medical Devices: Protect Your Products Against Forgery and Information Tampering!**

- Learn practical solutions for implementing digital signing on your medical device software
- Develop basic-crypto techniques to increase product security
- Help your company to sustain signer authenticity, accountability, data integrity and the non-repudiation of signed electronic documents and forms.

**Holger Mikolon, Senior Software Architect, PHILIPS HEALTHCARE**

12:45 Networking Lunch

## Increasing Success with Agile Practices

13:45 **Discover the Benefits of Implementing a Scaled Agile Framework**

- Discover why Agile methodologies are becoming common at the team level and how to scale it within the enterprise to create a truly Agile organization
- Learn how to use Lean-Agile values to drive innovation and increase your business's ability to increase time to Market and respond quickly to Market changes
- Move away from project based portfolio management to Development Stream funding
- Learn the importance of Alignment and transparency throughout the organization

**Bob Hunt, Senior Program Manager, DRÄGERWERK**

14:30 **Mob Programming - The Next Leap Forward in Agile Development**

- Uncover the unexpected benefits of having a whole team working on the same thing, at the same time, on the same computer
- Discover why and how this takes quality so much higher
- Learn what real teams have achieved using this innovative new practice

**Nancy Von Schooenderwoert, President and Managing Partner Development Practice, LEAN-AGILE PARTNERS**

15:15 Networking Coffee Break

## Innovative Ideas in Software Design for Medical Devices

15:45 **CASE STUDY: Innovation at Work: The PiCSO Impulse System – From Prototype to Product**

CASE STUDY

- Hear about improving the software validation/verification process using the hierarchical V-model
- Learn take-home methods to better track changes and bugs and move towards agile development
- Hear about the implementation of automatic and reproducible software builds
- Learn about tools to improve code quality (Polyspace Code Prover)
- Hear about alarm management: better usability without increasing risks

**Martin Haidacher, Project Manager Software Development and Data Analysis, MIRACOR MEDICAL SYSTEMS**

16:30 **How to Innovate in Product Fulfilment and Support: A Case Study with NayaMed**

CASE STUDY

- Discover how radical Business Model innovation takes place in a company
- Learn how to help hospitals do more with less and remain productive throughout budget restrictions
- Overcome challenges that have arisen from the change in paradigm with the new generation of young doctors

**Olivier Blandin, Head of Operations, NAYAMED**

17:15 **Chairman's Closing Summary and End of Conference**

**"For me the conference was a one stop shop for updated information. We also used it for brand awareness improvement"**

SoftGroup, **Delegate 2015**

# Maximise Your Involvement: Sponsorship and Exhibition Opportunities

Focused and high-level, the event will be the leading platform to initiate new business relationships. With tailored networking, sponsors can achieve the face-to-face contact that overcrowded trade shows cannot deliver.

### What makes Healthcare IQ's Sponsorship Package Superior to All Others?

There's really no magic, it is merely patient attention to what our sponsorship customers want, expect, need and value. Every sponsor wants to create customers, develop qualified sales leads, convert leads into sales and retain customers. Our tailored sponsorship packages help you to achieve these objectives.

### Engage and influence key decision makers

Work with us before, during, and after the event to engage your audience. Our reach across the construction industry is unprecedented.

### Benefit from:

- Thought leadership
- Brand awareness
- Face to face meetings
- More data
- New prospects

And much more…


### How to get involved

For exciting sponsorship opportunities please contact our sponsorship team on +44 (0) 207 368 9300 or email to sponsorship@iqpc.co.uk.

## Who Should Attend?

- Software Engineers
- Software Architects
- Quality Assurance Professionals
- Regulatory Assurance Professionals
- Consultants
- Validation and Verification Professionals

## Some of the companies who attended in 2015

- Siemens
- Medtronic
- Philips
- Convidien
- Delta
- ResMed
- Draeger
- B.Braun
- BSi
- Abbvie
- Systelab Technologies
- Felxtronics
- Texas Instruments
- TUV SUD
- Avalere Health
- Agfa Healthcare
- Reinshaw
- Roche
- Fraunhofer
- Abbott Labs

# Software Design for Medical Devices Europe™

Pre-Conference Workshops: 22nd February 2016
Main Conference: 23rd February - 24th February 2016
Munich, Germany

My registration code **PDFW**

Please contact our database manager on +44(0) 207 368 9300 or database@iqpc.co.uk quoting the registration code above to inform us of any changes or to remove your details.

## SPECIAL OFFER FOR ALL MEDICAL DEVICE MANUFACTURERS

**2-for-1 passes for the 2 day conference are available until 18th December 2015!**

To take advantage of this 241 offer email enquire@iqpc.co.uk or phone +44 (0) 207 368 9300

| Pass Includes | 3 Day Pass | 2 Day Pass |
|---|---|---|
| Main Conference (23rd-24th February) | ✔ | ✔ |
| Access to conference presentations post-event on B2B Shop at www.b2biq.com | ✔ | ✔ |
| Access to Pre-Conference Workshop (22nd February) | ✔ | ✗ |

| Package Options for Medical Device Manufacturers | 3 Day Pass | 2 Day Pass |
|---|---|---|
| ☐ Register & Pay by 20th November 2015* | €3099 + VAT SAVE €600 | €1999 + VAT SAVE €600 |
| ☐ Register & Pay by 18th December 2015* | €3299 + VAT SAVE €400 | €2199 + VAT SAVE €400 |
| ☐ Register & Pay by 22nd January 2016* | €3499 + VAT SAVE €200 | €2399 + VAT SAVE €200 |
| ☐ Standard Price | €3699 + VAT | €2599 + VAT |

| Solution Providers & Consultants | Price |
|---|---|
| Conference Only Pass - Register and pay after 18 December 2015* | €2699 + VAT |
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*To qualify for discounts, payment must be received with booking by the registration deadline.
Early booking discounts are not valid in conjunction with any other offer. German VAT is charged at 19%. VAT #: DE 261 1019 14
**Please select your choice of workshop A ☐ B ☐

## DELEGATE DETAILS - SIMPLY COMPLETE THIS FORM AND CLICK SUBMIT

Please photocopy for each additional delegate

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Nature of business

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☐ *I agree to IQPC's cancellation, substitution and payment terms*

Special dietary requirements: ☐ Vegetarian ☐ Non-dairy ☐ Other (please specify)

Please indicate if you have already registered by: ☐ Phone ☐ Fax ☐ Email ☐ Web
Please note: if you have not received an acknowledgement before the conference, please call us to confirm your booking.

## PAYMENT METHOD

Total price for your Organisation: (Add total of all individuals attending): Card Number: VISA ☐ M/C ☐ AMEX ☐

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## TEAM DISCOUNTS*

IQPC recognises the value of learning in teams. Groups of 3 or more booking at the same time from the same company receive a 10% discount, 5 or more receive a 15% discount, 7 receive a 20% discount. Only one discount available per person.

## VENUE & ACCOMMODATION

**Venue:**
Munich, Germany - Venue to be confirmed shortly.

**Accommodation:**
Travel and accommodation is not included in the registration fee. For updates on the venue and accommodation information, please visit: www.sdmdeurope.com

## TERMS AND CONDITIONS

Please read the information listed below as each booking is subject to IQPC Ltd standard terms and conditions. Return of this email will indicate that you accept these terms.

**Payment Terms** Upon completion and return of the registration form full payment is required no later than 5 business days from the date of invoice. Payment of invoices by means other than by credit card, or purchase order (UK Plc and UK government bodies only) will be subject to a €65 (+ VAT) per delegate processing fee. Payment must be received prior to the conference date. We reserve the right to refuse admission to the conference if payment has not been received.

**IQPC Cancellation, Postponement and Substitution Policy** You may substitute delegates at any time by providing reasonable advance notice to IQPC. For any cancellations received in writing not less than eight (8) days prior to the conference, you will receive a 90% credit to be used at another IQPC conference which must occur within one year from the date of issuance of such credit. An administration fee of 10% of the contract fee will be retained by IQPC for all permitted cancellations. No credit will be issued for any cancellations occurring within seven (7) days (inclusive) of the conference. In the event that IQPC cancels an event for any reason, you will receive a credit for 100% of the contract fee paid. You may use this credit for another IQPC event to be mutually agreed with IQPC, which must occur within one year from the date of cancellation. In the event that IQPC postpones an event for any reason and the delegate is unable or unwilling to attend in on the rescheduled date, you will receive a credit for 100% of the contract fee paid. You may use this credit for another IQPC event to be mutually agreed with IQPC, which must occur within one year from the date of postponement. Except as specified above, no credits will be issued for cancellations. There are no refunds given under any circumstances. IQPC is not responsible for any loss or damage as a result of a substitution, alteration or cancellation/postponement of an event. IQPC shall assume no liability whatsoever in the event this conference is cancelled, rescheduled or postponed due to a fortuitous event, Act of God, unforeseen occurrence or any other event that renders performance of this conference impracticable, illegal or impossible. For purposes of this clause, a fortuitous event shall include, but not be limited to: war, fire, labour strike, extreme weather or other emergency. Please note that while speakers and topics were confirmed at the time of publishing, circumstances beyond the control of the organizers may necessitate substitutions, alterations or cancellations of the speakers and/or topics. As such, IQPC reserves the right to alter or modify the advertised speakers and/or topics if necessary without any liability to you whatsoever. Any substitutions or alterations will be updated on our web page as soon as possible.

**Discounts** All 'Early Bird' Discounts require payment at time of registration and before the cut-off date in order to receive any discount. Any discounts offered whether by IQPC (including team discounts) must also require payment at the time of registration. All discount offers cannot be combined with any other offer.

**B2B shop:** The purchase of any conference audio, video or digital recording on B2B Shop (www.b2biq.com) includes keynote, topic and panel sessions where the presenters agree to grant permission for their presentation/sessions to be audio and/or video recorded by IQPC and further agree to release all rights to IQPC related to the contents of the recording, its distribution, sale, reproduction, broadcast in whole or in part and without limitation or compensation. Please be aware that in respect of this IQPC cannot guarantee the inclusion of any or all sessions until after the conference has taken place.



**PAYMENT MUST BE RECEIVED PRIOR TO THE CONFERENCE**