
WHY? SUMMITS
Featuring 2 conferences:
American MedTech Summit
Chicago, Illinois, USA
WorkLife Meetings by JLL, 222 W Merchandise Mart Plaza Chicago, IL 60654
Gold Sponsors
Planisware
rego consulting
Project and Portfolio Management Conference
2024 April 11 - 12
Medical Device Safety and Compliance Conference
2024 April 11 - 12

Event format

Why attend this exclusive joint 2 day-long event?

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

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

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

Our mission

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

Our vision

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

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

What to expect?

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

Key Topics

Project and Portfolio Management Conference

- Demonstrating and Increasing the value of the pmo
- Medical Device Risk Management – developing safe and effective devices efficiently
- How multifaceted skill sets win in a singular world
- Hybrid project management and adoption for business agility
- Bolstering Project Prioritization - tips for bringing objectivity to the process
- Medical Device Validation
- How can AI and data analytics help PM
- Professional Development - what's important for individuals and companies themselves

… and more!

Key Topics

Medical Device Safety and Compliance Conference

- Challenges of Dynamic Regulatory Landscape
- Medical Device Safety and Security
- FDA Position, Regulations and Standards
- Building Strong Quality Management System
- New Era of Cybersecurity Threats
- Effective Medical Device Vigilance Process
- Post Market Surveillance
- Next Generation Tech and Data
- Real World Data & Real World Evidence

... and more!

Speakers and Panelists

Planisware

Aimee Rodrigues
VP Life Sciences PPM Practices
Planisware

Alexis Kuhne
PMO Director

Johnson & Johnson

Carl Legge
E2E Portfolio Management Platform Lead, DePuy Synthes
Johnson & Johnson

Boston Scientific

Darrin Dickerson
VP of Program and Portfolio Management
Boston Scientific

rego consulting

Jacob Cancelliere
VP, Account Enablement
Rego Consulting

Jenny Finkbiner
Sr. Manager, PMO

Edwards

John Michelot
Senior director Program Management
Edwards Lifesciences

Elekta

Christian Hasselberg
Director, Head of Program – Oncology Informatics,
Elekta

BD

Graham Howe
Vice President
Program Management Office
BD Biosciences

BD

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

Speakers and Panelists

Michael O'Connor
Senior Research Program Director,
Program Management
Medtronic

Michael Seelig
Sr. Portfolio Manager
Dexcom

Mike McShane
Sr. Program Manager
Viant Medical

Monika Campbell
Sr. Manager, IT Project and Portfolio
Management
Karl Storz

In the Chair

Noel Sobelman
Partner
Accel Management Group

Susie Girard
Senior R&D Program Manager
J&J MedTech

Tim Rumbaugh
Vice President, Program Management
Edwards Lifesciences

Wes McCoubrie
VP, Delivery
Rego Consulting

Speakers and Panelists

Adhiraj Mamak
Sr. Manager, Quality Strategy & Alliances
Illumina

Almaas Qaderi
Director and Corporate Counsel
Jazz Pharmaceuticals

Bijan Elahi
Corporate Advisor, Educator
Medtronic

Elizabeth Baker
Associate Professor
Virginia Commonwealth University

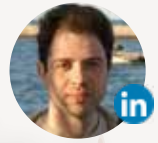
Faith Du
Associate Director of Regulatory Affairs
EUROIMMUN

Jeffrey Blatnik
Senior Vice President, Quality
Edwards Lifesciences

Karen Forsha
Sr. Manager, Quality Systems
Terumo

Medha Sateesh Bharadwaj
Senior Regulatory Affairs Specialist
Intuitive

Nicole Wydeven
Post Market Clinical Strategy, Sr. Manager
Boston Scientific



Oleg Yusim
VP, Chief Product Security Officer
Illumina

Speakers and Panelists

Paul Mlynarczik
Senior Analyst, Post Market Surveillance
Johnson&Johnson

Pat Baird
Regulatory Head of Global Software Standards
Philips

Sarah Paro
Associate Director-Corporate QMS
Zimmer Biomet

Taylor Dieringer
Staff Quality Engineer
iRhythm Technologies

In the Chair

Queenita Fernandes
Sr. Medical Safety Manager
Medtronic

Agenda

5:30pm

Night before the event - Meet & Greet

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

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

Day1

8.00am **REGISTRATION**

QUALITY MANAGEMENT FROM DIFFERENT POINT OF VIEWS

8.30am **KEYNOTE:** QUALITY MANAGEMENT AND COMPLIANCE - 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.

Sarah Paro, *Associate Director-Corporate QMS,* **Zimmer Biomet**

9.00am **PANEL DISCUSSION:** QUALITY MANAGEMENT AND COMPLIANCE – COMPLYING TO QUALITY SYSTEM REGULATIONS AROUND THE WORLD

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

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

Adhiraj Mamak, *Sr. Manager, Quality Strategy & Alliances,* **Illumina**
Sarah Paro, *Associate Director-Corporate QMS,* **Zimmer Biomet**
Karen Forsha, *Sr. Manager, Quality Systems,* **Terumo**

9.30am **RESERVED PRESENTATION:** TOP PPM AND WORK MANAGEMENT TRENDS FOR 2024

Each year, Rego Consulting guides hundreds of companies through implementations, upgrades, trainings, and organizational change management efforts. At the end of the year, we poll our +150 expert guides to identify the emerging trends and themes they have observed, firsthand, while working with these organizations. We compile these findings into our annual PPM and Collaborative Work Management Trends Report.

In this session, Rego's senior strategists will present the top trends for 2024 and highlight ways organizations can address these trends, including insights you can start putting into action.

Wes McCoubrie, *VP, Delivery,* **Rego Consulting**
Jacob Cancelliere, *VP, Account Enablement,* **Rego Consulting**

10.00am **NETWORKING BREAK**

Day1

10.30am **PANEL DISCUSSION:** PM ROLE IN THE QUALITY MANAGEMENT SYSTEM

- From which angles to look at the quality
- KPIs from user/ functional/ design requirements point of view vs. Stakeholders requirements
- Creation of Standards for operating in EU/US
- Cost of Poor Quality

Noel Sobelman, *Partner,* **Accel Management Group**
Christian Hasselberg, *Director, Head of Program – Oncology Informatics,* **Elekta**
Michael Seelig, *Sr. Portfolio Manager,* **Dexcom**
Susie Girard, *Senior R&D Program Manager,* **J&J MedTech**

11.00am **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.

Aimee Rodrigues, *VP Life Sciences PPM Practices,* **Planisware**

11.30am **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. Through examples, personal experience, and resources, the Karen Forsha will explore real-life situations to help 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, *Sr. Manager, Quality Systems,* **Terumo**

12.00pm **LUNCH BREAK**

FUTURE VALUE OF THE PMO AND PORTFOLIO FUNCTION

1.00pm **KEYNOTE:** DEMONSTRATING AND INCREASING THE VALUE OF THE PMO

How do we value the PMO? What role does the PMO play in value creation?

Graham Howe, *Vice President, Program Management Office,* **BD Biosciences**

1.30pm **PANEL DISCUSSION:** EVOLUTION OF PMO and the PORTFOLIO FUNCTION

- Maturity of the PMO in your organization might be different. Project Managers working on their projects in medical device companies face new requirements as their PMO evolves.
- Listen to this panel discussion to benchmark the role of Project Managers in both early stages of PMO and a mature PMO function. Challenges, methodologies and approaches to value creation topics will be discussed.

Jenny Finkbiner, *Sr. Manager, PMO,* **Stryker**
Carl Legge, *E2E Portfolio Management Platform Lead, DePuy Synthes,* **Johnson & Johnson**
Graham Howe, *Vice President, Program Management Office,* **BD Biosciences**
Tim Rumbaugh, *Vice President, Program Management,* **Edwards Lifesciences**
Monika Campbell, *Sr. Manager, IT Project and Portfolio Management,* **Karl Storz**
Gunther Lenz, *Vice President Software R&D, Biosciences,* **BD Biosciences**

2.00pm **CASE STUDY:** APPLYING SCALED AGILE FOR MEDICAL DEVICES

- How to integrate scaled agile effectively to achieve flow.

Christian Hasselberg, *Director, Head of Program – Oncology Informatics,* **Elekta**

2.30pm **CASE STUDY:** DIGITAL TRANSFORMATION IN PPM

Gunther Lenz, *Vice President Software R&D, Biosciences,* **BD Biosciences**

3.00pm **NETWORKING BREAK**

3.30pm **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 (see the topics on next page)

RISK MANAGEMENT AS KEY MANAGEMENT TOOL IN EVER CHANGING ENVIRONMENT

1.00pm **CASE STUDY:** RISK MEASUREMENT TOOLS AND METHOD ASSESSING EFFECTIVENESS OF RISK MANAGEMENT PLANS

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

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

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

Taylor Dieringer, *Staff Quality Engineer,* **iRhythm Technologies**

1.30pm **PANEL DISCUSSION:** SAFETY RISK MANAGEMENT IN THE WORLD OF ENHANCED CYBERSECURITY

As technology has advanced, so have the tactics of hackers. There is a new breed of cyberterrorism that's daunting. It's why enhanced cybersecurity must be a priority in all areas of healthcare, including medical devices. Medical information is exchanged between multiple stakeholders, such as manufacturers, healthcare providers, and suppliers. Robust security measures are required whenever data is exchanged through medical devices to mitigate breaches in security. In fact, the FDA is actively holding medical device manufacturers accountable for problems related to security, which is why risk management must remain a priority.

Medha Sateesh Bharadwaj, *Senior Regulatory Affairs Specialist,* **Intuitive**
Oleg Yusim, *VP, Chief Product Security Officer,* **Illumina**
Almaas Qaderi, *Director and Corporate Counsel,* **Jazz Pharmaceuticals**
Sarah Paro, *Associate Director-Corporate QMS,* **Zimmer Biomet**
Bijan Elahi, *Corporate Advisor, Educator,* **Medtronic**
Pat Baird, *Regulatory Head of Global Software Standards,* **Philips**

Roundtable Discussions

Day1

1. HYBRID PROJECT MANAGEMENT AND ADOPTION FOR BUSINESS AGILITY

Monika Campbell, *Sr. Manager, IT Project and Portfolio Management,* **Karl Storz**
Susie Girard, *Senior R&D Program Manager,* **J&J MedTech**

2. MEDICAL DEVICE DEVELOPMENT - WHAT TO BE PREPARED FOR AS A PROJECT MANAGER AT DIFFERENT STAGES OF MEDICAL DEVICE DEVELOPMENT

Michael O'Connor, *Senior Research Program Director, Program Management,* **Medtronic**
Michael Seelig, *Sr. Portfolio Manager,* **Dexcom**

3. BUILDING BENCH STRENGTH FOR A PMO

Jenny Finkbiner, *Sr. Manager, PMO*
Noel Sobelman, *Partner,* **Accel Management Group**

Safety & Compliance Track

Day1

2.00pm **WORKSHOP:** SAFETY RISK MANAGEMENT IN COMPLIANCE WITH ISO 14971:2019

In this workshop you will learn the fundamentals of risk management in compliance with ISO 14971.

- The requirements of ISO 14971
- Hazards, Hazardous Situations, and Harms
- How to benefit from risk management

You will learn the language and vocabulary of risk management and will be able to better communicate the concepts of risk management. The interactive workshop includes quizzes and opportunities to exercise what you learn during the workshop.

Bijan Elahi, *Corporate Advisor,* **Educator, Medtronic**

3.00pm **NETWORKING BREAK**

3.30pm **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 (see the topics on next page)

1. MANAGING POST MARKET AND CLINICAL STUDIES WITH REQUIREMENTS OF ISO 14155 AND MDR TO REMAIN IN COMPLIANCE
Nicole Wydeven, *Post Market Clinical Strategy,* **Sr. Manager**

2. DEMONSTRATING GOOD MANUFACTURING PRACTICES THROUGH GUIDANCE OF ISO 13485 FOR DEVICE QUALITY AND CONSISTENCY
Taylor Dieringer, *Staff Quality Engineer,* **iRhythm Technologies**

3. ESTABLISHING AND MANAGING YOUR ECONOMIC OPERATORS (EO) AND PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE (PRRC) PER MDR/IVDR REQUIREMENTS AND ASSOCIATED MDCG GUIDANCE
Adhiraj Mamak, *Sr. Manager, Quality Strategy & Alliances*, **Illumina**

4. MEDICAL DEVICE RISK MANAGEMENT AND HUMAN FACTORS ENGINEERING
Jeffrey Blatnik, *Senior Vice President, Quality,* **Edwards Lifesciences**

Project and Portfolio Track

Day2

PRIORITISATION AND CAPACITY PLANNING OF PORTFOLIO

9.00am **KEYNOTE:** BENEFITS & BASICS OF LONG RANGE PORTFOLIO PLANNING (MEDICAL DEVICE)

During this presentation, Carl Legge reviews how a medical device organization plans procedurally to protect long term capacity, building a more reliable logistical supply chain network and so much more.

Carl Legge, *E2E Portfolio Management Platform Lead, DePuy Synthes,* **Johnson & Johnson**

9.30am **KEYNOTE:** HOW TO STREAMLINE & AUTOMATE YOUR PMO IN THE 21ST CENTURY?

- What worked in the past will likely not work in the future.
- The pathway to reach PMO technological transformation.
- Is there existing technology that can accelerate our PMO transformation goals?
- Overcoming the change curve and how to maximize new technology adoption.

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

10.00am **PANEL DISCUSSION:** PORTFOLIO SIMPLIFICATION

Carl Legge, *E2E Portfolio Management Platform Lead, DePuy Synthes,* **Johnson & Johnson**
Noel Sobelman, *Partner,* **Accel Management Group**
Michael Seelig, *Sr. Portfolio Manager,* **Dexcom**
Gunther Lenz, *Vice President Software R&D, Biosciences,* **BD Biosciences**
John Michelot, *Senior director Program Management,* **Edwards Lifesciences**

10.30am **NETWORKING BREAK**

PROJECT RISK & RESOURCE MANAGEMENT IN MEDICAL DEVICES

11.00am **KEYNOTE:** VISUALISATION OF RISK MANAGEMENT

Risks need to be evaluated and communicated to ensure stakeholders are appropriately informed. People learn and retain information differently, so why not make risk management more visual? This session will look at different ways to view program/project risks with the goal of transparent communication.

Susie Girard, *Senior R&D Program Manager,* **J&J MedTech**

11.30am **PANEL DISCUSSION:** RESOURCE MANAGEMENT OF PPM ON PROJECTS IN MEDICAL DEVICE COMPANIES

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

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

Tim Rumbaugh, *Vice President, Program Management,* **Edwards Lifesciences**
Christian Hasselberg, *Director, Head of Program – Oncology Informatics,* **Elekta**
Michael Seelig, *Sr. Portfolio Manager,* **Dexcom**
Darrin Dickerson, *VP of Program and Portfolio Management,* **Boston Scientific**
John Michelot, *Senior director Program Management,* **Edwards Lifesciences**

Safety & Compliance Track

Day2

BUILDING EFFECTIVE VIGILANCE PROCESS

8.30am **KEYNOTE:** BUILDING YOUR GLOBAL MEDICAL DEVICE RECALL AND VIGILANCE PROGRAM

- Global Recall and Vigilance Reporting Requirements
- Global Device Recall and Vigilance Project Management
- Electronic Management of Incidents
- Global Incident Reporting Processes
- Distribution of Recall and Field Safety Notices
- Global Recall and Vigilance Program Effectiveness

Faith Du, *Associate Director of Regulatory Affairs,* **EUROIMMUN**

9.00am **INTERACTIVE INTERVIEW:** 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.

Faith Du, *Associate Director of Regulatory Affairs,* **EUROIMMUN**
Queenita Fernandes, *Sr. Medical Safety Manager,* **Medtronic**

COMPLYING TO POST MARKET SURVEILLANCE REGULATIONS

9.30am **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

Queenita Fernandes, *Sr. Medical Safety Manager,* **Medtronic**

10.30am **NETWORKING BREAK**

12.00pm **LUNCH BREAK**

SOFT SKILLS – PM´S BIGGEST WEAPON OR WEAKNESS?

1.00pm **KEYNOTE FOLLOWED BY A PANEL DISCUSSION:** LEVERAGING POWER SKILLS FOR PROJECT SUCCESS

Project Management is both an art and science. While technical skills are required to manage scope, schedule and costs, power skills such as collaboration, influence, adaptability, strategic thinking and problem-solving are required to take your project team's success to the next level. In this session we'll explore how to leverage the leading power skills that will transform your project management practice into an art form of true project leadership.

Presenter:

Alexis Kuhne, *former Global IT PMO CoE Leader*

Panelists:

Alexis Kuhne, *former Global IT PMO CoE Leader*

Michael O'Connor, *Senior Research Program Director, Program Management,* **Medtronic**

Graham Howe, *Vice President, Program Management Office,* **BD Biosciences**

Christian Hasselberg, *Director, Head of Program – Oncology Informatics,* **Elekta**

Susie Girard, *Senior R&D Program Manager,* **J&J MedTech**

Darrin Dickerson, *VP of Program and Portfolio Management,* **Boston Scientific**

Mike McShane, *Sr. Program Manager,* **Viant Medical**

11.00am **CASE STUDY:** HOW AGILE POST-MARKET SURVEILLANCE (PMS) ACTIVATES MEDICAL DEVICE INNOVATION – A "BEHIND THE SCENES" LOOK FROM DAY 1 OF LAUNCHING A TRANSFORMATIVE THERAPY (TAVR) FOR HEART VALVE FAILURE PATIENTS

Successful rollout and commercialization of new transformative medical technology hinges on the ability to react quickly to preliminary signals from the field during initial ramp-up and launch phases. Jeff will share with us:

- Key learnings on how innovation strategy evolved to improve the gold standard of care for heart valve failure patients Post-market surveillance was a crucial input to this evolving strategy.
- Best approaches to maintaining focus on achieving the best possible outcomes for patients while sustaining regulatory compliance obligations.

Jeffrey Blatnik, *Senior Vice President, Quality,* **Edwards Lifesciences**

11.30am **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

Paul Mlynarczik, *Senior Analyst, Post Market Surveillance,* **Johnson&Johnson**

Taylor Dieringer, *Staff Quality Engineer,* **iRhythm Technologies**

Jeffrey Blatnik, *Senior Vice President, Quality,* **Edwards Lifesciences**

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

Queenita Fernandes, *Sr. Medical Safety Manager,* **Medtronic**

Adhiraj Mamak, *Sr. Manager,* **Quality Strategy & Alliances, Illumina**

12.00pm **LUNCH BREAK**

DATA MANAGEMENT

1.00pm **KEYNOTE:** POST-MARKET SURVEILLANCE STATISTICAL SIGNAL DETECTION METHODOLOGY FOR LONG-TERM IMPLANTABLE DEVICES

While failure opportunities of single-use medical devices are finite and typically temporally correlated with moment of sale, long-term implantable devices carry infinite opportunities to fail over a time continuum spanning multiple years. To effectively monitor product quality and safety of long-term implantable medical devices, alternative statistical methodologies are appropriately applied to specific device cohort groupings to properly assess performance of devices manufactured under similar conditions within the same time period. Survival analysis using a Kaplan-Meier Model with bootstrap sampling allows for actionable insights to be identified from time-to-event customer complaint data. Supplementing this survival model analysis with deep learning data science methodologies allows for construction of a predictive model that enables time-to-event forecasting of probable long-term implantable medical device failures.

Paul Mlynarczik, *Senior Analyst, Post Market Surveillance,* **Johnson&Johnson**

Project and Portfolio Track

Day2

2.00pm **KEYNOTE FOLLOWED BY A PANEL DISCUSSION:** WE CAN BE BRILLIANT TOGETHER – SOLVING PROJECT FAILURE

Discover a game-changing revelation: a single root cause lies at the heart of all project failures. Together, drawing upon our vast collective experience and deep knowledge, let's unravel the complex and transform our profession into a new standard of success. Join me on this mission to pioneer a universal solution that makes the impossible possible; a brilliant future where project failure is a distant memory.

Presenter:

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

Panelists:

Tim Rumbaugh, *Vice President, Program Management,* **Edwards Lifesciences**
Darrin Dickerson, *VP of Program and Portfolio Management,* **Boston Scientific**
Gunther Lenz, *Vice President Software R&D, Biosciences,* **BD Biosciences**

3.00pm **NETWORKING BREAK**

3.30pm **ROUNDTABLE DISCUSSIONS**

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

Each delegate can choose to attend 2 discussions or 1 workshop (see the topics on next page)

4.30pm **THAT´S A WRAP**

Safety & Compliance Track

Day2

1.30pm **WORKSHOP:** A SYSTEMS-THEORETIC PROCESS ANALYSIS (STPA) APPLIED TO MEDICAL DEVICE SAFETY (60 minutes)

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**

2.30pm **KEYNOTE:** CLINICAL DECISION SOFTWARE SUPPORT AND ITS EVOLVING REGULATORY CLIMATE

Almaas Qaderi, *Director and Corporate Counsel,* **Jazz Pharmaceuticals**

3.00pm **NETWORKING BREAK**

3.30pm **ROUNDTABLE DISCUSSIONS**

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

Each delegate can choose to attend 2 discussions or 1 workshop (see the topics on next page)

4.30pm **THAT´S A WRAP**

Roundtable Discussions

Day2

1. RATIONALISATION DURING AN ECONOMIC DOWNTURN
Noel Sobelman, *Partner,* **Accel Management Group**

2. REGULATORY AFFAIRS
Michael O'Connor, *Senior Research Program Director, Program Management,* **Medtronic**

3. PROFESSIONAL DEVELOPMENT - WHAT'S IMPORTANT FOR INDIVIDUALS AND COMPANIES THEMSELVES
Jenny Finkbiner, *Sr. Manager, PMO*

4. WOMEN IN LEADERSHIP
Alexis Kuhne, *former Global IT PMO CoE Leader*

Roundtable Discussions

Day2

1. ANALYSING THE VALIDITY FOR RWE SUPPORT TO CLINICAL AND POST MARKET EVALUATIONS
Nicole Wydeven, *Post Market Clinical Strategy,* **Sr. Manager**

2. BUILDING OUT THE RIGHT PROCESSES TO ENSURE MEDICAL DEVICE SAFETY AND SECURITY
Medha Sateesh Bharadwaj, *Senior Regulatory Affairs Specialist,* **Intuitive**
Sarah Paro, *Associate Director-Corporate QMS,* **Zimmer Biomet**

2024 World tour at a glance

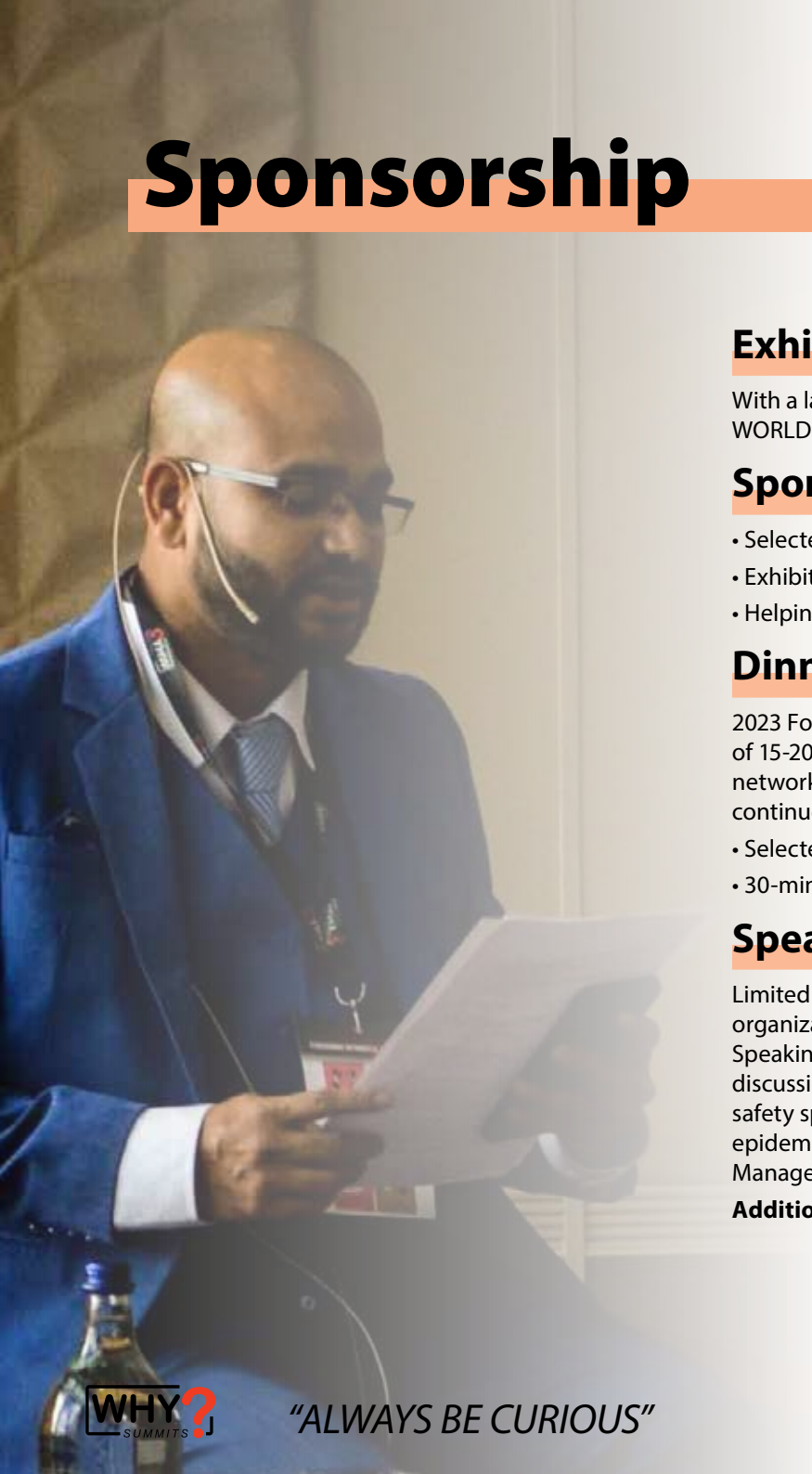
Project & Portfolio Management

1. March 7 - 8, London, United Kingdom
   25th European Pharma and Biotech Project, Program and Portfolio Management Conference
2. March 20 - 21, Munich, Germany
   2nd Global Project Management, Portfolio Planning and Partnerships for Generics
3. April 11 - 12, Chicago, IL, United States
   American Medical Device Project & Portfolio Management Conference
4. April 18 - 19, Philadelphia, PA, United States
   21st American Pharma and Biotech Project, Program and Portfolio Management Conference
5. May 22 - 24, Basel, Switzerland
   Portfolio Conference – Basel
6. June 6 - 7 San Francisco, CA, United States
   22nd American Pharma and Biotech Project, Program and Portfolio Management Conference
7. September 11 - 12 Mumbai, India
   2nd Strategic Project, Program and Portfolio Management Conference for Pharmaceuticals
8. September 19 - 20 Barcelona, Spain
   3rd Global Project Management, Portfolio Planning and Partnerships for Generics
9. October 2 - 3, London, United Kingdom
   26th European Pharma and Biotech Project, Program and Portfolio Management Conference
10. October 10 -11, Berlin, Germany
    2nd European Medical Device Project & Portfolio Management Conference
11. October 16 - 18 Boston, MA, United States
    23rd American Pharma And Biotech Project, Program And Portfolio Management Conference
12. November 13 - 15, Las Vegas, NV, United States
    Portfolio Conference – Las Vegas
13. November 20 - 22, Basel, Switzerland
    27th European Pharma And Biotech Project, Program And Portfolio Management Conference

Pharmacovigilance & Device Safety

1. April 11-12, 2024 Chicago, IL, United States
   American Medical Device Safety & Compliance Conference
2. May 30 - 31 London, United Kingdom
   9th Global Drug Safety & RWE Forum
3. September 26 - 27 Washington D.C., United States
   American Drug Safety Summit
4. October 20 - 23 Mumbai, India
   Global Drug Safety & PV Outsourcing Summit
5. November 27 - 29 Basel, Switzerland
   World Drug Safety Summit Basel

Sponsorship



Exhibiting

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

Sponsorship includes

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

Dinner Sponsorship

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

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

Speaking

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

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

WHY have we decided to create the World Tour of pharmaceutical summits focused on drug safety?

Pharmacovigilance started about 170 years ago, at that time it was just letters written by clinicians to publishers of important and famous scientific journals, whilst today we have modern and ultra-structured electronic registries. The medical industry is evolving rapidly but pharmacovigilance can still be considered a young science with many possibilities of improvement. Let me show you a personal example:

My story begins long before my birth. I come from a family, where, unlike in other families, it was wished to have a daughter instead of a son. We carry in our blood hemophilia genes (bleeding disorder), that are only harmful to boys. My grandfather, whom I do not even remember, suffered from a severe stage of hemophilia, thus he was not able to move or leave his apartment. The treatment of this disease was not very efficient back then. Nor safe. He died when I was just 2 years old.

I learnt about our family history when I turned 15. Since then I devoted myself to studying the disease as much as I could. I joined a hemophilia summer camp as a kid´s animator. It was both joyful to see their enthusiasm, and heart-breaking to see their arduous treatment – getting a shot of medication intravenously every two days. This experience made me realize how important it is to control the quality of treatment.

Thankfully, the treatment has improved marvelously in the past decade (latest news claim it to be enough to get the treatment once in 2 years, not in 2 days!) It makes me, and many others, relieved knowing my children's treatment will be safer. With rapidly improving drug and device safety I am really looking forward to seeing the world my children will live in.

For this reason – to contribute to making the world a safer place, we decided to create a network of pharmacovigilance professionals to help them in their journey and provide them with space to share their valuable ideas and reach their common goal – creating the safest drugs and devices to help patients all over the world.

Simona

Contact us

SPEAKING:

Simona Marcekova

simona.marcekova@whysummits.com

ATTENDING AND SPONSORING:

Niraj Kumar Singh

niraj@whysummits.com

REGISTER HERE

FROM

2349$

DISCLAIMER

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.