WHY? SUMMITS

Updated: 1 April, 2025
for the latest programe update, please download agenda on conference website

April 9 - 10, 2025

Chicago, Illinois, USA

DoubleTree by Hilton Hotel Chicago - Magnificent Mile
300 E. Ohio Street, Chicago, Illinois, 60611, USA

2nd Edition American MedTech Summit

Project and Portfolio Management Conference

&

Medical Device Safety and Compliance Conference

Premium Gold Partner

Planisware

Gold Partners

PDWARE

regoconsulting

planview

west monroe

IZIEL

FLINN

Silver Partners

GLOBALPARTNERSTRAINING

GLOBAL

Recall Results
A Division of Realtime Results

Why did we create American 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 American 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 Chicago 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 American Medtech Summit stand out?

The **American 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.
L&D Change Management and Training Leader
Terumo Medical Corp.
★★★★★

„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
- Patient-Centric Device Development and Usability

Industry Pioneers Attending From

PPM Speakers

In the Chair

Karen Forsha
L&D Change Management and Training Leader
Terumo Medical Corp.

James Pavlovich
Vice President Customer Experience and Operations
Straumann Group

Christian Hasselberg
Senior Delivery Leader
Elekta

Michael Seelig
Sr. Portfolio Manager
Dexcom

Noel Sobelman
Partner
Accel Management Group

Aimee Rodrigues
VP of Life Sciences
Planisware

Susan Schmitt
Sr. Program Manager, EU MDR
J&J (Vision Care)

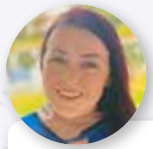
Verena Kieferle
Director Global Regulatory Affairs
Vantive

Bre Jacobs
Senior Program Manager, Strategy and New Opportunities, Cardiac Rythm Management
Medtronic

Dirk Gabriel
VP R&D Patient Monitoring Systems
Dräger

Christopher Buder
VP, Portfolio Strategy
Cardinal Health

Mitesh Sheth
NPI Manufacturing and Supplier Engineering Leader
Procept BioRobotics



Emily Shafer
Engineering Project Manager
Arthrex

PPM Speakers

Gianluca Puliti
Associate Director, R&D Program Excellence
BD

Vamsee Rangavajhala
General Manager - DoseWatch & Analytics
GE HealthCare

Jonathan Cote
R&D Program Management Associate Director
BD

Jacob Cancelliere
VP of Account Enablement
Rego Consulting

Wes McCoubrie
Senior Vice President
Rego Consulting

Fabrizio Battaglia
Executive Partner
Global Partners Training

Ori Schibi
Associate Partner
Global Partners Training

Douglas Mandart
Vice President of Professional Services
Planisware

Atul Mahajan
Director of Engineering Services
IZiel Healthcare

Sarra De Valence
VP of Operations and Medical Device Services
GLOBAL Regulatory Writing & Consulting

Phil Wolf
Senior Vice President, Enterprise & On Demand Products
PDWare

Carrie Nauyalis
Executive in Residence
Planview

Safety & Compliance Speakers

WHY? SUMMITS

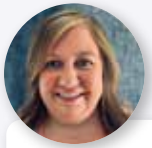
Abhinav Singh
Staff Software Quality Engineer
iRhythm Technologies

Adam Welsh
Partner Life Sciences
West Monroe

Astha Jaiswal
Manager, Regulatory Affairs
Cardinal Health

Elizabeth Baker
Associate Professor
Virginia Commonwealth University

Faiza Ahmed
Manager, Regulatory Affairs, Global Distribution
Intuitive



Natasha Nalle
Senior Quality Engineer
BLUE SPARK TECHNOLOGIES

Shannon Campbell
VP, Medical & Clinical Affairs
Optina Diagnostics

Sharon Perez
Vice President, Global Medical Safety
Novocure

Taylor Dieringer
Staff Quality Engineer - Risk Management
iRhythm Technologies

Guy Starbuck
Co-Founder and CTO
AIQ Solutions

Ruth Phillips
VP Medical Affairs
BLUE SPARK TECHNOLOGIES

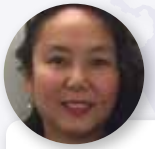
Wendel Smith
Sr VP Quality Product Safety
Edwards Lifesciences

Khaudeja Bano
Vice President Combination Product Quality
Genentech/Roche

Pat Baird
Sr. Regulatory Specialist
Philips

In the Chair

Melissa Pieplow
Director, Complaints Vigilance
Intuvie



Michelle Schiltz-Taing
Regulatory Affairs Manager
Hollister Incorporated

Ramya Sudula
Manager, Regulatory Affairs
BIOTRONIK Canada Inc.

Steven Lupo
Partner Life Sciences
West Monroe

Manisha Gokuli
Regulatory Affairs Consultant

Steven Reichen
Founding Member
Flinn.ai

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

EVER CHANGING REGULATORY ENVIRONMENT

8:30am

KEYNOTE: ADAPTING TO REGULATORY EVOLUTION: A CASE STUDY ON NAVIGATING EU MDR AND IVDR COMPLIANCE

Delve into a case study showcasing a medical device company's journey to align with the EU MDR and IVDR. This session will cover strategic planning, resource allocation, and overcoming regulatory hurdles, providing a roadmap for other companies facing similar challenges in maintaining compliance amidst evolving regulations.

Susan Schmitt, *Sr. Program Manager, EU MDR,* **J&J (Vision Care)**

9:00am

CASE STUDY: DRIVING MEDTECH INNOVATION: PRACTICAL INSIGHTS FOR BALANCING SPEED, RISK, AND QUALITY

In the fast-paced and high-stakes world of MedTech, balancing innovation with the need for speed and risk management is a critical challenge. This presentation explores strategies for effectively navigating the complex landscape of medical technology development, where rapid advancement often meets technological challenges, market competition, and clinical trial concerns. We will examine best practices for accelerating time-to-market without compromising product quality or compliance, discuss approaches for managing risk in the face of uncertainty, and highlight the role of benchmarking against industry standards. By leveraging practical insights, participants will gain actionable knowledge on how to drive innovation while maintaining a disciplined focus on both risk mitigation and operational efficiency in MedTech projects.

Aimee Rodrigues, *VP of Life Sciences,* **Planisware**
Douglas Mandart, *Vice President of Professional Services,* **Planisware**

SAFETY & COMPLIANCE TRACK

EU MDR/IVDR COMPLIANCE CHALLENGES

8:30am

KEYNOTE: GLOBAL MARKETS´ REGULATIONS – CHANGES, CHALLENGES AND MANUFACTURER'S CONTROLS.

This session will dive deep into the emerging medical device requirements and challenges. These requirements mandate controls and processes to be adopted by the manufacturer, which will also be highlighted.

Faiza Ahmed, *Manager, Regulatory Affairs, Global Distribution,* **Intuitive**

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?

Michelle Schiltz-Taing, *Regulatory Affairs Manager,* **Hollister Incorporated**
Astha Jaiswal, *Manager, Regulatory Affairs,* **Cardinal Health**
Sarra De Valence, *VP of Operations and Medical Device Services,* **GLOBAL Regulatory Writing & Consulting**

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

9:30am

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?

Moderator: Faiza Ahmed, *Manager, Regulatory Affairs, Global Distribution,* **Intuitive**
Christian Hasselberg, *Senior Delivery Leader,* **Elekta**
Vamsee Rangavajhala, *General Manager - DoseWatch & Analytics,* **GE HealthCare**
Michael Seelig, *Sr. Portfolio Manager,* **Dexcom**
Verena Kieferle, *Director Global Regulatory Affairs,* **Vantive**

10:00am NETWORKING BREAK

ACCELERATED TIME-TO-MARKET & INNOVATIONS

10:30am

KEYNOTE: A BLUEPRINT FOR PROGRAM EXCELLENCE

- Building a culture of excellence in R&D through leadership, collaboration and innovation
- Implementing lean and agile principles to optimize medical device development processes
- Aligning teams and resources to ensure seamless execution and successful program outcomes

Gianluca Puliti, *Associate Director, R&D Program Excellence,* **BD**
Jonathan Cote, *R&D Program Management Associate Director,* **BD**

SAFETY & COMPLIANCE TRACK

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
- 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

Sharon Perez, *Vice President, Global Medical Safety,* **Novocure**

10:00am NETWORKING BREAK

10:30am

CASE STUDY: COMPLAINTS: FRIENDS OR FOES

While complaint handling is an integral part of our regulatory duties and post market surveillance, complaints and well-constructed complaint handling program can provide invaluable insights for all aspects of your company's organization. It is also your forward-facing customer service piece and does your company see it as a crown jewel or a thorny part of the business.

Wendel Smith, *Sr VP Quality Product Safety,* **Edwards Lifesciences**

11:00am

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.

Sharon Perez, *Vice President, Global Medical Safety,* **Novocure**
Wendel Smith, *Sr VP Quality Product Safety,* **Edwards Lifesciences**
Ramya Sudula, *Manager, Regulatory Affairs,* **BIOTRONIK Canada Inc.**

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

11:00am

CASE STUDY: THE CORE CAPABILITIES OF A STRATEGIC PORTFOLIO MANAGEMENT (SPM) APPLICATION

SPM, at its foundation, is a framework of business capabilities, supporting processes, and enabling technology. To be considered a true SPM solution, enterprise tools must go beyond the traditional PPM functions. In this session, we will discuss and showcase a comprehensive list of those capabilities an industry leading SPM application, all while provide guidance for growth and maturation in the areas that are most important to your organization.

Jacob Cancelliere, *VP of Account Enablement,* **Rego Consulting**
Wes McCoubrie, *Senior Vice President,* **Rego Consulting**

11:30am

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.

Moderator: Noel Sobelman, *Partner,* **Accel Management Group**
Christian Hasselberg, *Senior Delivery Leader,* **Elekta**
Emily Shafer, *Engineering Project Manager,* **Arthrex**
Vamsee Rangavajhala, *General Manager - DoseWatch & Analytics,* **GE HealthCare**

12:00pm LUNCH BREAK

STRATEGIC ALLIANCES: SUPPLY CHAIN RESILIENCE

SAFETY & COMPLIANCE TRACK

POST-MARKET SURVEILLANCE AND REAL-WORLD DATA

11:30am

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, inform regulatory decisions, and drive innovation.

Taylor Dieringer, *Staff Quality Engineer - Risk Management,* **iRhythm Technologies**

12:00pm LUNCH BREAK

1:00pm

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

Shannon Campbell, *VP, Medical & Clinical Affairs,* **Optina Diagnostics**
Sharon Perez, *Vice President, Global Medical Safety,* **Novocure**
Melissa Pieplow, *Director, Complaints Vigilance,* **Intuvie**
Manisha Gokuli, *Regulatory Affairs Consultant*

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

1:00pm

KEYNOTE: BUILDING VENDOR RELATIONSHIPS MANAGEMENT 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

Mitesh Sheth, *NPI Manufacturing and Supplier Engineering Leader,* **Procept BioRobotics**

1:30pm

CASE STUDY: BETTER PMO DECISION-MAKING THROUGH DASHBOARDING

We have observed that organizations spend significant effort with PowerBI, Snowflake, and other BI tools building informational views & reports from their transactional data to support leadership. This is certainly a good approach for certain analysis, but a good portion of what the PMO needs for decision-making can be addressed in real-time, using a well thought out dashboarding strategy.

Phil Wolf, *Senior Vice President, Enterprise & On Demand Products,* **PDWare**

2:00pm

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.

Christopher Buder, *VP, Portfolio Strategy,* **Cardinal Health**
Mitesh Sheth, *NPI Manufacturing and Supplier Engineering Leader,* **Procept BioRobotics**
Verena Kieferle, *Director Global Regulatory Affairs,* **Vantive**

SAFETY & COMPLIANCE TRACK

1:30pm

CASE STUDY: PRACTICAL USES OF MEDICAL DEVICE DATA AND CYBERSECURITY IMPLICATIONS

- Secure collection, storage, and transfer of real-world data (RWD) to monitor device performance and address issues.
- Leveraging RWD from internal dashboards, customer feedback, and publications to enhance customer experience and meet PMS requirements (MDR/MDSAP/FDA).
- Ensuring device safety, effectiveness, and positive user experience to drive business growth.
- Collaborating with Medical Affairs for customer insights, data availability, and emerging information.

Natasha Nalle, *Senior Quality Engineer,* **BLUE SPARK TECHNOLOGIES**
Ruth Phillips, *VP Medical Affairs,* **BLUE SPARK TECHNOLOGIES**

2:00pm ROUNDTABLE SESSIONS (60 min)

ROUNTABLE 1: AI IN ACTION: ADDRESSING COMPLAINTS, COMPLIANCE & DECISION-MAKING

During this roundtable we will, explore current trends and how organizations are leveraging AI to address customer complaints & adverse events. Participants will collaborate to address safety & compliance concerns, regarding AI usage, to help drive decision making.

Steven Lupo, *Partner Life Sciences,* **West Monroe**
Adam Welsh, *Partner Life Sciences,* **West Monroe**

ROUNDTABLE 2: HANDLING FDA WARNING LETTERS

Melissa Pieplow, *Director, Complaints Vigilance,* **Intuvie**

3:00pm NETWORKING BREAK

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

2:30pm NETWORKING BREAK

TACKLING PMO CHALLENGES

3:00pm

KEYNOTE: DRIVING INNOVATION THROUGH INTEROPERABILITY: A PMO CHALLENGE

Interoperability is the ability to seamlessly exchange data between devices and systems in a standardized way. However, implementing interoperable solutions introduces additional challenges for project management. The PMO must address interfaces, portfolio management, priorities, and further non-functional aspects to manage complexity effectively. This presentation will address some examples.

Dirk Gabriel, *VP R&D Patient Monitoring Systems,* **Dräger**

3:30pm

CASE STUDY: NAVIGATING ACQUISITION INTEGRATION IN THE ERA OF AI: STRATEGIES FOR SEAMLESS TRANSITIONS AND ENSURING CONTINUITY

Topics Covered:

- Effective change management strategies for M&A success while ensuring compliance in a dynamic business environment.
- The impact of AI on change management strategies, enhancing M&A outcomes and compliance excellence in MedTech.
- AI's pivotal role in driving successful M&A activities, enabling data-driven decisions, and ensuring regulatory compliance.
- How AI streamlines M&A processes, focusing on compliance and operational efficiency.

Atul Mahajan, *Director of Engineering Services,* **IZiel Healthcare**

SAFETY & COMPLIANCE TRACK

3:30pm

WORKSHOP: HARMONIZING IMPACTS OF REAL-WORLD DATA (RWD) AND REAL-WORLD EVIDENCE (RWE) TO OBTAIN REGULATORY APPROVALS (60MIN)

- 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

Shannon Campbell, *VP, Medical & Clinical Affairs,* **Optina Diagnostics**

4:30pm ROUNDTABLE DISCUSSIONS (60 min)

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

Taylor Dieringer, *Staff Quality Engineer - Risk Management,* **iRhythm Technologies**

ROUNDTABLE 2: CYBERSECURITY CONSIDERATIONS FOR ARTIFICIAL INTELLIGENCE SYSTEMS

Pat Baird, *Sr. Regulatory Specialist,* **Philips**

ROUNDTABLE 3: REGULATORY PROJECT INVOLVEMENT AND INTERACTIONS WITH FDA: GETTING DEVICES TO US MARKET

Michelle Schiltz-Taing, *Regulatory Affairs Manager,* **Hollister Incorporated**

ROUNDTABLE 4: GLOBAL REGULATORY SHIFT TOWARDS PROACTIVE POST MARKET SURVEILLANCE: CONSIDERATIONS FOR MANUFACTURERS

Astha Jaiswal, *Manager, Regulatory Affairs,* **Cardinal Health**

5:30pm THE END

6:00pm COCKTAIL RECEPTION

Conference Agenda

DAY 1

PROJECT AND PORTFOLIO TRACK

4:00pm

KEYNOTE: UNACCOUNTABILITY IN PROJECT MANAGEMENT

What happens when organizations deliver outcomes that are wildly different from their stated objectives?

Why is it so hard to find root causes and just fix them?

Why is it that no one seems to own the decisions?

Why is it that the strategic vision does not fully align with operational challenges faced by frontline employees?

This presentation will:

- Give us a crash course in Cybernetics, which is the study of the control of systems.
- Provide the audience with a cheat code to understanding complex systems.
- Tips and tricks to creating more accountable and resilient organizations.
- Helping good people improve a bad system in order to avoid "least pain planning."

Christian Hasselberg, *Senior Delivery Leader,* **Elekta**

4:30pm ROUNDTABLE DISCUSSIONS (60 min)

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

Susan Schmitt, *Sr. Program Manager, EU MDR,* **J&J (Vision Care)**
Jonathan Cote, *R&D Program Management Associate Director,* **BD**

ROUNDTABLE 2: REGULATORY AFFAIRS DEVELOPMENT - REQUIREMENTS AND CHALLENGES

Verena Kieferle, *Director Global Regulatory Affairs,* **Baxter (Vantive)**

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

Bre Jacobs, *Senior Program Manager, Strategy and New Opportunities, Cardiac Rythm Management*, **Medtronic**
Christopher Buder, *VP, Portfolio Strategy,* **Cardinal Health**

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

Christian Hasselberg, *Senior Delivery Leader,* **Elekta**
Emily Shafer, *Engineering Project Manager,* **Arthrex**

ROUNDTABLE 5: DRIVING INNOVATION IN LEGACY ORGANIZATIONS

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

5:30 THE END

6:00pm COCKTAIL RECEPTION

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

DIGITAL TRANSFORMATION AND INTEGRATION OF AI IN PROJECT & PORTFOLIO MANAGEMENT

8:30am

KEYNOTE: HOW CAN AI AND DATA ANALYTICS HELP PM

With the constant evolution of artificial intelligence and the use of machine learning in medical devices, how do we decide when is AI helping or torturing us?

- How is AI and data enabling device innovation?
- Why are these technologies important?
- Where is AI now?
- How to stay on track with the increasing amount of data that digital technologies provide us?
- The future role of project management

Bre Jacobs, *Senior Program Manager, Strategy and New Opportunities,* **Cardiac Rythm Management**

9:00am

CASE STUDY: FROM PLANNING TO PROFITS: MAXIMIZING R&D INVESTMENT RETURNS

Discover the implementation framework that has enabled leading medical device companies to achieve extraordinary ROI from their Strategic PPM investments – accelerating time-to-market, improving on-time launches, and increasing project throughput. Learn critical practices for aligning outcomes to strategy, establishing performance baselines, optimizing processes for maximum efficiency, measuring progress, and fostering the cultural changes necessary for sustained success. Whether implementing PPM for the first time or looking to extract greater value from existing systems, you'll gain an actionable blueprint for achieving breakthrough ROI within your organization.

Carrie Nauyalis, *Executive in Residence,* **Planview**

SAFETY & COMPLIANCE TRACK

CYBERSECURITY IN MEDICAL DEVICES

9:00am

KEYNOTE: 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.

Guy Starbuck, *Co-Founder and CTO,* **AIQ Solutions**

9:30am

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.

Shannon Campbell, *VP, Medical & Clinical Affairs,* **Optina Diagnostics**
Guy Starbuck, *Co-Founder and CTO,* **AIQ Solutions**

10:00am

KEYNOTE: CLOUD COMPLIANCE IN MEDICAL DEVICES: PREPARING FOR THE NEW STANDARDS

This session will discuss the core challenge of using public cloud services in medical devices and the recommended approaches in the soon-to-be-published "Guidance for the appropriate use of public cloud computing to enable medical device functions."

Pat Baird, *Sr. Regulatory Specialist,* **Philips**

10:30am NETWORKING BREAK

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

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.

Christian Hasselberg, *Senior Delivery Leader,* **Elekta**
Abhinav Singh, *Staff Software Quality Engineer,* **iRhythm Technologies**
Michael Seelig, *Sr. Portfolio Manager,* **Dexcom**
Dirk Gabriel, *VP R&D Patient Monitoring Systems,* **Dräger**

10:00am

KEYNOTE: THE FUTURE OF PORTFOLIO AUTOMATION & AI

- What are the expectations for the future of automation and AI driven project portfolio management?
- How can you streamline and automate your PMO of the future today?
- Using collaborative technology to integrate your distributed PMOs across your organization?
- A look into how future innovations can streamline collaboration across departments such as new product development, IT, clinical, and regulatory.

Michael Seelig, *Sr. Portfolio Manager,* **Dexcom**

10:30am NETWORKING BREAK

SAFETY & COMPLIANCE TRACK

RISK MANAGEMENT AS KEY MANAGEMENT TOOL IN EVER CHANGING ENVIRONMENT

11:00am

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.

Khaudeja Bano, *Vice President Combination Product Quality,* **Genentech/Roche**

11:30am

CASE STUDY: REAL-WORLD AI VALIDATION SKILLS

No high-level fluff, hands-on value. Learn where to best use AI in your QM/RA processes and how to cut through the AI buzzword noise by understanding actual validation frameworks.

Steven Reichen, *Founding Member,* **Flinn.ai**

12:00am

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.

Guy Starbuck, *Co-Founder and CTO,* **AIQ Solutions**
Melissa Pieplow, *Director, Complaints Vigilance,* **Intuvie**
Manisha Gokuli, *Regulatory Affairs Consultant*

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

ALIGNING PROJECT AND PROGRAM EXECUTION TO CORPORATE STRATEGY

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

Christopher Buder, *VP, Portfolio Strategy,* **Cardinal Health**

11:30am

CASE STUDY: OPTIMIZING AI AND HUMAN SKILLS FOR CURRENT AND FUTURE CHALLENGES

What is the proper emphasis of your investments right now – Artificial intelligence or Human skills – and in what balance? How will critical management and contributor roles in this industry evolve as AI continues to surge? And how do you take advantage of today's rapid change to sharpen the skills and behaviors of your people for this exciting future?

Join former technology executives as they revolutionize learning designs and share a 'validated change framework' your company can put to work right away to address today's challenges and prepare for what is to come.

This session is ideal for MedTech executives and managers looking for solid footing in a fast-changing, AI-forward environment, with tips on how to help your people operate with greater confidence and optimism for their future!

Fabrizio Battaglia, *Executive Partner,* **Global Partners Training**
Ori Schibi, *Associate Partner,* **Global Partners Training**

SAFETY & COMPLIANCE TRACK

12:30pm LUNCH BREAK

AGILE EXCELLENCE IN MEDICAL DEVICE SOFTWARE

1:30pm

CASE STUDY: AGILE SOFTWARE DEVELOPMENT: A SOLUTION IN THE SOFTWARE DEVELOPMENT LIFECYCLE OF MEDICAL DEVICES FOR EARLY MARKET ENTRY

- Understand how Agile methodologies accelerate market entry while ensuring regulatory compliance.
- Explore key Agile practices to enhance collaboration, streamline processes, and improve software quality.
- Apply Agile principles to manage changes effectively, ensuring timely delivery of compliant medical device software.

Abhinav Singh, *Staff Software Quality Engineer,* **iRhythm Technologies**

QUALITY MANAGEMENT AND COMPLIANCE

2:00pm

CASE STUDY: HANDLING FDA WARNING LETTERS

Current Food and Drug Administration (FDA) standards require that quality systems ensure safe drug manufacturing and clinical trial oversight; these systems must include established regulatory compliance and risk mitigation processes.

Warning letters from the FDA or observations noted during an FDA inspection regarding noncompliance or nonconformance are a result of a dysfunctional quality system. This case study guides you how to work with FDA and handle similar situations that can occur during product development, process development & process maintenance.

Melissa Pieplow, *Director, Complaints Vigilance,* **Intuvie**

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

12:00pm

KEYNOTE: IS THIS A PROJECT?

The company strategy is set; annual department goals are set. The next step is to figure out how to deliver against those goals. When do we need the structure of a project? When do we need a project manager? Let's break down the criteria for needing the structure and focus of managing a project vs. managing people to achieve department goals.

James Pavlovich, *Vice President Customer Experience and Operations,* **Straumann Group**

12:30pm LUNCH BREAK

TALENT & STRATEGY MANAGEMENT AND DEVELOPMENT IN MEDICAL DEVICE

1:30pm

KEYNOTE: EMPLOYEE WELL-BEING AND ITS IMPACT ON ORGANIZATIONAL OUTCOMES: RESILIENT LEADERSHIP CAN BE YOUR SUPER POWER

This talk will delve into the critical concept of personal resilience, emphasizing its pivotal role in organizational success. It will unravel resilience and aid leaders in cultivating personal resilience within themselves and their teams. The program will underscore the significance of resilience in navigating challenges, fostering adaptability, and maintaining productivity amidst adversity. Additionally, it will highlight the interconnectedness between employee well-being and organizational performance, emphasizing the positive impact of a supportive and resilient workforce on overall outcomes. Through insight, participants will gain a deeper understanding of how fostering resilience and prioritizing employee well-being can drive organizational effectiveness and long-term success.

Karen Forsha Ph.D., *L&D Change Management and Training Leader,* **Terumo Medical Corp.**

SAFETY & COMPLIANCE TRACK

2:30pm

PANEL DISCUSSION: 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.

Khaudeja Bano, *Vice President Combination Product Quality,* **Genentech/Roche**
Ramya Sudula, *Manager, Regulatory Affairs,* **BIOTRONIK Canada Inc.**
Verena Kieferle, *Director Global Regulatory Affairs,* **Vantive**

3:00pm NETWORKING BREAK

3:30pm

WORKSHOP: 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.

Elizabeth Baker, *Associate Professor,* **Virginia Commonwealth University**

4:30pm THAT'S A WRAP!
END OF THE CONFERENCE.

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

2:00pm

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.

MODERATOR: Noel Sobelman, *Partner,* **Accel Management Group**
Bre Jacobs, *Senior Program Manager, Strategy and New Opportunities, Cardiac Rythm Management,* **Medtronic**
Christopher Buder, *VP, Portfolio Strategy,* **Cardinal Health**
Vamsee Rangavajhala, *General Manager - DoseWatch & Analytics,* **GE HealthCare**

2:30pm

PANEL DISCUSSION: 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.

MODERATOR: Noel Sobelman, *Partner,* **Accel Management Group**
Emily Shafer, *Engineering Project Manager,* **Arthrex**
Gianluca Puliti, *Associate Director, R&D Program Excellence,* **BD**
James Pavlovich, *Vice President Customer Experience and Operations,* **Straumann Group**
Sarra De Valence, *VP of Operations and Medical Device Services,* **GLOBAL Regulatory Writing & Consulting**

3:00pm NETWORKING BREAK

Conference Agenda

DAY 2

PROJECT AND PORTFOLIO TRACK

3:30pm BREAKOUT SESSIONS (60 min)
Participants can choose to participate either in a roundtable discussion or in the workshop.

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

Verena Kieferle, *Director Global Regulatory Affairs,* **Baxter (Vantive)**

ROUNDTABLE 2: SUCCESSFUL TEAMS - HOW TO MANAGE EVERYONE'S REQUESTS

Susan Schmitt, *Sr. Program Manager,* **EU MDR, J&J (Vision Care)**
James Pavlovich, *Vice President Customer Experience and Operations,* **Straumann Group**

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

Gianluca Puliti, *Associate Director, R&D Program Excellence,* **BD**

ROUNDTABLE 4: DATA READINESS FOR AI ADOPTION

Vamsee Rangavajhala, *General Manager - DoseWatch & Analytics,* **GE HealthCare**

WORKSHOP: CREATIVITY AND CREATIVE PROBLEM SOLVING

Creativity and creative problem solving consists of tools and habits that help you and your team become more creative. During this session, you will learn simple tricks and methods to encourage a more creative work environment. Learn how to better structure effective team meetings, workshops, and all-inclusive ideation sessions. These approaches will help you look at solving problems in a new creative way. You may even learn about some great work habits to boost your career!

Jacob Cancelliere, *VP of Account Enablement,* **Rego Consulting**

4:30pm THAT'S A WRAP! END OF THE 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. 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

west monroe

PDWARE

Tempus Resource 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: 1 April, 2025
for the latest programe update, please
download agenda on conference website

Attending:

Liza Zhaivoronok
Vice President, PPM World Tour
liza.zhaivoronok@whysummits.com

Speaking:

Andrea Beneová
andrea.b@whysummits.com

Speaking:

Kristína Šestáková
kristina.sestakova@whysummits.com

Sponsoring:

Srihari Kamban
shk@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

$2349