WHY? SUMMITS

Updated: 18 March, 2025
for the latest programe update, please
download agenda on conference website

June 11 - 12, 2025

Berlin, Germany

2nd Edition European MedTech Summit

Project and Portfolio Management Conference

&

Medical Device Safety and Compliance Conference

Why did we create European MedTech Summit?

„The future of healthcare is being written now.“

The MedTech industry is at a crossroads. Unprecedented **innovation meets complex regulatory landscapes.** The pressure to deliver safe, effective, and patient-centric devices is immense.

The European MedTech Summit

is your roadmap to navigate these challenges. It’s where visionaries converge to share best practices, explore **cutting-edge technologies,** and forge **strategic partnerships.**

Whether you’re **optimizing your portfolio,** accelerating time-to-market, ensuring patient safety, or navigating complex regulatory hurdles, this summit is your **platform for success.**

Answer the call.

Join us in Berlin as we redefine the future of MedTech together. Let’s build a healthcare ecosystem where innovation thrives and patient outcomes are paramount.

Who should attend:

Why Summits invites PMOs and C-Level Executives, EVPs, SVPs, VPs, Directors, Heads and Senior executives responsible for:

- Project/ Program/ Portfolio Management (PMO)
- Corporate Strategy/ Planning
- Digital Technology & Solutions
- Supply Chain Management
- Risk Management
- Cybersecurity
- Compliance & Safety
- Quality & Vigilance

Why does the European Medtech Summit stand out?

The **European MedTech Summit** is a gathering of the sharpest minds in medical devices, all under one roof. We're bringing together two worlds of expertise into one unforgettable event. That's exactly what you'll find at our combined **Project & Portfolio Management** and **Medical Device Safety & Compliance Conference** in Chicago.

#MedTech #PPM #interactive #dialogue #regulations #partnerships #safety #compliance #innovations #excellence #cybersecurity

Conference format

- Visionary Keynotes
- Best Practice Case Studies
- Expert Panel Discussions
- Interactive Workshops and Roundtables
- Networking For Lasting Business Friendship
- Fun and Icebreaking social events every evening

Testimonials

Karen Forsha, Ph.D.
Sr. Manager, Quality Systems
Terumo
★★★★★

„I had the opportunity to offer participants insight on how to positively impact others' well-being and influence organizational outcomes by viewing resilience, grit, and growth mindset as their leadership superpower! The dialogue afterwards was inspiring.“

Surinder Dhillon
Head of Commercial PMO, International
Hologic
★★★★★

„I found the sessions were well organized, with an interesting mix of attendees from across the industry. Various key topics were covered, all pertinent to the current MedTech landscape with good discussions on common challenges and sharing of useful lessons, practical applications and future proofing strategies.“

Gunther Lenz
Vice President Software R&D
Biosciences BD
★★★★★

“Digital Transformation in PPM at the #MedTechSummit! It's always inspiring to connect with fellow professionals who are equally passionate about harnessing digital tools to revolutionize project and portfolio management in healthcare. Let's continue this conversation and keep the ideas flowing!“

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

“The fact that the conference is relatively small generates a very open dialog and it makes it easy to network”

Susanna Girard, MBA, PMP, ACP
Senior R&D Program Manager
J&J MedTech
★★★★★

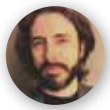
„Great discussions! It was my pleasure to be a part of it and get to know so many great people working in the industry.“

Arite Wildau
Director Patient Safety
BIOTRONIK
★★★★★

“Great open dialogue in an expert community. Many valuable presentations, panel discussions and time for networking to share best practices and different views on similar challenges. Warm atmosphere to grow as team over two fabulous days. Also excellently organized and moderated by the WHY SUMMIT TEAM. Happy to join next year as well!”

Sarah Paro
Global QMS Associate
Director
★★★★★

„Last week I had the opportunity to share my experiences and learn from industry experts at Why Summits MedTech Summit. It was an incredible experience!“



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

“I joined the conference in Spring 2023 and really enjoyed it. The program covered several topics of direct relevance to my daily activities, while also giving me perspectives on 'macro trends' of the medical devices industry. Speakers were experts and participants motivated to interact between sessions.”

What will be DISCUSSED?

WHY? SUMMITS

TRACK 1

MEDICAL DEVICE PROJECT & PORTFOLIO MANAGEMENT

The medical device industry is undergoing rapid transformation driven by technological advancements, regulatory changes, and increasing patient expectations. This dynamic environment necessitates a robust project and portfolio management approach. Discuss & learn about the latest trends in:

- Digital Transformation and Integration of AI
- Supply Chain Disruptions
- Accelerating Time-to-Market without Compromising Quality
- Innovating Under Pressure: Managing Risk and Speed in MedTech Projects
- Agile PPM for Medical Devices
- Optimizing Resource Allocation
- Talent Management and Development in Medical Device
- Navigating Global Regulatory Affairs

TRACK 2

MEDICAL DEVICE SAFETY & COMPLIANCE

Explore the latest trends in medical device safety and compliance, including AI integration, cybersecurity, post-market surveillance, and EU MDR/IVDR challenges. Learn about sustainability, patient-centric design, and the evolving regulatory landscape shaping the future of healthcare technology.

- Regulatory Hurdles and Ethical Considerations of AI in Medical Devices
- Proactive Cybersecurity
- EU MDR/IVDR Compliance Challenges
- Building Strong Quality Management System
- Effective Medical Device Vigilance Process
- Post Market Surveillance & RWD
- Balancing Safety and Sustainability: The Next Frontier in Medical Device Design
- Patient-Centric Device Development and Usability

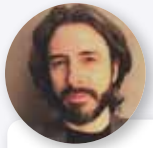
Industry Pioneers Attending From

2025 Speakers

Andreas Silber
Director of Global Pricing
Dentsply Sirona

Andrew Whytock
Head of Digitalization, Pharma Business Segment
Siemens

Ariana Adjani
Co-Founder and MD
FINE TREATMENT



Benjamin Rochette
Vice President, Global Regulatory Affairs
Coloplast

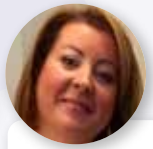
Edwige Strippe
Global Manager Medical Device Safety Vigilance
Santen

In the Chair PV Day 1

Fatima Sanfourche
Sr. Director of QA & RA Compliance for Medical devices, Combination products and eHealth
Bayer

Herbert Mauch
Director Clinical Operations EMEA
Cochlear

Leo Hovestadt
Director Governmental Affairs EU
Elekta



María José Lopéz Romeu
Sr. Manager Quality Compliance
BD

Marta Carnielli
Head of Certification IVD
TUV SUD GmbH

Marta Martínez
Senior Vigilance Process Manager
Novartis

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

Maurizio Zaccheddu
Senior Quality Assurance Manager
Medela

Mircea Ciuca
Global Head Medical Safety
Organon

Peter Fairhurst
Director Programs and Projects
NovoNordisk

Pavel Kušnierik
Head of Regulatory Affairs
Contipro

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

Tim Rumbaugh
Vice President Program Management
Edwards Lifesciences

Conference Agenda

DAY 1

NIGHT BEFORE THE EVENT

5:30pm 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, handshakes, smiles, hugs, whether with your old or new friends from the industry - everyone is welcome!

PROJECT AND PORTFOLIO TRACK

ACCELERATED TIME-TO-MARKET & INNOVATIONS

8:30am

KEYNOTE: ASSESSING R&D AND INNOVATION INVESTMENTS BY ACTIVELY MANAGING THE PORTFOLIO VALUE

- Understanding enterprise long-term goals
- Creating screening methodology for potential opportunities and assessing business cases
- Prioritizing innovative programs and opportunities against current investments
- Determining the process to actively manage the portfolio/investments

9:00am

PANEL DISCUSSION: SPEED VS. SAFETY: ACCELERATING TIME-TO-MARKET WITHOUT COMPROMISING QUALITY

In an era of rapid innovation, getting products to market quickly is crucial, but not at the expense of quality or safety. This panel explores the tension between speed and thoroughness, discussing agile project management, efficient resource use, and maintaining rigorous testing standards to ensure that fast-tracked devices meet both regulatory and patient safety standards.

Andreas Silber, *Director of Global Pricing,* **Dentsply Sirona**

SAFETY & COMPLIANCE TRACK

EU MDR/IVDR Compliance Challenges

8:30am

KEYNOTE: CLINICAL EVALUATION FOR ARTIFICIAL INTELLIGENT PRODUCTS - COMBINING THE MDR WITH THE AI ACT

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

9:00am

PANEL DISCUSSION: EU MDR/IVDR: INDUSTRY PERSPECTIVES ON COMPLIANCE AND INNOVATION

- How to effectively balance requirements of EU MDR/IVDR with the need for innovation and time-to-market?
- What are the most significant challenges in generating and gathering the required clinical evidence under EU MDR/IVDR? How can the industry collaborate with regulators and healthcare providers to streamline this process?
- What are the emerging trends and challenges in the medical device industry that are likely to shape the regulatory landscape in the coming years? How can industry and regulators collaborate to prepare for these developments and ensure patient safety?

Edwige Strippe, *Global Manager Medical Device Safety Vigilance,* **Santen**
Leo Hovestadt, *Director Governmental Affairs EU,* **Elekta**
Marta Carnielli, *Head of Certification IVD,* **TUV SUD GmbH**
Pavel Kušnierik, *Head of Regulatory Affairs,* **Contipro**

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

9:30am

RESERVED PRESENTATION: CURRENT TRENDS IN THE PPM

10:00am NETWORKING BREAK

STRATEGIC ALLIANCES: SUPPLY CHAIN RESILIENCE

10:30am

KEYNOTE: BUILDING CRO/VENDOR RELATIONSHIPS WITH A LEVEL OF VISIBILITY THAT IS ADEPT TO OVERCOME DISRUPTIONS

- Establishing stakeholders as an extension of the team and scheduling regular meetings for updates
- Identifying vendors that can deliver their part and cutting off relationships that aren't meeting expectations
- Being involved in the vendor's part without micromanaging for a balance of trust and visibility
- Navigating challenges when losing a long-standing vendor due to supply-chain or other disruptions
- Leveraging the right relationships to finding complex parts that are harder to obtain

11:00am

PANEL DISCUSSION: RESILIENT SUPPLY CHAINS: STRATEGIES TO MITIGATE RISKS IN MEDTECH

With global supply chains under pressure, this panel will address how medical device companies can anticipate and respond to disruptions. Topics include supply chain diversification, contingency planning, and leveraging digital tools for better visibility and management, ensuring that projects stay on track despite external challenges.

11:30am

RESERVED PRESENTATION: OUTSOURCING AND PARTNERSHIPS

Considering outsourcing or partnering with external organizations for specific tasks or projects to alleviate resource constraints. This can help access specialized skills, increase capacity, and improve efficiency

SAFETY & COMPLIANCE TRACK

9:30am

KEYNOTE: NAVIGATING THE IVDR: STRATEGIES FOR SUCCESS IN A CHANGING REGULATORY LANDSCAPE

This presentation will provide an overview of IVDR, highlighting the key changes and their implications for medical device companies. It will offer strategies for navigating the complex regulatory environment, including tips for successful certification and ongoing compliance.

Marta Carnielli, *Head of Certification IVD,* **TUV SUD GmbH**

10:00am NETWORKING BREAK

10:30am

KEYNOTE: COMBINATION PRODUCT: MEDICAL DEVICE WITH ANCILLARY MEDICINAL SUBSTANCE - SPECIFICS IN REGULATORY REQUIREMENTS

Class III medical devices are connected to the highest risk class. An even more specific case is having an ancillary medicinal substance as part of the device. This is connected with differences in biocompatibility evaluation, clinical evaluation, as well as conformity assessment procedures. This presentation will offer insights on a possible approach to successfully cover all nuances in the regulatory process of such devices.

Pavel Kušnierik, *Head of Regulatory Affairs,* **Contipro**

11:00am

RESERVED PRESENTATION: CURRENT TRENDS IN SAFETY AND COMPLIANCE

ENVIRONMENTAL AND SUSTAINABILITY CONSIDERATIONS

11:30am

CASE STUDY: ECO-DESIGN IN PRACTICE: DEVELOPING A SUSTAINABLE MEDICAL DEVICE

This case study will showcase the development of a medical device designed with sustainability in mind. It will cover the challenges and successes in reducing the environmental impact throughout the product lifecycle, from material selection to end-of-life disposal.

Ariana Adjani, *Co-Founder and MD,* **FINE TREATMENT**

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

12:00pm LUNCH BREAK

EVER CHANGING REGULATORY ENVIRONMENT

1:00pm

KEYNOTE: WHEN REGULATIONS EVOLVE: A CASE STUDY ON OVERCOMING MDR CHALLENGES IN MEDICAL DEVICE INNOVATION

Delve into a case study showcasing a medical device company's journey to bring a new medical device to CE-mark under the EU MDR. This session will cover strategic planning and overcoming regulatory hurdles when navigating through the grey areas of the MDR when it comes to pathways for clinical evaluation and nanomaterials.

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

1:30pm

PANEL DISCUSSION: LEVERAGING PMO FOR GLOBAL GOVERNANCE OF PROJECTS

- How can organizations ensure that regulatory compliance is embedded into project and portfolio management from the outset?
- What are the benefits of aligning regulatory affairs with strategic project planning?
- What are the common risks in medical device development from regulatory perspective? How to implement these risks early in governance of projects?
- What are the best practices for fostering collaboration between regulatory affairs, project management, and governance teams?

Benjamin Rochette, *Vice President, Global Regulatory Affairs,* **Coloplast**
Peter Fairhurst, *Director Programs and Projects,* **NovoNordisk**
Tim Rumbaugh, *Vice President Program Management,* **Edwards Lifesciences**

2:00pm

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

SAFETY & COMPLIANCE TRACK

12:00pm LUNCH BREAK

1:00pm

PANEL DISCUSSION: BALANCING SAFETY AND SUSTAINABILITY: THE NEXT FRONTIER IN MEDICAL DEVICE DESIGN

- What are the key challenges and opportunities in selecting sustainable materials for medical device design? How can the industry ensure that these materials meet the stringent safety and performance requirements?
- How can the concept of the circular economy be applied to medical devices? What are the barriers to implementing closed-loop systems and reusing or recycling medical devices?
- What emerging technologies or trends have the potential to significantly impact the sustainability of medical devices?

Ariana Adjani, *Co-Founder and MD,* **FINE TREATMENT**

POST-MARKET SURVEILLANCE AND REAL-WORLD DATA

1:30pm

RESERVED PRESENTATION: MANAGING POST MARKET AND CLINICAL STUDIES WITH REQUIREMENTS OF ISO 14155 AND MDR TO REMAIN IN COMPLIANCE

2:00pm

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 annual update of occurrence rates Probability of Occurrence of Harm (POH) and risk level based on complaint data

Moderator: Marta Carnielli, *Head of Certification IVD,* **TUV SUD GmbH**
Fatima Sanfourche, *Sr. Director of QA & RA Compliance for Medical devices, Combination products and eHealth,* **Bayer**

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

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?

Edwige Strippe, *Global Manager Medical Device Safety Vigilance*, **Santen**

2:30pm NETWORKING BREAK

3:00pm

WORKSHOP: ESTABLISHING PROGRAM AND PORTFOLIO KANBANS TO OPTIMIZE THE FLOW OF BUSINESS VALUE TO CUSTOMERS

- Using Kanban to manage portfolios, programs, and large projects to eliminate miscommunication and surprises.
- Bridging the gap between leadership, developers, and stakeholders alike.
- Visualizing work, organizational capacity, and maximizing the flow of value.
- Sequencing work to produce the maximum economic benefits in the shortest time.
- Key metrics to evaluate customer satisfaction, streamline delivery pipeline performance, and to eliminate waste.

4:00pm ROUNDTABLE DISCUSSIONS (60 minutes)

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

ROUNDTABLE 1: HYBRID PROJECT MANAGEMENT AND ADAPTATION OF ORGANISATION WITH BUSINESS AGILITY

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

ROUNDTABLE 2: CREATING A REGULATORY COMPLIANCE CULTURE WITHIN THE ORGANIZATION

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

ROUNDTABLE 3: PORTFOLIO MANAGEMENT - HOW TO MANAGE A COMPLEX PIPELINE

Herbert Mauch, *Director Clinical Operations EMEA*, **Cochlear**

SAFETY & COMPLIANCE TRACK

2:30pm NETWORKING BREAK

3:00pm

KEYNOTE: THE NEW ERA OF POST-MARKET SURVEILLANCE: LEVERAGING REAL-WORLD DATA FOR SAFETY AND INNOVATION

This keynote will focus on the importance of post-market surveillance and the use of real-world data in ensuring ongoing device safety and effectiveness. It will explore how real-world evidence can be harnessed to improve patient outcomes, generate market access and drive innovation.

Herbert Mauch, *Director Clinical Operations EMEA*, **Cochlear**

3:30pm

CASE STUDY: POST MARKET LITERATURE SURVEILLANCE – MEDICAL SAFETY AT THE FOREFRONT, BEST PRACTICES, CASE-STUDY

A rigorous and strategic systematic literature review (SLR) to support ongoing post-market literature surveillance activities within one's organization is not an option anymore. In this session the speaker shall illustrate how she and her team approached SLR within Medtronic and how they leveraged the award-winning process to support Post-Market Surveillance activities. The session would cover:

- Need of PMLS/SLR
- Challenges & Opportunities
- Simplifying the process
- Defining and Executing Proactiveness
- Wins

4:00pm ROUNDTABLE DISCUSSIONS (60 minutes)

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

ROUNDTABLE 1: DEMONSTRATING GOOD MANUFACTURING PRACTICES THROUGH GUIDANCE OF ISO 13485 FOR DEVICE QUALITY AND CONSISTENCY

Pavel Kušnierik, *Head of Regulatory Affairs,* **Contipro**

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

ROUNDTABLE 4: MEDICAL DEVICE DEVELOPMENT - WHAT TO BE PREPARED FOR AS A PROJECT MANAGER AT DIFFERENT STAGES OF MEDICAL DEVICE DEVELOPMENT

Tim Rumbaugh, *Vice President Program Management,* **Edwards Lifesciences**

ROUNDTABLE 5: BUILDING BENCH STRENGTH FOR A PMO

5:00pm COCKTAIL RECEPTION

6:00pm End of Day1

SAFETY & COMPLIANCE TRACK

ROUNDTABLE 2: CONTROLLING RISK AND BIOLOGICAL SAFETY AT THE MANUFACTURING LEVEL TO CONFORM TO GUIDANCE UNDER ISO 10993

ROUNDTABLE 3: RISK MANAGEMENT AND VIGILANCE

María José Lopéz Romeu, *Sr. Manager Quality Compliance,* **BD**

ROUNDTABLE 4: AI ACT

Maurizio Zaccheddu, *Senior Quality Assurance Manager,* **Medela**

ROUNDTABLE 5: MASTERING COMPLIANCE: TRAINING STRATEGIES FOR IMPLEMENTING NEW MEDICAL DEVICE REGULATIONS

Marta Martínez, *Senior Vigilance Process Manager,* **Novartis**

5:00pm COCKTAIL RECEPTION

6:00pm End of Day1

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

DIGITAL TRANSFORMATION AND INTEGRATION OF AI IN PROJECT & PORTFOLIO MANAGEMENT

8:30am

KEYNOTE: AI IS NOT YOUR NEXT STEP – GET YOUR HOUSE IN ORDER FIRST

Project management experts continually refer to AI as a "solution" that is essential to our profession, yet without defining the problems that AI will solve. And the hype is not helpful. The vast majority of current research, podcasts and articles on "AI in PM" provide generic predictions, assumptions, expectations and recommendations; none of which inform our profession of the why, what, how, when, or how much. So that's where we start. Distilling all the noise down to practical steps that are essential to deploy AI for Project Management in a coherent and meaningful way.

Tim Rumbaugh, *Vice President Program Management,* **Edwards Lifesciences**

9:00am

RESERVED PRESENTATION: TRANSFORMING HEALTHCARE: CASE STUDIES IN DATA READINESS FOR AI ADOPTION

We'll explore the pivotal role of robust data management and an adaptable organizational culture in harnessing AI and predictive analytics in the medical technology field. We'll share insights from real-world examples to illustrate the journey of companies at varying stages of data readiness, and highlight the seamless integration of technology with human expertise to drive innovation and strategic growth.

9:30am

PANEL DISCUSSION: SECURING THE FUTURE: CYBERSECURITY AND DATA PRIVACY IN CONNECTED MEDICAL DEVICES

As medical devices become increasingly connected, cybersecurity risks and data privacy concerns are rising. This panel will discuss best practices for embedding robust security measures throughout the development lifecycle, regulatory considerations, and strategies to protect patient data while maintaining device functionality and compliance.

10:00am NETWORKING BREAK

SAFETY & COMPLIANCE TRACK

CYBERSECURITY IN MEDICAL DEVICES

8:30am

KEYNOTE: PROACTIVE CYBERSECURITY: COLLABORATIVE APPROACHES TO THREAT MITIGATION

This keynote delves into steps that can be taken to mitigate cybersecurity risks in medical devices. Topics will include collaboration between stakeholders, the role of software updates, and the challenges of maintaining security over the device's lifespan.

9:00am

PANEL DISCUSSION: REGULATING AI IN MEDICAL DEVICES: BALANCING INNOVATION WITH PATIENT SAFETY

This panel will explore the evolving regulatory landscape for AI/ML-based medical devices. It will highlight the challenges and opportunities in balancing the rapid innovation of AI with the rigorous safety standards required in healthcare. The keynote will also address the importance of transparency, validation, and continuous learning in AI models to ensure patient safety.

Maurizio Zaccheddu, *Senior Quality Assurance Manager,* **Medela**
Mircea Ciuca, *Global Head Medical Safety,* **Organon**

9:30am

RESERVED PRESENTATION: BUILDING RESILIENT MEDICAL DEVICES: THE IMPERATIVE OF CYBERSECURITY

The presentation will address the growing threat of cybersecurity breaches in medical devices and the importance of building resilient systems. It will cover the regulatory landscape, including the FDA's cybersecurity guidelines, and discuss best practices for integrating cybersecurity into the device lifecycle from design through to post-market.

10:00am NETWORKING BREAK

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

ALLIGINING PROJECT AND PROGRAM EXECUTION TO CORPORATE STRATEGY

10:30am

KEYNOTE: Transitioning from project to program management: when does this make sense and how and lessons learned

- What are the differences in running a major project, to, running a major program in a pharmaceutical environment?
- How do you set up senior project managers for success for running major programs, and, what additional skill sets are required?
- This talk will deep dive into theory, reality and lessons learned in the major finished goods on going capacity expansion that NovoNordisk is presently experiencing

Peter Fairhurst, *Director Programs and Projects*, **NovoNordisk**

11:00am

KEYNOTE: ALIGNING PROJECTS TO CORPORATE STRATEGY

The alignment between projects and programs with business goals ensures that the company's resources are effectively utilized, and that the projects and programs contribute to achieving the organization's strategic objectives. This presentation gives insights to help link execution to corporate strategy:

- Developing strategy and balanced portfolio of projects and programs that address the organization's short-term needs and long-term strategic goals
- Resource allocation and continuous adjustments to align with the organization's strategic objectives
  - Performance measurement
  - Change management
  - Continuous improvement
- Leadership support

Andreas Silber, *Director of Global Pricing*, **Dentsply Sirona**

SAFETY & COMPLIANCE TRACK

RISK MANAGEMENT AS KEY MANAGEMENT TOOL IN EVER CHANGING ENVIRONMENT

10:30am

RESERVED CASE STUDY: RISK MEASUREMENT TOOLS AND METHOD ASSESSING EFFECTIVENESS OF RISK MANAGEMENT PLANS

Medical Device Manufacturers can manage and reduce risk more effectively by integrating risk thinking early in development and revisiting it throughout the process. Risk management is crucial for ensuring device usability, safety, and regulatory compliance, and is a competitive tool for global market access. Key considerations include developing optimal risk management strategies, balancing routine vs. additional risk minimization measures, ensuring feasibility without overburdening healthcare systems, implementing and evaluating these measures globally, and identifying tools and criteria for assessing their effectiveness.

11:00am

KEYNOTE: ISO 14971 RISK MANAGEMENT FOR MEDICAL DEVICES WITH AI

With the introduction of the AI Act, legal manufacturers of medical devices containing Artificial intelligence will need to show evidence that their products comply to the new regulation.

While the AI functionalities and features will bring many benefits for the end customers or patients, they raises also challenges for manufactures that will have to show compliance to it. One of the requirements is that manufactures need to perform Risk management activities to identify and mitigate the potential risks of the AI system to health, safety, and fundamental rights during the lifetime of the AI system.

Risk management for AI devices brings many challenges as well. Key challenges will be presented, together with some possible recommendation on how to deal with them.

Maurizio Zaccheddu, *Senior Quality Assurance Manager*, **Medela**

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

11:30am

RESERVED PRESENTATION: ALIGNING RESOURCE MANAGEMENT WITH PORTFOLIO PRIORITIZATION

To overcome the challenges in aligning resource management with portfolio prioritization, pharma and biotech PPM managers can adopt the following strategies:

- Implement a robust PPM framework
- Enhance visibility and communication
- Develop accurate forecasting models
- Foster a culture of agility and adaptability
- Invest in training and skill development
- Implement effective governance and risk management

12:00pm

PANEL DISCUSSION: FROM STRATEGY TO IMPACT: ENSURING VALUE DELIVERY THROUGH EFFECTIVE EXECUTION

- Defining and tracking value delivery metrics across portfolios.
- Navigating the trade-offs between strategic intent and operational execution.
- Building resilience and adaptability into project and program management.
- Leveraging data and analytics for better decision-making.
- Cultivating a culture that prioritizes value over volume in project execution.

Herbert Mauch, *Director Clinical Operations EMEA,* **Cochlear**
Peter Fairhurst, *Director Programs and Projects,* **NovoNordisk**
Tim Rumbaugh, *Vice President Program Management,* **Edwards Lifesciences**

12:30pm LUNCH BREAK

TALENT MANAGEMENT AND DEVELOPMENT IN MEDICAL DEVICE

1:30pm

DON'T BE AFRAID - IT'S JUST ACADEMIA! BUILDING SUSTAINABLE INDUSTRIAL/ACADEMIC RELATIONS.

In a rapidly evolving MedTech landscape, the alignment of academic innovation with market demands is more critical than ever. This session will explore strategies to bridge the divide between academic research and industry expectations. Topics include cul-

SAFETY & COMPLIANCE TRACK

11:30am

PANEL DISCUSSION: MEDICAL DEVICE RISK MANAGEMENT AND HUMAN FACTORS ENGINEERING

Risk management is a critical component of medical device development and manufacturing. When working to minimize any use-related hazards and risks associated with your medical device, you must focus on how users interact with the device. The panelist will discuss how using the standards laid out in ISO 14971 you can determine whether the benefits of your medical device outweigh any potential risks and present the data to the FDA.

María José Lopéz Romeu, *Sr. Manager Quality Compliance,* **BD**

12:00pm LUNCH BREAK

BUILDING EFFECTIVE VIGILANCE PROCESS

1:00pm

KEYNOTE: BUILDING YOUR MEDICAL DEVICE VIGILANCE PROGRAM

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

Marta Martínez, *Senior Vigilance Process Manager,* **Novartis**

1:30pm

KEYNOTE: DEVICE VIGILANCE REPORT PREPARATION AND SUBMISSION

- Medical device reporting requirements
- Integrating complaint data into risk management and post market surveillance to balance these processes
- Developing best practices for complaint trending to analyze and correctly report those complaints

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

tivating top talents through effective management, minimizing project disruptions, and fostering collaboration between academic institutions and industry stakeholders.

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

2:00pm

RESERVED PRESENTATION: SPECIALIZED TALENT ACQUISITION

Attracting and retaining specialized talent with the necessary skills and expertise may involve partnering with academic institutions, offering targeted training programs, or promoting internal mobility to develop the required skills within the organization.

2:30pm

PANEL DISCUSSION: HUMAN RESOURCE MANAGEMENT

Effective resource management can mean the difference between success and failure.

- What is the role of the PM in resource management?
  - What does flexibility mean in resource management?
  - How to stay effective when transitioning from a smaller to large-scale company.

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

3:00pm NETWORKING BREAK

3:30pm ROUNTABLE DISCUSSIONS

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)

1. STAKEHOLDER MANAGEMENT: MERGERS & ACQUISITIONS, STRATEGIC ALLIANCES AND JOINT VENTURES

2. SUCCESSFUL TEAMS: HOW TO MANAGE EVERYONE'S REQUESTS

Andreas Silber, *Director of Global Pricing,* **Dentsply Sirona**

3. PROFESSIONAL DEVELOPMENT: WHAT'S IMPORTANT FOR INDIVIDUALS AND COMPANIES THEMSELVES

4:30pm THAT´S A WRAP

SAFETY & COMPLIANCE TRACK

- Solidifying ideas on the structure for documentation within safety systems and how to document user errors and near misses
- How to make post-market surveillance reporting quicker and more efficient

María José Lopéz Romeu, *Sr. Manager Quality Compliance,* **BD**

2:00pm

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

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

Marta Martínez, *Senior Vigilance Process Manager,* **Novartis**
María José Lopéz Romeu, *Sr. Manager Quality Compliance,* **BD**
Mircea Ciuca, *Global Head Medical Safety,* **Organon**

2:30pm NETWORKING BREAK

3:00pm WORKSHOP SESSIONS

WORKSHOP 1: HARMONIZING IMPACTS OF REAL-WORLD DATA (RWD) AND REAL-WORLD EVIDENCE (RWE) TO OBTAIN REGULATORY APPROVALS

- Discussing the varying impact of RWD and RWE on the health care community
- Highlighting examples of using RWE/RWD in clinical development, and cases for using RWE to obtain regulatory approvals
- Discussing some of the dynamics that have revolutionized the application and evaluation of RWE

Outlining considerations for using RWD from electronic health records (EHRs) as a component of safety studies

Conference Agenda

DAY 2

SAFETY & COMPLIANCE TRACK

WORKSHOP 2: A SYSTEMS-THEORETIC PROCESS ANALYSIS (STPA) APPLIED TO MEDICAL DEVICE SAFETY

Description: Safety failures in medical devices lead to poor patient outcomes and poor corporate financial outcomes, as the cost of device recalls and the specter of litigation around medical devices directly impact a company's financial performance. Current safety methods need to be enhanced to incorporate safety into the design phase of systems engineering rather than something that is done once the system is created. RCA techniques fall short in safety hazard analysis because these methods do not consider the unintended emergent effects of complex systems such as cyber-physical medical devices. These unintended emergent effects can lead to unsafe device use conditions, leading to hazards and potentially a loss, hazards not always found in RCA analysis. The presentation will walk through how STPA can be applied to medical devices using the example of a continuous glucose monitoring system. Presentation attendees will gain knowledge on STPA and STAMP methods, how STAMP methods are different from RCA safety approaches, and have an example STPA hazard analysis presented for a common medical device.

4:30pm THAT´S A WRAP

2025 WORLD TOUR AT A GLANCE

Project & Portfolio Management

1
22 - 23 January, BARCELONA
28th European Pharma and Biotech Project, Program and Portfolio Management Conference

2
29 - 30 January, SAN DIEGO
American Strategic Portfolio Management in Life Sciences – West Coast

3
3 - 4 April, BASEL
29th European Biopharma Project Program and Portfolio Management Conference

4
9 - 10 April, CHICAGO
2nd American Medical Device Project & Portfolio Management Conference

5
15 - 16 April, PHILADELPHIA
24th American Pharma and Biotech Project, Program and Portfolio Management Conference

6
14 - 15 May, LONDON
European Strategic Portfolio Management in Life Sciences

7
3 - 4 June, COPENHAGEN
Biopharma PPM in Clinical Research and Development Summit Edition

8
11 - 12 June, BERLIN
2nd European MedTech Summit 2025 - Medical Device Project & Portfolio Management Conference

9
11 - 12 June, SAN FRANCISCO
25th American Pharma and Biotech Project, Program and Portfolio Management Conference

10
5 - 6 August, SINGAPORE
Asian Pharma and Biotech Project, Program and Portfolio Management Conference

11
3 - 4 September, MELBOURNE
Pharma and Biotech Project, Program and Portfolio Management Conference

12
10 - 11 September, MUMBAI
3rd Strategic Project, Program and Portfolio Management Conference for Pharmaceuticals

13
8 - 9 October, BASEL
30th European Pharma and Biotech Project, Program and Portfolio Management Conference

14
15 - 17 October, BOSTON
26th American Pharma and Biotech Project, Program and Portfolio Management Conference

15
22 - 23 October, LONDON
31st European Pharma and Biotech Project, Program and Portfolio Management Conference

16
9 - 11 December, LAS VEGAS
2nd Annual PPM TOOLBOX SUMMIT

2025 WORLD TOUR AT A GLANCE

Pharmacovigilance & Device Safety

1. 25 - 26 February, BARCELONA
   European Drug Safety & PV Outsourcing Summit
2. 12 - 13 March, BOSTON
   American Drug Safety Summit 2025 - East coast
3. 2 - 3 April, LONDON
   10th Global Pharmacovigilance & RWE FORUM
4. 9 - 10 April, CHICAGO
   2nd Annual American MedTech Summit
5. 4 - 5 June, TORONTO
   Canadian Pharmacovigilance Management & Compliance Conference
6. 11 - 12 June, BERLIN
   2nd Annual European MedTech Summit
7. 23 - 24 June, MUMBAI
   2nd annual Global Drug Safety & PV Outsourcing Summit
8. 24 - 25 September, WASHINGTON D.C
   American Pharmacovigilance Management & Compliance Conference
9. 25 - 26 November, BASEL
   3rd annual World Drug Safety Summit
10. 7 - 8 December, SAN DIEGO
    American Drug Safety Summit 2025 - Westcoast

Our Partners

WHY? SUMMITS

smartsheet

Syneos Health

Planisware

Sciforma

PDWARE

TempusResource by ProSymmetry

rego consulting
Let Rego Be Your Guide

Atlas

project widgets

CAI

CAPTARIO

Intelligencia AI

cmkselect

i2e Consulting

IPM

proggio

flexpro

Sensei

cora

enrich

Contact us

Updated: 18 March, 2025
for the latest programe update, please
download agenda on conference website

Vice President
PPM World Tour:

Liza Zhaivoronok
liza.zhaivoronok@whysummits.com

Speaking:

Andrea Beneová
andrea.b@whysummits.com

Sponsoring:

Lohith Babu
lohith@whysummits.com

Disclamer:
Please note - all of the information in this document is subject to change at any time. Whilst every effort has been made to ensure the accuracy of the information, statements and decisions recorded in them, their status will remain that of a draft until such time as they are confirmed as a final version prior the subsequent meeting, Additionally, the user information is only valid at a certain moment in time and is subject to change due to movement and changes in bit rate requirements.

“Always be Curious”

www.whysummits.com

REGISTER HERE

€2399