Pharma iQ a division of IQPC Proudly presents

SDMD Software Design for Medical Devices Europe™

Pre-conference workshop: 21st February 2017 | **Main Conference Dates:** 22nd – 23rd February 2017 **Post-Conference Agile Training Day:** 24th February 2017

Hilton, Munich City, Germany

The Only International Gathering for Medical Software Design, Agile Development and Compliance

Key Speakers for 2017 include:

Orna Nesher
Manager, Software Design QA
Medtronic

Jordi Manzano
Instruments R&D Director
Diagnostic Grifols

Erich Zanner
Senior Quality Site Leader
GE Healthcare

Cornelia Wiedenbrueg
Project Manager (SW) Multisite Scaled Scrum
Sivantos

Adrian Gerhaeusser
Department Head Release Management, Digital Factory Division, Factory Automation
Siemens

Jan Van Moll
Head of Quality Management System, Audits & Compliance,
Philips

Top Reasons to Attend SDMD 2017

- Secure your device with a spotlight on Cyber Security for medical devices, with insight on the FDA's Postmarket Management of Cyber Security in Medical Devices guidelines
- A full-day Agile Development training course run by Expert Agile Trainers from Shoebar Associates and Lean Agile Partners that address the issues which inevitably come up in Agile adoption, to help you determine your own unique strategy
- Exclusive case studies on embedding agile risk analysis into development cycles with insight from Grifols
- Innovative thinking in software verification and validation processes with tips from Medtronic
- Insight into the advantages and disadvantages of the brand new Medical Device Single Audit Program with help from GE Healthcare

100+ Attendees

20+ Senior Speakers

30+ Hours of case studies, training and interactive discussions

Insight from across software development, regulatory compliance, human factors and security

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WELCOME ADDRESS

Dear Colleagues,

Advances in Medical Device Software are changing the way patients are treated. Increasingly innovative and effectively designed software components are speeding device time to market, and increasing product life times – the benefits of which are passed on to manufacturers and patients alike.

The nature of medical devices means that tight regulations are imperative to guarantee patient safety, but the heavily regulated landscape presents a multitude of challenges. Now, more than ever, efficient product design, quality assurance, validation and verification are absolute necessities. By understanding the latest tools and solutions available to them, manufacturers of medical devices will be able to utilise these advancements to get ahead of competitors and provide the best possible offering to patients.

In order to help you keep up with this shifting landscape, Pharma IQ is proud to present the 7th annual Software Design for Medical Devices conference on the 21st - 24th February in Munich, Germany.

SDMD 2017 will bring together 100+ professionals from across the medical device industry with the end goal of addressing their regulatory and technical challenges. The next few pages will tell you everything you need to know about SDMD 2017.

Look out for these key highlights:

- LERO join us for the first time to tell us all about the FDA's new cyber security guidelines
- America's most knowledgeable human factors expert, Ed Israelski, talks us through everything we need to know about the emerging and more rigorous international standards for human factors engineering
- We've brought back (by popular demand) the full-day Agile Development training courses
- Introducing insight into the advantages and disadvantages of the brand new MDSAP which could save you a lot of time and money!

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.

I look forward to meeting you in February!

Katherine Gordon, Conference Director

"For smaller companies SDMD might be the lighthouse which brings you back on the right track for SW development."

Project Manager SW Development and Data Analysis, Miracor Medical

"It made us realize our overall status of our products and how we develop them. Interesting to see how other companies work and handled challenges."

QA/RA Manager, SyntheticMR

"SDMD Europe always yields fresh ideas to bring home and evolve"

Software Project Manager, Systemlab Technologies

"Extremely interesting sessions related to risk analysis and cyber security"

Quality Assurance Manager, Inpeco SA

EXPERT 2017 SPEAKER PANEL

Orna Nesher
Manager, Software Design QA
Medtronic

Jordi Manzano
Instruments R&D Director
Diagnostic Grifols

Pat Baird
Regulatory Head of
Global Software Standards
Philips

Brian Shoemaker
Principal Consultant
Shoebar Associates

Ed Israelski
Former Director Human Factors
AbbVie

Hannah Murfet
Vice Chair
CQI's Next Generation Network

Erich Zanner
Senior Quality Site Leader
GE Healthcare

Nancy Von Schooenderwoert
President and Managing Partner
Development Practice
Lean-Agile Partners

Cornelia Wiedenbrueg
Project Manager (SW),
Multisite Scaled Scrum
Sivantos

Tony Hewer
Senior Quality &
Regulatory Affairs Director
Medidata

Emanuela Keller
Founder
NeMoDevices

Isabel Anton
Software Testing and
Quality Manager
Diagnostic Grifols

GRIFOLS

Fergal Mc Caffery
Director of the Regulated
Software Research Centre,
Dundalk Institute of Technology,
and Member
LERO – The Irish Software research Company

Adrian Gerhaeusser
Department Head
Release Management,
Digital Factory Division,
Factory Automation
Siemens

Marco Rigamonti
Director, Engineering & Design
Flex

Jan Van Moll
Head of Quality Management
System, Audits & Compliance
Philips

Analysing Risk in Medical Device Software

Workshop A 09:00-11:00

Software failures in medical devices can lead to catastrophic situations, which mean that it's absolutely critical to handle software related risks when developing medical devices. The first step is risk identification and risk analysis, which gives input to an organisation's introduction of a software risk management process. This workshop will focus on user risks based on scenarios describing the expected use of the medical device in its target environment. Beginning with how you define the safety class (A, B or C?) – A short presentation will be followed up by an interactive forum that allows you to get right into the nitty-gritty and test your ideas with industry experts.

Attend this workshop to:

- Define what class your software actually is – a challenge much more difficult than it sounds!
- Learn best practice strategies to identify and analyse risk factors in your device software
- Hear examples of scenarios where risk management was not conducted properly and avoid these mistakes
- Develop water-tight risk management processes, and check your ideas with risk-management experts

Facilitated by:

Pat Baird, Regulatory Head of Global Software Standards, **Philips**

Pat is currently the Regulatory Head of Global Software Standards at Philips, where he represents Philips on software standards committees (e.g. interoperability, security, privacy, etc.) and works collaboratively with regulators, trade groups, customers, and other stakeholders regarding standards, guidances, whitepapers etc. He was previously the technical lead for Risk Management activities in Baxter's Risk & Reliability engineering department. In that rolePat act as an internal consultant for project teams across multiple product lines and business units, helping them assess and improve their risk management processes. He has published and presented over 50 papers on topics such as software development, change management, stakeholder management, and risk management. Pat is highly active in "Policy Engineering" of standards and guidances - developing policies that meet the needs of regulators, manufacturers, healthcare providers, and patients. In the past few years, he has become fascinated and very passionate about patient safety - so much so that while working full-time at Baxter, he returned to school and received a Masters in Patient Safety from Northwestern. Pat is extremely active in the device industry, both inside the US and internationally, including: Team lead, Industry-competency development, MDIC - Team lead, pre-production, Xavier/FDA/MDIC Measures project - Co-Chair AAMI Infusion Devices Committee - Co-Chair AAMI Software Assurance Committee - Chair, AAMI Assurance Case Guidance (Technical Information Report) - Founder and Chair, Infusion Systems Safety Council - Founder and Chair, Coalition of Organizations Reporting Events - Chair, AdvaMed Infusion Pump Working Group, - Co-Chair, AdvaMed Software Working Group, - AAMI Standard Strategy Committee, - AAMI Alarm Management Committee, - AAMI Quality Health Information Software Committee, - AAMI Cybersecurity, - AdvaMed Case for Quality Committee, - Editorial Board Member: AAMI Biomedical Instrumentation & Technology, - Strategy Board Member: AAMI Standards Strategy. He has also have earned multiple industry awards for my work to advance patient safety.

Incorporating Human Factors & Usability into Marketable Medical Devices to Ensure Product Success

Workshop B 11:30-13:30

This year the FDA published their document "Applying Human Factors and Usability Engineering to Medical Devices", highlighting the need to incorporate serious usability thinking into your medical device design! But usability and human factors can do so much more than help you achieve compliance. A thorough understanding of human factors principles and usability guidelines as part of the software design for medical devices' development process will optimise product success, reduce user-risk, and increase performance. Moreover, 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.

Attend this workshop to:

- Define the basic foundations for applying human factors and learn how you can utilise this to see real ROI
- Scrutinise the regulatory requirements of FDA (including the CDRH's Human Factors Pre-Market Review Team) and determine how they relate to the FDA approval process during the design of a medical device
- Compare best strategies to design and engineer innovative medical devices that successfully integrate the needs of diverse users
- Understand user-testing methods and metrics to optimise product usability and safety

Facilitated by:

Ed Israelski, Director Human Factors, **AbbVie**

Ed Israelski is now an independent Human Factors consultant specializing in medical device design, evaluation and regulatory submissions. He is a retired director of human factors at AbbVie a biopharmaceutical company. He joined Abbott now AbbVie in 2001, where he led a cross-division team to imbed best-practice human factors design methods into all of AbbVie's products, to ensure safety and usability. He is co-convener of both JWG4 and MT 25 with IEC and ISO in developing international HF medical standards including IEC 62366. Ed is past co-chair of the AAMI Human Factors Engineering committee, which develops HF standards for medical devices, e.g. HE-75. He is a certified human factors professional CHFP. He has authored fourteen book chapters and numerous articles in the area of human factors. Ed holds thirty patents. He is a fellow of the Human Factors and Ergonomics Society and a member of APA, UXPA and serves on the National Academy of Sciences Board for Human Systems Integration. He has been a juror for the MDEA medical device excellence awards. He was named to the 2008 MDDI list of 100 notable people in medical device development.
He has worked as a systems engineer, product manager, market researcher, industrial/organizational psychologist as well as a human factors engineer. He was technical manager of the human factors systems group at Lucent Technologies - Bell Labs, formerly AT&T. Later he was director of HF for SBC/Ameritech for telecommunications products. In 2000, he became chief technology officer at Human Factors International, a user interface design and consulting firm in information technology. He received a B.S. in electrical engineering from New Jersey Institute of Technology, an M.S. in operations research from Columbia University and a Ph.D. in industrial and engineering psychology from Stevens Institute of Technology

CONFERENCE AGENDA DAY ONE:
WEDNESDAY 22ND FEBRUARY 2017

08:00 Registration and Coffee

08:55 **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

REGULATIONS AND STANDARDS – Making Sense of the Alphabet Soup

09:10 **Alphabet Soup – ICE, ISO, FDA, EMA, etc!**

Making sense and keeping track of all the relevant medical device standards and regulations is no easy feat! In this interactive session that relies on you to share your regulatory challenges, you will:

- Get a complete overview of the regulations you need get familiar with and strategise on how to meet them
- Share you regulatory challenges and finally hear practical advice on addressing them
- Learn how your company can achieve regulation compliance without sacrificing process efficiency
- Get ahead of the curve with a 'close-up' of what to expect from the new change to the European Medical Device Directive

Hannah Murfet, Vice Chair, CQI's Next Generation Network

09:40 **The MDSAP Audit – Everything You Need to Know!**

Like the idea of being audited just once for compliance with the standard and regulatory requirements of up to five different medical device markets? The MDSAP program might just be for you …

- Understand the program's main mission to leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers
- Discover the finer details of the MDSAP from a QA expert, and figure out if it could help you save time and increase compliance
- Develop an understanding of the numerous advantages and potential disadvantages of the program, to evaluate its value for your organisation
- Learn about the 2016 pilot phase, and what to expect from the program as it enters a new phase in 2017

Erich Zanner, Senior Quality Site Leader, GE Healthcare

10:10 **People Bingo: Interactive Speed Networking**

A highlight of Pharma IQ events, now at SDMD! Be ready to meet your peers and share best practices. You will have several 2 minute conversations to enable you to introduce yourself to your peers and add to your contact pool. There is a prize in it for the winner so get networking!
Please Share:

1. Who you are
2. The scope of your job role
3. What you plan to achieve from attending this event
4. Your #1 challenge

10:30 Networking Coffee Break

11:00 **Emerging and More Rigorous International Standards and Regulations for Medical Device Human Factors Engineering**

Ask the Expert

Discover everything you ever wanted to know about human factors standards and regulations, including:

- New ISO/IEC Usability Engineering/Human Factors standards for medical devices – IEC 62366 Parts 1 and 2
- New MHRA Human Factors standards for the UK
- New AAMI standards for HFE
- New FDA guidance for HFE for medical devices and combination products
- How all of these raise the bar for more comprehensive and more rigorous application of HFE for medical devices including software driven devices

Ed Israelski, Former Director Human Factors, Abbvie

11:30 **Documentation for Agile Development - Shared Understanding, Vacation Photos, and Compliance**

- Discover how to produce the required documentation requirements for design, tests, hazard analysis, usability, and traceability medical devices, while still achieving the hallmarks of the agile approach: Working rapidly and flexibly, and demonstrating a working product regularly
- Analyse two almost contradictory challenges of documenting an Agile process for medical devices: Allowing ready sharing, exchange, and revision to build shared understanding and satisfying the legal/regulatory demand
- Take a tour through the documentation landscape and consider the primary document deliverables. How can we gather these as development proceeds, while minimising overhead? How can we assure that inputs are reviewed and approved, without getting mired in the document signoff spiral? How can we address design reviews without bogging down the team in long, droning meetings? How can we capture traceability as a natural outcome of our work?
- Hear examples and case studies to put these theories into context!

Brian Shoemaker, Principal Consultant, Shoebar Associates

CONFERENCE AGENDA DAY ONE:
WEDNESDAY 22ND FEBRUARY 2017

STAY AHEAD OF THE COMPETITION – With Innovative Thinking and Design

12:00 **Innovative Thinking and Pioneering Mind Set Shifts: Medtronic's Software Verification and Validation Processes**

- Hear about how Medtronic's Given Imaging Solutions (GIS) has implemented a state of the art software verification and validation processes, combining usability testing within an incremental software development
- Discover why this process, using Agile methodology, has led to further innovation
- Learn about combining a usability process during verification and validation within an incremental software development
- Hear how the processes and the company structure that made Medtronic a successful innovation site

Orna Nesher, Manager, Software Design QA, Medtronic

12:30 Networking Lunch

13:30 **Cloud Considerations for Medical Devices: Capability and Complexities**

- Discover the impact that network-connected medical devices can offer to patients and providers alike
- Examine the key considerations including leveraging existing technologies, using best practices, defining non-functional requirements, building in security and privacy features, partnering with a cloud service provider
- Develop the necessary strategies, tools, and team expertise to monitor and manage the cloud
- Factor in pricing considerations and figure out what costs will be incurred

Tony Hewer, Senior Quality & Regulatory Affairs Director, Medidata

14:00 **Innovation By Design: The NeMo System, From Research to Product**

- Hear from a start-up about how they used innovative thinking to take an idea and turn it into a successful company
- Learn how you can apply their strategies to your own company and drive internal creativity and innovation
- Discover how to inspire and motivate your employees to be innovative thinkers and maximise output

Emanuela Keller, Founder, NeMoDevices

14:30 Networking Coffee Break

15:00 **Campfire Round Table Discussions**

The best strategies are formed through expert collaboration! Break off into small groups of 8-10 people and collaborate with your peers in these interactive roundtable discussions…with a twist!

A campfire theme gives these round tables an intimate and open feel, with campfire snacks provided to get everyone in the mood! Warm your hands and your imagination.

Topics will include:

1. Cyber Security – The regulations and guidelines
2. Security in Practice – Design strategies to keep your products secure
3. Usability and Human Factors- Beat the competition with better designed products
4. EU Regulations – The updates and how to stay compliant and inspection ready
5. Documentation Management – strike that balance and make your life easier!
6. Best Practice Agile Development – Compare with peers and walk away with ideas

16:00 **Improving Your Product by Maximising Usability through Human Factor Methodologies**

- Understand of the importance of usability and human factors, and how it can vastly improve the value of your products
- Strategise on how to incorporate these considerations throughout the development process
- Optimise device design by improving safety and efficiency and minimise user-related hazards and risks
- Gain a leading edge on competitors by producing better, easier-to-use products

16:30 **Chairman's Summary of Day One**

16:45 Networking Drinks Reception

Enjoy some informal networking over a well earned drink (or two…)

18:30 Dinner at Zum Franziskaner

Indulge in a favourite SDMD tradition! Today filled your appetite for medical device software knowledge; tonight will fill your appetite for schweinshaxe, currybrust and weissbeer. Guaranteed.

CONFERENCE AGENDA DAY TWO:
THURSDAY 23RD FEBRUARY 2017

08:30 Registration and Welcome Coffee

08:50 **Chairman's Recap of Day One**

09:00 **Post-market Management of Cybersecurity in Medical Devices – The FDA's New Guidelines**

- Familiarise yourself with the FDA's new cyber security guidelines
- Ensure you are well positioned to meet the 2020 enforcement date by developing early enforcement strategies for post-market surveillance
- Learn how your company can achieve regulation compliance without sacrificing process efficiency
- Address the most common challenges companies face with regulatory compliance and develop strategies to stay on top of the situation!

Fergal Mc Caffery Director of the Regulated Software Research Centre, Dundalk Institute of Technology, and Member LERO – The Irish Software research Company

09:40 **A Challenge of Design vs. Security: Medical Mobile Apps**

- Discover how the cyber security considerations for medical mobile apps can help secure your device software
- Examine how the medical mobile app model is a perfect example of the challenges of design vs. human factor and agile development
- Assess relevant regulations relating to Medical Mobile Apps for the EU and USA

Marco Rigamonti, Director, Engineering & Design, Flex

10:20 Networking Coffee Break

10:50 **CASE STUDY: Embedding Agile Risk Analysis in an Agile Development Cycle**

- Discover strategies for factoring risk analysis into the beginning of your development cycles
- Reduce time to market and likelihood of recalls with a detailed risk management plan, and design your test plans accordingly
- Hear a case study from Grifols and discover what they did right and wrong, and have you can learn from their successes and mistakes!

Jordi Manzano, Instruments R&D Director, Diagnostic Grifols And **Isabel Anton,** Software Testing and Quality Manager Diagnostic Grifols

11:30 **Safety First: Cyber Security for Medical Devices**

- Overtake your competitors with insider insight into the biggest current and future cyber threats to medical device software
- Uncover hidden vulnerabilities in your device software with expert tips and tricks and develop plans to protect your products
- Implement long-term strategies to address the most common cyber security threats and make sure your devices are not vulnerable to malicious attacks

12:10 Networking Lunch

13:10 **ROUND TABLE DISCUSSIONS**

Simply choose the roundtable topic of most interest to you and join the discussion! These sessions are open, informal and a great opportunity to really gauge what your peers are planning and to share ideas and lessons learned. You will walk away with tangible ideas on how to solve your biggest challenges

Table 1 Implementing Usability and Human Factors Considerations into Development Cycles

Table 2 Achieving Effective Documentation Preparation

Table 3 Maximising Agile Developments Benefits

Table 4 Perfecting Application Security

Table 5 Perfecting Cloud Security

13:50 **Root Cause Analysis for Medical Devices – Effective & Compliant Approaches**

- Discover how to perform powerful Root Cause Analysis (RCA) on issues with (Software) Medical Devices (pre and post release)
- See how to ensure a compliant approach for use in e.g. CAPA, Complaint Investigations and Design Controls
- Learn to avoid the pitfalls of RCA to prevent recurrence of issues
- See the struggles in RCA in industry by looking at embarrassing but meaningful real-life examples of issues

Jan Van Moll, Head of Quality Management System, Audits & Compliance, Philips

14:30 **Large Scale Agile Transition With Off-Shore Partner Sites and Global Team Considerations**

- Take home key lessons for managing large and distributed teams for software projects across multiple sites
- Review lessons learned from software development processes at Siemens, and implement the best bits for your own processes
- Assess an overview of the process framework used and develop strategies for managing uncertainty

Adrian Gerhaeusser, Department Head Release Management, Digital Factory Division, Factory Automation, Siemens

15:40 Networking Coffee Break

Agile Development and the FDA in Medical Device Software Development: Insights from the Transition to Agile

- Hear key insights that will increase the likelihood of your transition to agile running smoothly
- Ensure you remain regulation compliant and inspection ready throughout your agile development cycle
- Discover new strategies that will speed up your development cycles and decrease your product's time to market

Cornelia Wiedenbrueg, Project Manager (SW), multisite Scaled Scrum, Sivantos

16:20 **Building Software of a Higher Quality**

Ask the Expert

- Meet regulations, improve device quality and reduce risk with medical device software of a higher quality
- Track defects and expose weaknesses in your software with expert insight on planning, coding, and testing
- Hear about 'extreme programming' and other innovative techniques that can speed up your development time without sacrificing quality

Nancy Von Schooenderwoert, President and Managing Partner Development Practice, Lean-Agile Partners

17:00 **Chairman's Closing Summary and End of Day 2**

POST-CONFERENCE AGILE TRAINING DAY
FRIDAY 24TH FEBRUARY 2016

Introduction to Agile Adoption for Regulated Medical Software: Business and Regulatory Impacts

The Agile approach is well established in other industries; adoption of Agile in medical device development has been increasing in the past five years. Experience is showing that both quality and safety are improved when the development team is agile, and that regulatory requirements can still be met. By walking through a safety critical project, Nancy Van Schooenderwoert and Brian Shoemaker will delve into several key areas for applying Agile in the medical device context, including:

* Countering the village rumors
* Understanding the REAL regulatory requirements
* Agile is a mindset, not a canned method
* Fitting together hardware and software development, and being Agile in both
* Applying Impact Mapping and Story Mapping practices to chart the way
* Bringing everyone on board, not just software
* Applying Agile to larger scale organizations / projects
* Metrics - how to use them and what to avoid

Rather than focusing on any methodology class (Scrum, Kanban, Crystal, XP), this course aims to build understanding of the fundamentals which underlie all methods, so that teams can determine their own blend based on what works in their context, and address the issues which inevitably come up in Agile adoption. Practical illustrations will be demonstrated by use of specific tools, but the tools themselves are not the focus.

Who should attend?

* Regulatory specialists
* Functional managers - Software, Test, Hardware
* Other development specialists (mechanical, engineering, other)
* Project managers (especially for cross-functional teams)
* Software Developers
* Business Analysts, requirements analysts
* Product managers
* Portfolio Managers

This will be an introductory course, and makes no assumptions about previous knowledge or experience with the Agile approach.

Facilitated by:
Brian Shoemaker, Principal Consultant, **ShoeBar Associates**

Brian Shoemaker consults for healthcareproducts companies in computer system validation, software quality assurance,and electronic records and signatures. Hehas conducted validation both on product software and on internal software, developedsoftware quality systems, audited software quality processes (including agilemethodology), and evaluated 21 CFR Part 11 compliance. He has had clients in clinical diagnostics,medical device engineering, medical imaging, medical-device fabricsmanufacturing, contract lyophilization, clinical trial software, dentalprosthetics, and bone-repair implants. Hehas worked with companies in Germany and Switzerland as well as the U.S. Previous to founding ShoeBar Associates,Brian had quality roles at PPD Informatics, Doxis, Inc., and Behring Diagnostics, Inc. Brian earned his Ph.D.in chemistry from the University of Illinois; he has achieved the ASQ Software Quality Engineer certification.

Nancy Van Schooenderwoert, Principal Consultant, **Lean Agile Partners**

Nancy Van Schooenderwoert does Agile Enterprise coaching— everything from launching new agile technical teams to advising executives on how to take Agile and Lean principles far beyond software development in their drive to deliver more customer value faster. She works with large and small companies. Nancy pioneered agile practices for embedded software development beginning in 1998. Her background in electronics and software development for avionics, factory automation, medical, and defense systems brings a unique perspective to her coaching practice. Nancy holds a Scrum Master certification, has edited a column for the Agile Times, and served on the IEEE 1648 committee to define a standard for customers of agile teams. She has been a regular presenter at various Agile-related conferences since 2003. Her work in applying Agile methods to embedded systems has been referenced by Jim Shore and Mary Poppendieck in their books. She is a founder and past president of Agile New England, Boston's largest Agile professional group.

SPONSORSHIP OPPORTUNITIES

MAXIMISE YOUR INVOLVEMENT: SPONSORSHIP AND EXHIBITION OPPORTUNITIES

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Pre-conference workshop day: 21st February 2017 | **Main Conference Dates:** 22nd – 23rd February 2017
Post-Conference Agile Training Day: 24th February 2017 - **Hilton, Munich City, Germany**

SPECIAL OFFER FOR ALL MEDICAL DEVICE MANUFACTURERS:
2-for-1 passes valid for the 3 day conference are available until 9th December 2016

Pass includes	4 Day Pass	3 Day Pass	2 Day Pass
Main Conference (22nd - 23rd February 2017)	✔	✔	✔
Access to conference presentations post-event via our B2B Shop at www.b2biq.com	✔	✔	✔
End of Day One Networking Dinner at Zum Franziskaner	✔	✔	✔
Access to Pre-Conference Workshop Day (21st February **	✔	✔	✘
Access to Post-Conference Agile Training Day (24th February **	✔	✘	✘
Package Options For Medical Device Manufacturers	**4 Day Pass** ☐	**3 Day Pass** ☐	**2 Day Pass** ☐
Register & Pay By 11th November 2016*	€3,899 + VAT SAVE €600	€3,199 + VAT SAVE €600	€2,099 + VAT SAVE €600
Register & Pay By 9th December 2016*	€4,099 + VAT SAVE €400	€3,399 + VAT SAVE €400	€2,299 + VAT SAVE €400
Register & Pay By 13th January 2017*	€4,299 + VAT SAVE €200	€3,599 + VAT SAVE €200	€2,499 + VAT SAVE €200
Standard Price	€4,499 + VAT	€3,799 + VAT	€2,699 + VAT
Solution Providers & Consultants - Conference Only	☐ **Price**		
Register & Pay By 9th December 2016*	€2699+VAT		
Conference Only - Standard Price	€2899+VAT		
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*All 'Early Bird' Discounts must 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

☐ **Please select either Pre-Conference Workshop Day or Post-Conference Agile Training Day

☐ German VAT is charged at 19%. VAT #: DE 261 1019 14

DELEGATE DETAILS - SIMPLY COMPLETE THIS FORM AND CLICK SUBMIT

Please photocopy for each additional delegate

☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Dr ☐ Other

First Name _____

Family Name _____ Job Title _____

Tel No. _____

Email _____

☐ Yes I would like to receive information about products and services via email

IQPC Point of contact _____

Organisation _____

Nature of business _____

Address _____

Postcode Country _____

Fax _____

Telephone _____

Approving Manager _____

Name of person completing form if different from delegate _____

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 ☐

_____

Exp. Date: _____ Sec: _____

Name On Card: _____

Billing Address (if different from above): _____

City/County/Postcode _____ Cheque enclosed for: € _____ (Made payable to IQPC Ltd.)

By Direct Transfer: IQPC Bank Details: HSBC Bank, 67 George Street, Richmond, Surrey, TW9 1HG
Account name: IQPC Ltd Bank: HSBC Account number: 59090618 Sort code: 40 05 15
IBAN: GB98MIDL40051559090618 SWIFT: MIDLGB22
Ref: Please include name of the attendee(s) and the conference code 19409.007

CONFERENCE CODE: 19409.007

4 WAYS TO REGISTER

PHONE:
+44 (0) 207 368 9300

EMAIL:
ENQUIRE@IQPC.CO.UK

POST:
RETURN YOUR BOOKING FORM TO:
IQPC LTD, 129 WILTON RD
LONDON, SW1V 1JZ

WEB:
WWW.SDMDEUROPE.COM

TEAM DISCOUNTS*

IQPC recognises the value of learning in teams.
Team of 4 - **10%** on any ticket
Team of 7 - **15%** on any ticket
Team of 10 - **30%** on any ticket
Only one discount available per person. Team discounts are not applicable in conjunction with another discount.

VENUE & ACCOMMODATION

Venue: Hilton, Munich City, Germany

Travel and accommodation are not included in the conference fee.

Please note: IQPC will never recommend, approve or appoint any third party rooming service to act on our behalf. Please be extremely wary if you are approached by any such companies. We will always endeavour to negotiate the best available rates for you so please use the Hotel´s website link provided

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 (plus 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. Conference Material 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