WHY? SUMMITS

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Featuring conferences: 2

European Med-Tech Summit Berlin

June 13 - 14

Project and Portfolio Management Conference

June 13 - 14

Medical Device Safety and Compliance Conference

Strategic partner Planisware

Silver partner smartsheet

Why attend this exclusive joint 2 day-long event?

We are creating an extraordinary event where we are bringing together two very expected conferences – Project and Portfolio Management Conference and Medical Device Safety and Compliance Conference. Both of these under one roof in the beautiful Berlin.

These two conferences are here to offer you a 2 day-long event full of interesting and burning topics with more than 40+ speakers and their keynotes, case studies and hot panel and roundtable discussions. We will all together create a friendly environment for discussing troubling issues and offering a safe space for stimulating, inspiring, and fruitful discussions about current trends and challenges in the field of medical device safety and compliance and in the field of project and portfolio management.

It is a wonderful opportunity for all professionals from the MedTech Industry to come together at this highly professional event where you can present the latest results of your work or knowledge to a wider professional public from the same field – there is so much learning and connecting to be done!

Our mission

... is to bring together relevant experts from the Medical Device field to present and discuss the latest developments and trends in medical device safety management, compliance, regulations along with all the project and portfolio objections. The main aim is to identify key challenges facing the area and shed light on the best strategies and solutions to overcome these challenges.

Our vision

… is to build a unique platform for sharing insightful ideas and experiences and to set good examples for coping with new challenges to constantly improve the quality of work delivered to the end customer - to the patient.

Our conference will feature numerous assisted networking sessions which will help you to create those critical business friendships needed for fruitful cooperation with professionals from the industry for many years to come. We believe that our thoughtfully planned conference will fill in any missing pieces in your plans on the mission to deliver your projects faster, more efficiently and with ease and satisfaction.

What to expect?

- 2 day-long conference filled with the TOP industry speakers
- Interesting Keynotes, Case Studies and Panel Discussions
- Workshops and Roundtables for a deeper dive into important topics in the MedTech industry now
- Creative and inspiring platform for fruitful discussion
- Sharing new ideas and building strong connections
- The friendly and highly stimulating atmosphere in a smaller circle (around 150 attendees per conference)
- Fun and icebreaking social events every evening with delegates, speakers and sponsors of the event

Key Topics
Project and Portfolio Management Conference

- Demonstrating and Increasing the value of the PMO
- Medical Device Quality & Resource Management for PPMs
- Stakeholders management
- Importance of soft skills for PPMs
- Regulatory dynamics and new standards
- Impact of the MDR on organisations
- Rationalisation of portfolio in times of uncertainty
- Cultural change in organisation
- Hybrid project management and adoption for business agility
- Bolstering Project Prioritization - tips for bringing objectivity to the process
- How can AI and data analytics help PM
- Importance of Cybersecurity in Medical Device projects

… and more!

Key Topics
Medical Device Safety and Compliance Conference

- Challenges of Dynamic Regulatory Landscape
- Medical Device Safety and Security
- Quality Management and Compliance
- Startups and Innovations
- ISO 14971 Regulations and Standards
- Quality Management
- Quality and Innovative Medical Devices
- Safety Risk Management
- Cybersecurity
- Medical Device Vigilance Process
- Monitoring and Reporting
- Post-market Surveillance
- New Era of Tech and Data

... and more!

In the Chair

Project and Portfolio Management Conference

Paul Gebauer

Senior Director, Head of Global Portfolio Marketing, Connected Care
Philips Healthcare

Medical Device Safety and Compliance Conference

Ariana Adjani

Co-Founder
Fine Treatment

Medical Device Safety and Compliance Conference

Fatima Bennai-Sanfourche

Senior Director of QA & RA Compliance for Medical Devices and eHealth
Bayer

Speakers and Panelists

Anthony Sichra
Senior PMO Manager
Business Transformation Program
Philips

Benjamin Rochette
Vice President, Global Regulatory Affairs
Coloplast

Carsten Mahrenholz
Founder & CEO
COLDPLASMATECH

Daniela Dougal
Project Manager, EMEA
Cochlear Deutschland

Daniel Cho
Head of Strategic Pricing Centre of Excellence
Philips Healthcare

Ercan Arslan
General Manager
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Herbert Mauch
Director Clinical Operations EMEA
Cochlear

Jack Featherstone
Solutions Engineer
Smartsheet

John Dolan
PMO Site Lead (Operations)
Boston Scientific

Laurence Kerans
Regional Director, Large Enterprise - DACH
Smartsheet

Massimo Kubon
Deputy Dean of Studies, Medical Engineering, Clinical Technologies
Furtwangen University

Nico Lange
Cybersecurity Solutions Architect
Ottobock

Nicola Travierso
President
VELIT BIOPHARMA

Noel Sobelman
Partner
Accel Management Group

Souria Zeroual
Senior Program Manager, Global PMO BSH (Breast and Skeletal Health)
Hologic

In the Chair

Paul Gebauer
Senior Director, Head of Global Portfolio Marketing, Connected Care, Philips Healthcare

Surinder Dhillon
Commercial PMO Lead
Hologic

Svenja Merle
Project/Program Director
B. Braun

Tim Rumbaugh
Sr. Director, Program Management
Edwards Lifesciences

Speakers and Panelists

Ana Mendonça
Sr. Vigilance Process Manager
Novartis

In the Chair

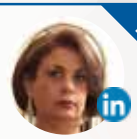
Ariana Adjani
Co-Founder
Fine Treatment

Arite Wildau
Director Patient Safety
BIOTRONIK

Crystal D'Silva
Manager (Preclinical Toxicology - Quality)
Baxter

Daniel Kvak
CEO
Carebot

Dardan Uka
Global PMS and Implants/ Instruments Vigilance Manager
Corin

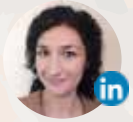


In the Chair

Fatima Bennai-Sanfourche
Senior Director of QA & RA Compliance for Medical Devices and eHealth
Bayer

Heinrich Martens
Vice President Regulatory Affairs
Fresenius Kabi

Ida Søholm
Senior Project Manager, Regulatory Affairs – Software
3Shape



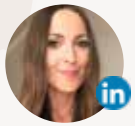
Lea Caramma
Senior Post Market Surveillance Specialist
Limacorporate

Leo Hovestadt
Director Governmental Affairs EU
Elekta

Leon Doorn
Head of Regulatory Compliance, Aidence

María José Lopez
Sr. Manager Quality Compliance
Edwards Lifesciences

Maurizio Zaccheddu
Senior Quality Assurance Manager
Sonova



Mette Luxhøj
Head of Regulatory Affairs, Software
3Shape

Per Maegaard
Director
MQC

Renea Schønemann Olsen
Senior Post-Market Surveillance Manager, Scientific Affairs
3shape

Talia Milosevic
Senior Manager, Clinical Safety, Surgical Structural Heart
Edwards Lifesciences

Thomas Mehler
Global Quality Director Product Supply Medical
Essity

Agenda

5.30pm

Night before the event - Meet & Greet

Welcome to our event! We are so honored and grateful to have you with us!

Come and join us for some drinks, where you will be able to do an early bird registration along with some first hand networking! All the delegates will start arriving and we will all have a chance to get to know one another - the sooner the better. Drinks, conversations, hand shakes, smiles, hugs, whether with your old or new friends from the industry - everyone is welcome!

Day1

EVER CHANGING REGULATORY ENVIRONMENT

8:30am **KEYNOTE::** TOP BUSINESS CHALLENGE OF MEDICAL DEVICE MANUFACTURERS? : EVER CHANGING REGULATORY ENVIRONMENTS

The session will give an overlook of recent changes in the regulatory framework ensuring safe and effective use of medical devices for patients and users as a crucial responsibility for manufacturers and developers.

Recent developments in Europe and the US show that this trend will continue for industry. The European Medical Devices Regulation (MDR), introduces major changes to CE Marking, clinical data and related requirements, necessitating ongoing transition efforts by manufacturers. And in the US, the Food and Drug Administration also introduces significant overhaul of its 510(k) premarket notification program which results in more rigorous premarket device reviews and clinical data requirements for more types of devices.

Leo Hovestadt, *Director Governmental Affairs EU,* **Elekta**

9:00am **RESERVED PRESENTATION: USING TECHNOLOGY TO ADDRESS THE NEED FOR SPEED AND COMPLIANCE**

Leaders are being asked to get products to market as quickly as possible— while ensuring quality and regulatory compliance at every step of the way. How have companies moved from archaic tools and processes like spreadsheets and email to empowered teams who more efficiently manage projects, processes and resources, driving innovation at scale and providing real-time visibility across the portfolio to drive better patient outcomes?
Learn how Roche and Philips to do just that and transformed how they worked to drive innovation and results.

Laurence Kerans, *Regional Director, Large Enterprise - DACH,* **Smartsheet**

9:30am **PANEL DISCUSSION:** HANDLING QUALITY MANAGEMENT AND COMPLIANCE IN INNOVATIVE STARTUPS AND SMEs

In This Panel discussion innovative start-ups will share their experience in complying to regulation and staying innovative

- Ensuring Highest Quality Devices while Encouraging innovation
- Start-up dilemma of choosing between quality and innovation
- Constant struggle of the Quality/regulatory department with the R&D department and investors
- How taking short-cuts can actually delays in the long-run in obtaining regulatory approvals

Leo Hovestadt, *Director Governmental Affairs EU,* **Elekta**
Ida Søholm, *Senior Project Manager, Regulatory Affairs – Software,* **3Shape**
Daniel Kvak, *CEO,* **Carebot**
Ariana Adjani, *Co-Founder,* **Fine Treatment**
Carsten Mahrenholz, *Founder & CEO,* **COLDPLASMATECH**

10:00am **NETWORKING BREAK**

10:30am **KEYNOTE:** INNOVATION OF AI MEDICAL DEVICES IN A REGULATORY CONTEXT

- What are the current trends for AI medical devices?
- How to balance medical device innovation within the emerging AI legal framework?
- How can manufacturers ensure compliant documentation for AI medical devices?

Mette Luxhøj, *Head of Regulatory Affairs, Software,* **3Shape**
Ida Søholm, *Senior Project Manager, Regulatory Affairs – Software,* **3Shape**

Day1

11:00am **KEYNOTE:** THE REGULATORY DYNAMICS IN PROJECT MANAGEMENT

Bringing new medical devices from idea to launch requires project teams to build nimble regulatory strategies that articulate the regulatory environment with the commercial ambition and the R&D journey. The complexity of the evolving regulatory landscape often translates into ambiguity on possible pathways and risks, notably in terms of time to market and financial viability. This presentation will cover how to approach regulatory inputs in a dynamic way throughout the project lifecycle via milestone-based regulatory strategies and spot-on interactions with regulatory authorities at the right time.

Benjamin Rochette, *Vice President, Global Regulatory Affairs,* **Coloplast**

11:30am **PANEL DISCUSSION:** MDR - INTERNAL IMPACT ON ORGANIZATION

- What resources are necessary to compete in the market following the MDR
- Risks and opportunities for the product portfolio
- Territorial implementation of the new MDR
- Analysis of existing products and investment to upgrade documentation with new studies to comply with the new MDR

Nicola Travierso, *President,* **VELIT BIOPHARMA**
Benjamin Rochette, *Vice President, Global Regulatory Affairs,* **Coloplast**
Mette Luxhøj, *Head of Regulatory Affairs, Software,* **3Shape**
Leon Doorn, *Head of Regulatory Compliance,* **Aidence**

12:00pm **LUNCH BREAK**

Project and Portfolio Management Conference Day1

DEVELOPING SUCCESSFUL PORTFOLIO & CRITICAL SUCCESS FACTORS

1:00pm **PANEL DISCUSSION:** EVOLUTION OF PMO and PORTFOLIO FUNCTION

Maturity of the PMO in your organisation might be different. Project Managers working on their individual projects in medical device companies face new requirements when the PMO function is evolving.

Listen to this panel discussion to benchmark the role of Project Managers in both, early stages of PMO and mature PMO function. Challenges, methodologies and approaches to value creation topics will be discussed.

John Dolan, *PMO Site Lead (Operations),* **Boston Scientific**
Anthony Sichra, *Senior PMO Manager, Business Transformation Program,* **Philips**
Tim Rumbaugh, *Sr. Director, Program Management,* **Edwards Lifesciences**
Surinder Dhillon, *Head of Commercial PMO, International,* **Hologic**
Souria Zeroual, *Senior Program Manager, Global PMO BSH (Breast and Skeletal Health),* **Hologic**
Noel Sobelman, *Partner,* **Accel Management Group**

1:30pm **KEYNOTE:** HOW TO FOCUS ON DEVELOPING PORTFOLIO OF SOLUTIONS THAT GENERATE VALUE FOR OUR CUSTOMERS, WHAT PITFALLS SHOULD WE AVOID?

In this keynote Daniel Cho will explain the following points:

1) Philips approach to Value Based Pricing and Selling.

2) How to translate features into benefits and customer values?

3) What are our experiences throughout our journey to become a value based solution company?

4) What are the potential pitfalls, and how to avoid them?

Daniel Cho, *Head of Strategic Pricing Centre of Excellence,* **Philips Healthcare**

Medical Device Safety and Compliance Conference Day1

RISK MANAGEMENT AS KEY MANAGEMENT TOOL IN EVER CHANGING ENVIRONMENT

1:00pm **CASE STUDY:** RISK MEASUREMENT TOOLS AND METHOD ASSESSING EFFECTIVENESS OF RISK MANAGEMENT PLANS

Medical Device Manufacturers can manage and reduce risk more effectively by including risk thinking as early as possible in device or process development and revisiting those issues systematically throughout the development process.

Risk Management has become an important competitive tool to gain access to foreign markets. Risk management is necessary to ensure device usability, safety, and regulatory compliance.

- Development of optimal risk management strategy, what risks to mitigate with routine vs additional risk minimisation measures
- How to develop risk minimisation measures that are adequate, balanced, and feasible, and do not create an undue burden to the healthcare system
- How to implement and evaluate risk minimisation measures globally
- Recognizing that the evaluation of the effectiveness of risk minimisation measures is an evolving area of medical sciences with a need for further development of methods and harmonised approaches
- How to identify primary tools for measuring effectiveness of risk minimisation, criteria for when (and how deeply) to assess effectiveness of risk minimisation measures and how to define what constitutes success in risk minimisation

Leon Doorn, *Head of Regulatory Compliance,* **Aidence**

Project and Portfolio Management Conference — Day1

2:00pm **PANEL DISCUSSION:** BRINGING VALUE TO CUSTOMERS, COMPANIES & STAKEHOLDERS - HOW TO STAY AHEAD FROM COMPETITION
Paul Gebauer, *Senior Director, Head of Global Portfolio Marketing, Connected Care,* **Philips Healthcare**
Daniel Cho, *Head of Strategic Pricing Centre of Excellence,* **Philips Healthcare**
Carsten Mahrenholz, *Founder & CEO,* **COLDPLASMATECH**

2:30pm **KEYNOTE:** REVOLUTIONIZING MEDTECH: NAVIGATING THE PATH FROM INNOVATION TO MARKET PENETRATION
Listen to this insightful session on revolutionizing the MedTech industry through innovative product development and successful market entry strategies. Our esteemed speaker will share their first-hand experience in developing a groundbreaking class 2b medical device, from its inception to achieving certification as a medical product. Discover how they transformed the existing system and business model, transitioning from product sales to establishing 40 Plasma Competence Centers across Germany. Learn about the challenges faced in maintaining market presence amidst a healthcare system that prioritizes patient treatment over long-term healing. Gain valuable insights into navigating regulatory hurdles, fostering partnerships, and ensuring sustainable success in the ever-evolving MedTech landscape.
Carsten Mahrenholz, *Founder & CEO,* **COLDPLASMATECH**

Medical Device Safety and Compliance Conference — Day1

1:30pm **CASE STUDY:** INNOVATIVE PRODUCT DESIGN - HOW TO IMPLEMENT RISK MANAGEMENT FROM THE START OF THE DESIGN TO AVOID LATER PITFALLS
Ariana Adjani, *Co-Founder,* **Fine Treatment**

2:00pm **WORKSHOP (60 MIN):** BIOLOGICAL RISK ASSESSMENT - LESSONS LEARNT FROM EU MDR SUBMISSIONS
- Overview of biological risk assessment process for medical devices
- Biological safety evaluation requirements for EU MDR
- Case study – biological risk assessment of an Acute Therapies device
- Lessons learned from notifying body feedback for successfully completed submissions

Crystal D'Silva, *Manager (Preclinical Toxicology - Quality),* **Baxter**

3:00pm **NETWORKING BREAK**

3:30pm **ROUNDTABLE DISCUSSIONS (3:30 - 4:30PM)**
Join roundtable discussions with our speakers and engage in discussions on trending topics moderated by industry experts.. Each delegate can choose to attend 2 discussions (see the topics on next page)

Roundtable Discussions

Day1

ALL ROUNDTABLE DISCUSSION TOPICS ARE TO RUN SIMULTANEOUSLY TWICE IN A ROW, SO EACH DELEGATE CAN CHOOSE TO ATTEND 2 ROUNDTABLE DISCUSSIONS.

ROUNDTABLE 1: HYBRID PROJECT MANAGEMENT AND ADAPTATION OF ORGANISATION WITH BUSINESS AGILITY
Surinder Dhillon, *Head of Commercial PMO,* **International, Hologic**
Souria Zeroual, *Senior Program Manager, Global PMO BSH (Breast and Skeletal Health),* **Hologic**

ROUNDTABLE 2: REGULATORY AFFAIRS DEVELOPMENT - REQUIREMENTS AND CHALLENGES
Benjamin Rochette, *Vice President, Global Regulatory Affairs,* **Coloplast**

ROUNDTABLE 3: PORTFOLIO MANAGEMENT - HOW TO MANAGE A WIDE RANGE OF PROJECTS AT ONCE
Herbert Mauch, *Director Clinical Operations EMEA,* **Cochlear**

ROUNDTABLE 4: PROJECT MANAGEMENT METHODOLOGIES FOR START-UPS
Ercan Arslan, *General Manager,* **Body Products**
Massimo Kubon, *Deputy Dean of Studies, Medical Engineering, Clinical Technologies,* **Furtwangen University**

ROUNDTABLE 5: BUILDING BENCH STRENGTH FOR A PMO
Noel Sobelman, *Partner,* **Accel Management Group**

ROUNDTABLE 6 : BOLSTERING PROJECT PRIORITISATION THROUGH DIFFERENT METHODS OF ASSESSING WHAT IS MOST CRUCIAL
John Dolan, *PMO Site Lead (Operations),* **Boston Scientific**

Roundtable Discussions

Day1

ALL ROUNDTABLE DISCUSSION TOPICS ARE TO RUN SIMULTANEOUSLY TWICE IN A ROW, SO EACH DELEGATE CAN CHOOSE TO ATTEND 2 ROUNDTABLE DISCUSSIONS.

ROUNDTABLE 1: MANAGING POST MARKET AND CLINICAL STUDIES WITH REQUIREMENTS OF ISO 14155 AND MDR TO REMAIN IN COMPLIANCE
Talia Milosevic, *Senior Manager, Clinical Safety, Surgical Structural Heart,* **Edwards Lifesciences**

ROUNDTABLE 2: DEMONSTRATING GOOD MANUFACTURING PRACTICES THROUGH GUIDANCE OF ISO 13485 FOR DEVICE QUALITY AND CONSISTENCY
Leon Doorn, *Head of Regulatory Compliance,* **Aidence**

ROUNDTABLE3: CONTROLLING RISK AND BIOLOGICAL SAFETY AT THE MANUFACTURING LEVEL TO CONFORM TO GUIDANCE UNDER ISO 10993
Crystal D'Silva, *Manager (Preclinical Toxicology - Quality),* **Baxter**

ROUNDTABLE 4: SAFETY RISK MANAGEMENT IN THE WORLD OF ENHANCED CYBERSECURITY
Mette Luxhøj, *Head of Regulatory Affairs, Software,* **3Shape**

ROUNDTABLE 5: SOCIAL MEDIA DATA COLLECTION – NEW SOURCE OF INFORMATION AND HOW TO ASSESS THEM
Renea Schønemann Olsen, *Senior Post-Market Surveillance Manager, Scientific Affairs,* **3shape**

RATIONALISATION, PRIORITISATION AND CAPACITY PLANNING OF PORTFOLIO

8:30am **KEYNOTE:** PORTFOLIO RATIONALISATION DURING AN ECONOMIC DOWNTURN

As market uncertainty continues and economic recession appears likely, corporate leaders are rethinking their innovation portfolio objectives. In this session, Noel Sobelman will provide some practical tips to right size your innovation portfolio and improve R&D productivity.

Noel Sobelman, *Partner,* **Accel Management Group**

9:00am **PANEL DISCUSSION:** PRIORITISATION OF PORTFOLIO

Given the common constraints of limited budget and finite resources, prioritisation will help decision makers to decide: - not a bullet point

- Which initiatives should we invest in?
- Which initiatives are more important than others?
- What initiatives should get priority access to resources?

Noel Sobelman, *Partner,* **Accel Management Group**
Svenja Merle, *Project/Program Director,* **B. Braun**
John Dolan, *PMO Site Lead (Operations),* **Boston Scientific**

9:30am **RESERVED PRESENTATION: HOW TECHNOLOGY CAN DRIVE PERFORMANCE**

Smartsheet connects strategy to work by empowering anyone to build and scale projects efficiently. Plan, align, implement, and scale projects, programs, and portfolios to deliver results faster. Work with flexibility and security—from small projects to large-scale processes and entire portfolios. Learn how Smartsheet helps to transform how teams manage projects, processes and resources and drive innovations at scale.

Jack Featherstone, *Solutions Engineer,* **Smartsheet**

10:00am **NETWORKING BREAK**

PROJECT RISK & RESOURCE MANAGEMENT IN MEDICAL DEVICES

10:30am **KEYNOTE:** PROJECT RISK MANAGEMENT - THE RISK OF WHAT?

No matter the product, service, industry, company, culture, or location, project risk management every project has one thing in common - the potential to fail or succeed.

- Based on years of research, we will walk through a simple framework that reveals the root causes of both failure and success
- We will view a project as a system and how that both helps and hinders our ability to mitigate risk
- Be able to assess your own risk management mindset and whether you are truly connecting all of the dots

Tim Rumbaugh, *Sr. Director, Program Management,* **Edwards Lifesciences**

BUILDING STRONG QUALITY MANAGEMENT SYSTEMS AS KEY COMPETITIVE TOOL

8:30am **KEYNOTE:** HOW TO EFFECTIVELY PREPARE FOR EXTERNAL AUDITS ENSURING INSPECTION READINESS

Managing external regulatory audits and inspections is challenging for quality management professionals as they must remain abreast of increasingly stringent regulations and implement timely changes. To ensure the audit proceeds smoothly, quality management professionals must prepare before regulatory inspections or audits by conducting internal audits at planned intervals to ensure the QMS conforms to international standards. This session will highlight how to utilize the internal audit process to prepare for notified body and third-party inspection. Through this session, attendees will also gain insights on how to ensure audit readiness by identifying areas of deficiency and appropriate team and leadership for the audit.

Thomas Mehler, *Global Quality Director*

9:00am **PANEL DISCUSSION:** QUALITY MANAGEMENT AND COMPLIANCE – COMPLYING TO QUALITY SYSTEM REGULATIONS AROUND THE WORLD

Our expert panelists have unparalleled experience and knowledge in every aspect of medical device development and approval in the EU, US, and other regions of the world.

We will discuss the most common pitfalls you can experience in complying to different safety regulations around the world to bring your medical device products into desired markets.

Maurizio Zaccheddu, *Senior Quality Assurance Manager,* **Sonova**
Leon Doorn, *Head of Regulatory Compliance,* **Aidence**
Thomas Mehler, *Global Quality Director Product Supply Medical,* **Essity**
Per Maegaard, *Director,* **MQC**
María José Lopez, *Sr. Manager Quality Compliance,* **Edwards Lifesciences**

BUILDING EFFECTIVE VIGILANCE PROCESS

9:30am **KEYNOTE:** BUILDING YOUR MEDICAL DEVICE VIGILANCE PROGRAM

- Device Vigilance Project Management
- Collection and Follow-up of Medical Device Incidents
- Electronic Management of Incidents
- Expedited Reporting of Medical Device Incidents to Competent Authorities
- Distribution of Field Safety Corrective Actions and Field Safety Notices

Arite Wildau, *Director Patient Safety,* **BIOTRONIK**

10:00am **NETWORKING BREAK**

10:30am **PANEL DISCUSSION:** BUILDING EFFECTIVE PROCESS FOR MONITORING OF ADVERSE EVENTS, COMPLAINT PROCESSING AND STREAMLINE THEIR REPORTING

Our expert panelists will share their best practice of operational excellence to build effective vigilance processes to avoid costly recalls and warnings from regulatory agencies.

Talia Milosevic, *Senior Manager, Clinical Safety, Surgical Structural Heart,* **Edwards Lifesciences**
Arite Wildau, *Director Patient Safety,* **BIOTRONIK**
Lea Caramma, *Senior Post Market Surveillance Specialist,* **Limacorporate**
Per Maegaard, *Director,* **MQC**
María José Lopez, *Sr. Manager Quality Compliance,* **Edwards Lifesciences**

11:00am **PANEL DISCUSSION:** RESOURCE MANAGEMENT OF PPM ON PROJECTS IN MEDICAL DEVICE COMPANIES

Effective resource management can mean the difference between success and failure. How to stay effective when transiting from a smaller to large-scale company.

- What is the role of the PM in resource management?
- What does flexibility mean in resource management?

HerbertMauch, *Director Clinical Operations EMEA,* **Cochlear**
Nicola Travierso, *President,* **VELIT BIOPHARMA**
Tim Rumbaugh, *Sr. Director, Program Management,* **Edwards Lifesciences**

11:30am **KEYNOTE:** PROJECT MANAGEMENT FOR MEDICAL ENGINEERING STUDENTS: WHO ARE WE DEALING WITH IN THE FUTURE?

- Educational content for project managers with focus on the Medtech industry
- Special skills needed when becoming a "Medtech Project Manager"
- The chances with Gen Z and beyond.

Massimo Kubon, *Deputy Dean of Studies,* **Medical Engineering, Clinical Technologies, Furtwangen University**

12:00pm **LUNCH BREAK**

SOFT SKILLS – PM´S BIGGEST WEAPON OR WEAKNESS?

1:00pm **KEYNOTE FOLLOWED BY A PANEL DISCUSSION:** WHAT KIND OF (SOFT) SKILLS ARE NEEDED TO MANAGE YOUR STAKEHOLDERS?

While tools and technologies change, one of the most impactful skills to master is how you apply and hone your own soft skills, making sure they work for you, and not against you at work. Surinder Dhillon will discuss the value of these skills to engage and build relationships fast with new teams and stakeholders, helping you influence effectively, while noting there are additional considerations when you switch teams and environments.

You will likely reflect on your own experiences on where things worked out well (or didn't) in the past – where you may have found people being "difficult", or resistant to your messages. You will leave with a broader appreciation of how you could approach things differently next time, and why there is nothing soft about soft skills.

Key takeaways:

- How to establish a well-functioning connection and credibility fast and lead SME´s to deliver
- Why the connection is a crucial and means the difference between swimming or sinking in challenging environments
- Rules to follow when applying soft skills: 1) Communication, 2) Setting Expectations, 3) Taking care of your Stakeholders

Presenter:
Surinder Dhillon, *Head of Commercial PMO, International,* **Hologic**
Panelists:
Surinder Dhillon, *Head of Commercial PMO, International,* **Hologic**
Daniela Dougal, *Project Manager, EMEA,* **Cochlear Deutschland**
Tim Rumbaugh, *Sr. Director, Program Management,* **Edwards Lifesciences**
Massimo Kubon, *Deputy Dean of Studies, Medical Engineering, Clinical Technologies,* **Furtwangen University**

11:00am **KEYNOTE:** IMPLEMENTING VIGILANCE & PMS SYSTEMS FOR DRUG-DEVICE COMBINATION PRODUCTS (DDCs)

- Regulatory framework for DDCs
- Vigilance Process and Systems: Best Practices
- Challenges of Post-Market Surveillance for DDCs
- DDC & Software: a new paradigm for proactive PMS

Ana Mendonça, *Sr. Vigilance Process Manager,* **Novartis**

COMPLYING TO POST MARKET SURVEILLANCE REGULATIONS

11:30am **CASE STUDY:** Creating a fit-for-purpose Post-Market Surveillance (PMS) system

- Understanding the new requirements for PMS under MDR
- Creation of a system that meets company needs beyond the scope of regulatory requirements
- Discussion of the value of PMCF studies in PMS
- Addressing the challenges facing PMS in the current regulatory landscape

Dardan Uka, *Global PMS and Implants/Instruments Vigilance Manager,* **Corin**

12:00pm **LUNCH BREAK**

1:00pm **CASE STUDY:** STRENGTHENING POST MARKET CLINICAL FOLLOW-UP (PMCF) STUDIES – IDENTIFYING REQUIREMENTS

- Discovering how EU MDR changes requirements of PMCF
- Establishing understanding of PMCF Requirements under MDD
- Identifying important considerations with PMCF studies
- Use of PMS- and PMCF-Data to support MDR Claims

Heinrich Martens, *Vice President Regulatory Affairs,* **Fresenius Kabi**

1:30pm **PANEL DISCUSSION:** DEFINING RELATIONSHIP BETWEEN POST MARKET SURVEILLANCE AND HOW IT INTERSECTS WITH RISK MANAGEMENT

- Taking measure of risk assessment for each complaint, including risk identification and mitigation
- Identifying how newly uncovered risks leads to record management document updates
- Defining the relationship between post market surveillance and how it intersects with risk management
- Assessing risk level based on complaint data

Heinrich Martens, *Vice President Regulatory Affairs,* **Fresenius Kabi**
Dardan Uka, *Global PMS and Implants/Instruments Vigilance Manager,* **Corin**
Maurizio Zaccheddu, *Senior Quality Assurance Manager,* **Sonova**
Mette Luxhøj, *Head of Regulatory Affairs, Software,* **3Shape**
Fatima Bennai-Sanfourche, *Senior Director of QA & RA Compliance for Medical Devices and eHealth,* **Bayer**
Ariana Adjani, *Co-Founder,* **Fine Treatment**

Project and Portfolio Management Conference

Day2

2:00pm **KEYNOTE:** INCREASING PROJECT SUCCESS BY MANAGING COMPLEXITY

- Defining successful project beyond the traditional criteria
- Dynamic and Adaptive Leadership approach to manage complexity
- Practical ways how deal with complexity in strategic projects - based on real examples

Anthony Sichra, *Senior PMO Manager, Business Transformation Program,* **Philips**

2:30pm **KEYNOTE:** HOW MUCH PROJECT MANAGEMENT CAN BE DONE BY AI - AND WILL IT REPLACE PROJECT MANAGERS

In this session Svenja Merle will talk about:

How do software solutions help project and portfolio management?

1. How to stay on track with the increasing amount of data digital tools provide us?
2. The future role of project management

Svenja Merle, *Project/Program Director,* **B. Braun**

Medical Device Safety and Compliance Conference

Day2

2:00pm **CASE STUDY:** VOLUNTARY RECALLS

Hear interesting and informative stories about crisis communication in medical devices recall. Session is focused on what actions should companies take, and those actions need to be taken fast. Learn from best experience how to avoid mistakes.

María José Lopez, *Sr. Manager Quality Compliance,* **Edwards Lifesciences**

2:30pm **PANEL DISCUSSION:** ANALYSING THE VALIDITY FOR RWE SUPPORT TO CLINICAL AND POST MARKET EVALUATIONS

- Analysing different approaches to avoid invalidation of RWE output data
- Utilising RWE in supporting clinical evaluation and market authorization in other countries
- Incorporating RWE into risk assessments
- Deciding how to incorporate RWE post market feedback into your risk management

Leo Hovestadt, *Director Governmental Affairs EU,* **Elekta**

Renea Schønemann Olsen, *Senior Post-Market Surveillance Manager, Scientific Affairs,* **3shape**

Fatima Bennai-Sanfourche, *Senior Director of QA & RA Compliance for Medical Devices and eHealth,* **Bayer**

Per Maegaard, *Director,* **MQC**

3:00pm **NETWORKING BREAK**

3:30pm **WORKSHOPS & ROUNDTABLES**

Join roundtable discussions or workshops with our speakers and engage in discussions on trending topics moderated by industry experts. Each delegate can choose to attend 2 discussions or 1 workshop (see the topics on next page)

4:30pm **THAT´S A WRAP**

Roundtable Discussions

Day2

ALL ROUNDTABLE DISCUSSION TOPICS ARE TO RUN SIMULTANEOUSLY TWICE IN A ROW, SO EACH DELEGATE CAN CHOOSE TO ATTEND 2 ROUNDTABLE DISCUSSIONS.

ROUNDTABLE 1: SUCCESSFUL TEAMS - HOW TO MANAGE EVERYONE´S REQUEST
Svenja Merle, *Project/Program Director,* **B. Braun**

ROUNDTABLE 2: IMPORTANCE OF CYBERSECURITY IN MEDICAL DEVICE PROJECTS
Nico Lange, *Cybersecurity Solutions Architect,* **Ottobock**

WORKSHOP: CULTURAL CHANGE IN ORGANISATION - HOW NOT TO FEAR TO FAIL IN AGILE PROJECTS.
In this workshop you will learn about corporate culture and it will help you answer the questions about how to initiate a cultural shift, which culture fosters the agile mindset and how and provide you with some models, experiments and blue prints to try out.
Daniela Dougal, *Project Manager, EMEA,* **Cochlear Deutschland**

Q&A Roundtables

Day2

ASK US ANYTHING! - DISCUSSION WITH DAY TWO SPEAKERS

Speakers from day 2 will each host a roundtable discussion to answer your questions!

2023 World Tour at a Glance

Project & Portfolio Management

1. March 14 - 15, Munich, Germany
   Global Project Management, Portfolio Planning and Partnerships for Generics
2. March 22 - 23, Basel, Switzerland
   23rd European Pharma and Biotech Project, Program and Portfolio Management Conference
3. April 19 - 20, London, UK
   22nd European Pharma and Biotech Project, Program and Portfolio Management Conference
4. April 25 - 26, Philadelphia, PA, United States
   18th American Pharma and Biotech Project, Program and Portfolio Management Conference
5. June 13 - 14, Berlin, Germany
   European Medical Device Project & Portfolio Management Conference
6. June 13 - 14, North Bethesda, USA
   American Drug Developers' Project, Program and Portfolio Management Conference
7. June 22 - 23, Mumbai, India
   Strategic Project, Program, and Portfolio Management Conference for Pharmaceuticals
8. September 5 - 6, Singapore
   APAC Strategic Project, Program and Portfolio Management Conference for Pharmaceuticals
9. October 4 - 5, Chicago, IL, United States
   American Medical Device Project & Portfolio Management Conference
10. October 18 - 19, Basel, Switzerland
    24th European Pharma and Biotech Project, Program and Portfolio Management Conference
11. October 26 - 27 Boston, MA, United States
    19th American Pharma and Biotech Project, Program and Portfolio Management Conference
12. November 16 - 17 San Francisco, CA, United States
    20th American Pharma and Biotech Project, Program and Portfolio Management Conference
13. December 5 - 6, London, UK
    24th European Pharma and Biotech Project, Program and Portfolio

Pharmacovigilance & Device Safety

1. March 8 - 9 London, UK
   8th Global Pharmacovigilance Forum
2. June 13 - 14 Berlin, Germany
   European Medical Device Safety & Compliance Conference
3. September 13 - 14 Philadelphia, PA, United States
   American Pharma and Biotech Advancements in Drug Safety Summit
4. October 4 - 5 Chicago, IL, United States
   American Medical Device Safety Management Conference
5. November 16 - 17 San Francisco, CA, United States
   17th American Drug Safety Biotech & Pharma Conference
6. November 29 - 30 Basel, Switzerland
   10th Annual European Drug Safety Pharma & Biotech Conference
7. January 18 -19 Mumbai, India
   Global Drug Safety & PV Outsourcing Summit
8. spring 2024 London, United Kingdom
   9th Global Drug Safety & RWE Forum

Sponsorship

Exhibiting

With a large and senior audience and decision makers, thoroughly selected, exhibiting at any Summit at 2023 FoP SUMMIT WORLD is a popular sponsorship option with great value for solution providers.

Sponsorship includes

- Selected Summit Three Access Passes
- Exhibition space
- Helping to prearrange face to face meetings with selected participants

Dinner Sponsorship

2023 FoP SUMMIT WORLD TOUR will host a series of dinners These dinners bring together thoughtfully selected groups of 15-20 peers from established pharma, biotech, healthcare, and medtech companies. The dines start with a 30-minute networking reception followed by a 60-minute seated dinner, with the option for participants to remain afterward to continue networking.

- Selected Summit Three Access Passes
- 30-minute reception, and 60 minute seated dinner

Speaking

Limited speaking opportunities are available for our sponsoring partners to demonstrate the expertise of their organization. Be sure to ask about these early so we can ensure your presentation flows seamlessly with the overall content. Speaking sponsorships has several options – keynote presentations, case study presentations, expert presentations, panel discussions, workshops, or roundtable leadership. Speaking opportunities are available for experts in the field of Drug safety specialists, QPPVs, Safety Heads, C-level pharmaceutical and biotech executives, hospital management, clinicians, epidemiologists, pharmacologists, Project and Portfolio Management, Contract Management, Consultancy, CROs, Data Management, Artificial Intelligence, Robotics and Digital Innovation experts

Additional sponsorship opportunities are available for those who wish to further customize their involvement.

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Contact us

FOR PROJECT AND PORTFOLIO MANAGEMENT CONFERENCE

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ATTENDING AND SPONSORING:
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FROM **2399€**

FOR MEDICAL DEVICE SAFETY AND COMPLIANCE CONFERENCE

SPEAKING:
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FROM **2399€**

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