WHY? SUMMITS

Updated: 3 June, 2025
for the latest programe update, please download agenda on conference website

June 11 - 12, 2025

Berlin, Germany
NH Berlin Alexanderplatz
Landsberger Allee 26,
10249 Berlin, Germany

2nd Edition European MedTech Summit

Project and Portfolio Management Conference

&

Medical Device Safety and Compliance Conference

Gold Partners

FLINN

PATCH & SPARKS
PASSION FOR SUCCESS

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
★★★★★

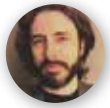
„Great discussions! It was my pleasure to be a part of it and get to know so many great people working in the industry.“

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

In the Chair PPM Day 1

Andreas Silber
Director of Global Pricing
Dentsply Sirona

Andrew Whytock
Head of Digitalization, Pharma Business Segment
Siemens

In the Chair PV Day 2

Ariana Adjani
Co-Founder and MD
FINE TREATMENT

Baoleri Lee Rauhe
Regulatory Specialist, Global Regulatory Affairs
Radiometer Medical Aps.

Benjamin Rochette
Vice President, Global Regulatory Affairs
Coloplast

Dr. Carsten C. Mahrenholz
Founder & CEO
COLDPLASMATECH

Cédric Kahl
Global Senior Project Leader & Portfolio Manager for the Clinical Diagnostic Group
former Bio-Rad Laboratories

Edwige Strippe
Director Global Regulatory Affairs, Medical Device Group
Santen

In the Chair PV Day 1

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

Jens Melander
Managing Director
Patch & Sparks Inc

Leo Hovestadt
Director Governmental Affairs EU
Elekta

Lorenz Strehl
Market Expansion Lead UK/IR
Flinn.ai

2025 Speakers

Maria Liwei Han
Regulatory Specialist, Global Regulatory Affairs
Radiometer Medical Aps.

Marta Carnielli
Head of Certification IVD
TUV SUD GmbH

Marta Martínez
Senior Vigilance Process Manager
Novartis

Massimo Kubon
Vice Dean of Faculty Engineering & Technology: Marketing & International Affairs
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

Verena Kieferle
Director Global Regulatory Affairs
Vantive

Yasmin Mahua
Senior Regulatory Affairs Specialist
J&J MedTech

Conference Agenda

DAY 1

NIGHT BEFORE THE EVENT

17:30 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

8:30 REGISTRATION & MORNING NETWORKING

Start your day by checking in at registration, where you'll receive your badge. Grab a fresh cup of coffee to energize yourself for the day ahead. Take this opportunity to connect with fellow attendees, exchange ideas, and build new professional relationships.

STRATEGIC ALLIANCES & SUPPLY CHAIN RESILIENCE

9:00

CASE STUDY: FROM BREAKTHROUGH TO BUYOUT: BUILDING A COMPANY INVESTORS BELIEVE IN

Turning a groundbreaking medical innovation into an attractive investment opportunity takes more than just excellent science. In this session, Dr. Carsten Mahrenholz shares the strategic journey of Coldplasmatech—from developing a novel cold plasma therapy to aligning the company's portfolio and positioning for international investment. Using real-world insights, he outlines how making a company "investment-ready" involves more than regulatory approval or clinical success. It requires understanding what potential partners value, adapting to strategic fit, and actively shaping a story that resonates with investors and acquirers alike.

Dr. Carsten C. Mahrenholz, *Founder & CEO,* **COLDPLASMATECH**

SAFETY & COMPLIANCE TRACK

8:30 REGISTRATION & MORNING NETWORKING

Start your day by checking in at registration, where you'll receive your badge. Grab a fresh cup of coffee to energize yourself for the day ahead. Take this opportunity to connect with fellow attendees, exchange ideas, and build new professional relationships.

EU MDR/IVDR Compliance Challenges

9:00

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

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

9:30

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

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

9:30

KEYNOTE: SUPERCHARGE YOUR PPM STRATEGY WITH AI

Explore the power of real-time AI chatbots in your PPM/SPM environment to effortlessly access competitor insights and public clinical trial benchmarks. Go beyond data retrieval—use this intelligence in predictive modeling to optimize your studies, outpace the competition, and speed up your path to market.

Jens Melander, *Managing Director,* **Patch & Sparks Inc**

10:00

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**
Maria Liwei Han,
Regulatory Specialist, Global Regulatory Affairs,
Radiometer Medical Aps.
Verena Kieferle, *Director Global Regulatory Affairs,* **Vantive**

10:30 NETWORKING BREAK

11:00

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

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.

Ariana Adjani, *Co-Founder and MD,* **FINE TREATMENT**
Andrew Whytock, *Head of Digitalization, Pharma Business Segment,* **Siemens**
Verena Kieferle, *Director Global Regulatory Affairs,* **Vantive**

SAFETY & COMPLIANCE TRACK

regulators collaborate to prepare for these developments and ensure patient safety?

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

10:00

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

This presentation will provide an overview of the 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**

10:30 NETWORKING BREAK

11:00

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**

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

11:30

ROUNDTABLE DISCUSSIONS (60 MIN)

Join roundtable discussions with our speakers and engage in discussions on trending topics moderated by industry experts.

Each delegate can choose to attend both discussions

ROUNDTABLE 1: FROM OPERATIONAL SUPPORT TO STRATEGIC PARTNER: INTEGRATING STRATEGIC, FINANCIAL, AND PORTFOLIO PLANNING IN THE PMO—WHY IT MATTERS AND HOW TO ACHIEVE IT?

In today's dynamic business environment, the PMO is evolving from a traditional operational support role to a strategic partner integral to organizational success. This roundtable explores the critical importance of integrating strategic, financial, and portfolio planning processes—a transformation highlighted in the Sciforma 2025 PMO Outlook Report, which notes that 72% of resources are not well aligned with strategic priorities. Through shared experiences and discussions, we will examine the challenges of siloed planning, the benefits of integrated approaches, and practical steps the PMO can take to drive alignment and value delivery. Participants will gain insights into transitioning their PMOs into strategic enablers that effectively bridge strategy and execution.

Cédric Kahl, *Global Senior Project Leader & Portfolio Manager for the Clinical Diagnostic Group,* **former Bio-Rad Laboratories**

ROUNDTABLE 2: STAKEHOLDER MANAGEMENT – MERGERS & ACQUISITIONS, STRATEGIC ALLIANCES AND JOINT VENTURES

Dr. Carsten C. Mahrenholz, *Founder & CEO,* **COLDPLASMATECH**
Verena Kieferle, *Director Global Regulatory Affairs,* **Vantive**

12:30 LUNCH BREAK

SAFETY & COMPLIANCE TRACK

11:30

KEYNOTE: LEVERAGING AI FOR CLINICAL EVALUATIONS & PMS: REAL LIVE USE CASES AND CHALLENGES TO OVERCOME

Monitoring PMS safety databases like FDA Maude, Health Canada, BfArM, MHRA and the like is not only time-consuming—it also comes with substantial compliance risks. This talk uncovers the most common pitfalls in manual surveillance processes, including inconsistent relevance evaluation, insufficient data coverage, and audit-readiness challenges.

You'll learn how automation and AI can overcome these barriers—streamlining workflows, minimizing human error, and freeing up your team to focus on high-value activities.

Lorenz Strehl, *Market Expansion Lead UK/IR,* **Flinn.ai**

12:00

ROUNDTABLE DISCUSSIONS (60 MIN)

Join roundtable discussions with our speakers and engage in discussions on trending topics moderated by industry experts.

Each delegate can choose to attend both discussions

ROUNDTABLE 1: FROM IVDR/MDR TO GLOBAL COMPLIANCE: LABELLING STRATEGY FOR EU MANUFACTURERS

Explore key approaches and considerations for adapting IVDR/MDR-compliant labelling for global markets. By understanding below critical factors, manufacturers could achieve smooth market access while maintaining regulatory compliance across diverse regions.

Baoleri Lee Rauhe, *Regulatory Specialist, Global Regulatory Affairs,* **Radiometer Medical Aps.**
Han Maria Liwei, *Regulatory Specialist, Global Regulatory Affairs,* **Radiometer Medical Aps.**

ROUNDTABLE 2: MASTERING COMPLIANCE: TRAINING STRATEGIES FOR IMPLEMENTING NEW MEDICAL DEVICE REGULATIONS

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

13:00 LUNCH BREAK

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

EVER CHANGING REGULATORY ENVIRONMENT

13:30

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**

14:00

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?

Andrew Whytock, *Head of Digitalization, Pharma Business Segment,* **Siemens**
Benjamin Rochette, *Vice President, Global Regulatory Affairs,* **Coloplast**
Peter Fairhurst, *Director Programs and Projects,* **NovoNordisk**
Tim Rumbaugh, *Vice President Program Management,* **Edwards Lifesciences**
Baoleri Lee Rauhe, *Regulatory Specialist, Global Regulatory Affairs,* **Radiometer Medical Aps.**

SAFETY & COMPLIANCE TRACK

ENVIRONMENTAL AND SUSTAINABILITY CONSIDERATIONS

14:00

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**

POST-MARKET SURVEILLANCE AND REAL-WORLD DATA

14:30

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**
Renea Schønemann Olsen, *Senior Post-Market Surveillance Manager, Scientific Affairs,* **3shape**
Yasmin Mahua, *Senior Regulatory Affairs Specialist,* **J&J MedTech**

15:00 NETWORKING BREAK

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

14:30

KEYNOTE: 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 and adapts to continuous changes in global regulation.

Edwige Strippe, *Director Global Regulatory Affairs, Medical Device Group,* **Santen**

15:00 NETWORKING BREAK

15:30

AFTERNOON ASK & LEARN 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 Both discussions

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

Massimo Kubon, *Vice Dean of Faculty Engineering & Technology: Marketing & International Affairs,* **Furtwangen University**

ROUNDTABLE 2: CREATING A REGULATORY COMPLIANCE CULTURE WITHIN THE ORGANIZATION

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

16:30 END OF DAY 1

17:00 EVENING PROGRAM

Unwind after a full day of sessions by joining us for the evening networking program. We'll gather at a nearby restaurant to continue conversations, exchange ideas, and connect in a relaxed atmosphere. This informal meet-up is the perfect way to build relationships and wrap up the day.

SAFETY & COMPLIANCE TRACK

15:30

AFTERNOON ASK & LEARN 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 both discussions

ROUNDTABLE 1: BALANCING SAFETY AND SUSTAINABILITY: THE NEXT FRONTIER IN MEDICAL DEVICE DESIGN

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

ROUNDTABLE 2: Post-Market Clinical Follow-Up (PMCF) for Software Medical Devices

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

16:30 END OF DAY 1

17:00 EVENING PROGRAM

Unwind after a full day of sessions by joining us for the evening networking program. We'll gather at a nearby restaurant to continue conversations, exchange ideas, and connect in a relaxed atmosphere. This informal meet-up is the perfect way to build relationships and wrap up the day.

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

DIGITAL TRANSFORMATION AND INTEGRATION OF AI IN PROJECT & PORTFOLIO MANAGEMENT

9:00

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**

ALLIGINING PROJECT AND PROGRAM EXECUTION TO CORPORATE STRATEGY

9:30

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.

Peter Fairhurst, *Director Programs and Projects,* **NovoNordisk**
Tim Rumbaugh, *Vice President Program Management,* **Edwards Lifesciences**

SAFETY & COMPLIANCE TRACK

CYBERSECURITY IN MEDICAL DEVICES

9:00

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**

RISK MANAGEMENT AS KEY MANAGEMENT TOOL IN EVER CHANGING ENVIRONMENT

9:30

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

10:00

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**

10:30 NETWORKING BREAK

11:00

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

BUILDING EFFECTIVE VIGILANCE PROCESS

10:00

KEYNOTE: BUILDING YOUR MEDICAL DEVICE VIGILANCE SYSTEM

- Overview of the medical device requirements for legal manufacturers
- Collection of medical device events
- Device vigilance reporting
- Device safety signals and trends
- Field Safety Corrective Actions
- Vigilance compliance monitoring

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

10:30 NETWORKING BREAK

11:00

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**
Mircea Ciuca, *Global Head Medical Safety,* **Organon**
Renea Schønemann Olsen, *Senior Post-Market Surveillance Manager, Scientific Affairs,* **3shape**

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

11:30

ROUNDTABLE DISCUSSIONS 60MIN

Join roundtable discussions with our speakers and engage in discussions on trending topics moderated by industry experts.
Each delegate can choose to attend both discussions.

ROUNDTABLE 1: REGULATORY AFFAIRS DEVELOPMENT - REQUIREMENTS AND CHALLENGES

Verena Kieferle, *Director Global Regulatory Affairs,* **Vantive**

ROUNDTABLE 2: 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**

12:30 LUNCH BREAK

TALENT MANAGEMENT AND DEVELOPMENT IN MEDICAL DEVICE

13:30

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

Massimo Kubon, *Vice Dean of Faculty Engineering & Technology: Marketing & International Affairs,* **Furtwangen University**

SAFETY & COMPLIANCE TRACK

11:30

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**

ROUNDTABLE 3: AI ACT

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

12:30 LUNCH BREAK

14:00

ROUNDTABLE 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)

ROUNDTABLE 1: SUCCESSFUL TEAMS: HOW TO MANAGE EVERYONE'S REQUESTS

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

ROUNDTABLE 2: HUMAN RESOURCE MANAGEMENT

Massimo Kubon, *Vice Dean of Faculty Engineering & Technology: Marketing & International Affairs,* **Furtwangen University**

15:00 END OF CONFERENCE

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. 7 - 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

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WHY? SUMMITS

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Disclamer:
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