GENERIS

EUROPEAN MEDICAL DEVICE SUMMIT 2024

May 30-31, 2024

emdsummit.com

TOMORROW'S CONNECTION TODAY

Designing a new future for manufacturing, quality and supply chain leaders

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PROGRAMME

PROGRAMME · DAY 1

30 MAY 2024

* JOIN US FOR THE PRE-EVENT HAPPY HOUR ON 29 MAY 2024 FROM 18.00 – 19.00 CET

7.00 – 8.00 CET

REGISTRATION AND NETWORKING BREAKFAST

8:00 – 8:10 CET

CHAIR'S WELCOME AND OPENING REMARKS

PRODUCT DEVELOPMENT

KENDRA HILEMAN, PH.D.
VP and Head, Instrumentation R&D
Alcon

QUALITY & REGULATORY

FREDERIQUE PEDRETTI-ABEL
VP, International Quality
Becton Dickinson

8.10 – 8.40 CET

OPENING KEYNOTE

JASON WEIDMAN
SVP and President, Coronary and Renal Denervation
Medtronic

UNLOCKING INNOVATION: A VIEW INTO MEDTRONIC'S PIONEERING PRODUCT DEVELOPMENT STRATEGIES

- Prioritising patient-centricity to ensure that products are addressing real-world patient needs
- Mitigating regulatory roadblocks to expedite product development
- Diving into the role of data analysis and evidence-based decision-making in reshaping the device's development trajectory
- Case study: Medtronic's journey to regulatory approval for their renal denervation system

8.40 – 9.10 CET

PLENARY

MIZANU KEBEDE
Chief Quality and Regulatory Officer
Smith+Nephew

NAVIGATING THE CURRENT REGULATORY CHANGES IN THE EUROPEAN MEDICAL DEVICE INDUSTRY

- Analysing the impact of how the new EU Medical Device Regulation (MDR) influences product development, data reporting and quality assurance
- Unpacking the need to recertify existing products and the related timelines
- Understanding the need for new post-market surveillance requirements
- Analysing the ramifications of MDR in the short- and long-term and defining a path forward
- How early adopters of MDR requirements will have a competitive edge in the market

9.10 – 9.40 CET

PLENARY

ROBERT KOSSMANN, M.D.
EVP and Global Head, Medical Affairs and Chief Medical Officer, Care Enablement
Fresenius Medical Care

INNOVATE TO INTEGRATE: RETHINKING HEALTHCARE THROUGH CUTTING-EDGE MEDICAL DEVICE DEVELOPMENT

- Propelling medical affairs to synchronize seamlessly with advancing medical device technologies
- Guiding regulatory strategies to ensure compliance while fostering innovation in medical device development
- Fostering strategic partnerships globally to advance medical affairs and integrate cutting-edge medical devices
- Spearheading innovative solutions at the nexus of medical affairs and progressive medical device technologies
- Steering initiatives for sustainable transformation, harmonizing healthcare goals with medical device excellence

9.40 – 11.20 CET

REFRESHMENTS, NETWORKING, AND PRE-ARRANGED 1-2-1 MEETINGS

11.25 – 11.55 CET

SESSIONS

PRODUCT DEVELOPMENT

JEAN CHAOUI, PH.D.
VP, Digital, Robotics and Enabling Technology
Stryker

PUSHING THE BOUNDARIES OF MEDICAL TECHNOLOGY TO DRIVE PATIENT OUTCOMES

- Understanding customer needs to enhance product development
- Driving digital transformation in healthcare
- Defining cutting edge technology pipeline solutions
- Diving into Stryker's commitment to technology adoption through computer assisted surgery, AI, robotics and IoMT

QUALITY & REGULATORY

FRANK MOLONEY
VP, QA/RA, EMEA
Zimmer Biomet

UNDERSTANDING HOW NEW REGULATORY REQUIREMENTS WILL AFFECT OPERATIONS

- Understanding how the European Health Data Space serves as a regulatory pathway to access health datasets and how it could affect IP
- Emphasising the importance of post-market surveillance and vigilance in ensuring the safety and performance of medical devices in the EU
- The impact of EU MDR and IVDR on the type, quality and quantity of post-market data

12.00 – 12.35 CET

WORKSHOPS

PRODUCT DEVELOPMENT

CIARAN DILLANE
Lead, Global Medical Solutions, Seco and Managing Director, Premier Machine Tools
Seco Tools

EMPOWERING MEDICAL MANUFACTURING INNOVATION: DISCOVERING HOW CUTTING-EDGE SOLUTIONS IN END TO END MANUFACTURING DELIVERS PROFITABILITY AND SUSTAINABILITY

- Discussing how to meet market demand for cost reduction through improved productivity
- Exploring how tools and technology can drive continuous improvement in medical device manufacturing
- Understanding how service solutions are optimising serial product output, whilst facilitating faster delivery of patient specific products
- Delivering on circular manufacturing and facilitating users' sustainability goals

QUALITY & REGULATORY

KIM KAPLAN
Senior Product Manager
ISACA

UNLOCK IMPROVED DEVICE QUALITY AND LESSEN REGULATORY BURDEN WITH THE VOLUNTARY IMPROVEMENT PROGRAM

- Boosting capacity and quality using an approach that meets your business needs
- Leveraging US FDA opportunities for expedited PMA and Site Change submissions, and more benefits from FDA
- See Final Guidance "Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program"
- Enhancing manufacturing efficiency for faster innovation
- Using a maturity model to measure capabilities
- Fostering a culture of continuous improvement for superior device quality

12.35 – 13.35 CET

LUNCH & LEARN ROUNDTABLE DISCUSSIONS AND OPEN SEATING LUNCH

Benefit from additional learning by joining a moderated roundtable discussion on pressing issues in the industry. Registration is required, and attendance for moderated roundtables on Day 1 is limited to attendees and speakers.
Choose from:

STEVE BLATCHER
Head of MedTech
Team Consulting

DEVELOPING HEALTHCARE INNOVATIONS THAT DELIVER GREATER BENEFITS AT LOWER COSTS TO THE HEALTHCARE SYSTEM - WHAT ARE THE ACTIONABLE TENDS?

SPEAKER TBA

Enhanced Compliance

REGULATORY INTELLIGENCE: STAYING COMPLIANT IN A RAPIDLY CHANGING ENVIRONMENT

KIM KAPLAN
Senior Product Manager
ISACA

ACCELERATING A QUALITY CULTURE WITHIN YOUR ORGANIZATION

WILLIAM MOSS
CEO
3Aware

LEVERAGING REAL-WORLD EVIDENCE TO OPTIMIZE PROFITABILITY

BEST PRACTICES IN IMPLEMENTING ISO 13485: NAVIGATING THE REQUIREMENTS FOR A SUCCESSFUL QMS

THE IMPORTANCE OF TALENT DEVELOPMENT IN REGULATORY INTELLIGENCE

13.40 – 14.10 CET

SESSIONS

PRODUCT DEVELOPMENT

DONNY PATEL
VP, Digital Platforms and Innovation
Baxter

ADVANCING CONNECTED CARE TO IMPROVE PATIENT OUTCOMES AND CLINICIAN EXPERIENCE

- Exploring the current connected care landscape and how we got here
- Identifying the opportunities and challenges we face in advancing connected care
- What's in store for the future of medical device connectivity

QUALITY & REGULATORY

STEFAN FISCHER
SVP, Regulatory Affairs
Paul Hartmann

DIGITALISING REGULATORY PROCESSES TO DRIVE EFFICIENCY

- Implementing new technological processes to streamline regulatory workflows
- Prioritising scalable solutions to accommodate changing regulations and global standards
- Staying ahead by continuously learning and adapting in the dynamic technological landscape
- Understanding the critical nature of safeguarding data in the digital realm
- Case study: Sharing Paul Hartmann's path to reducing time-to-market through digital compliance methods

14.15 – 14.50 CET

WORKSHOPS

PRODUCT DEVELOPMENT

LEVERAGING IOT AND LIFECYCLE ANALYTICS FOR AGILITY, SPEED AND COMPLIANCE

- Combining big data information with engineering intelligence to ensure quality. optimum performance and manufacturing excellence
- Designing and developing processes across your entire value chain
- Combining digital twins with big data analytics and moving them in tandem across the product lifecycle
- Investing in advanced machine learning algorithms to uncover valuable insights that provide a competitive advantage

QUALITY & REGULATORY

PRIYA BHUTANI
Founder and CEO
RegDesk

REGULATORY SUBMISSION AND DOCUMENTATION: PATH, PITFALLS AND THE USE OF ARTIFICIAL INTELLIGENCE

- Exploring the most common regulatory submission preparation pathways
- Discussing concerns regarding the current method of submission
- Looking at where regulatory submission and AI interlink and how this can streamline submissions
- Uncovering which parts of the regulatory submissions process can utilize AI most effectively
- Sharing resources and practical tips for implementation

14.55 – 16.15 CET

REFRESHMENTS, NETWORKING AND PRE-ARRANGED 1-2-1 MEETINGS

16.20 – 17.05 CET

PANEL DISCUSSION

JULES KEGHIE, PH.D.
VP and Head, System Engineering and Architecture
Elekta

MAGNUS KARLBERG
VP, Product Development
Arjo

RICHARD WILLMANN, PH.D.
VP, R&D, Image-Guided Therapy Systems
Philips

YONGJI FU, PH.D.
VP, R&D
B. Braun

WALID BEYLOUNI
VP, Medical Division
Leica Microsystems

ISABELLE FOURTHIN, M.D.
VP, Medical Affairs
Baxter

UNLOCKING THE FUTURE OF MEDICAL DEVICES AND DEFINING THE PATH FORWARD

- How will emerging technologies shape the future of medical device design and production?
- Identifying which collaborations and partnerships will be essential for advancing the medical device industry in the coming years
- Looking at the role the new MDR and IVDR regulations will play on future innovations
- Exploring how medical device companies can leverage data analytics and real-world evidence to drive product development
- Predicting the biggest disruptors in the industry over the next 10 years

17.05 – 17.35 CET

PLENARY

STEFANIE HIRSCH
President, Quality and Regulatory Affairs
Dräger

ENHANCING QUALITY MANAGEMENT WITHIN REGULATORY FRAMEWORKS

- Supporting a continuous improvement approach to quality management in order to sustainably support business strategies
- Driving cultural awareness and commitment to quality and ensuring a focus on patient safety and customer needs
- Enhancing digital transformation in regulatory process management
- Developing agile regulatory strategies and overcoming the increasing regulatory complexity

17.35 – 18.20 CET

PANEL DISCUSSION

NATALIYA DEYCH
VP, Regulatory Affairs
Edwards Lifesciences

MANOJA RANAWAKE
VP, Regulatory Affairs, EMEA
Becton Dickinson

JASON GORMAN
VP, Quality, Regulatory and Compliance
Propeller Health, a ResMed Company

JESSICA SMITH
Chief Regulatory Officer and Corporate VP
Integra LifeSciences

PIERRE BOISIER
Chief Quality Officer
Olympus

ANKUR KAUSHAL
VP, Global Regulatory Affairs
Advanced Bionics, a Sonova company

NAVIGATING THE PATH TO QUALITY AND REGULATORY EXCELLENCE IN THE MEDICAL DEVICE SECTOR

- Addressing the impact of MDR on the medical device industry
- Sharing insights on developing and implementing effective Quality Management Systems (QMS)
- Exploring the delicate balance between innovation and safety requirements
- Discussing strategies to conduct quality risk assessments and act proactively
- Setting a path forward for the medical device industry with best practices and lessons learned

18.20 – 18.30 CET

CHAIR'S CLOSING REMARKS

PRODUCT DEVELOPMENT

KENDRA HILEMAN, PH.D.
VP and Head, Instrumentation R&D
Alcon

QUALITY & REGULATORY

FREDERIQUE PEDRETTI-ABEL
VP, International Quality
Becton Dickinson

PROGRAM · DAY 2

31 MAY 2024

7.00 – 8.00 CET

REGISTRATION AND NETWORKING BREAKFAST

8.00 – 8.10 CET

CHAIR'S WELCOME AND OPENING REMARKS

PRODUCT DEVELOPMENT

KENDRA HILEMAN, PH.D.
VP and Head, Instrumentation R&D
Alcon

QUALITY & REGULATORY

FREDERIQUE PEDRETTI-ABEL
VP, International Quality
Becton Dickinson

8.10 – 8.40 CET

OPENING KEYNOTE

JIJO JAMES, M.D.
Chief Medical Officer, MedTech and External Innovation
Johnson & Johnson

PROMOTING PATIENT CENTERED INNOVATION THROUGH DATA, SCIENCE, AND BIOETHICS

- Leading with science, data, and purpose to deliver innovation for patients
- Navigating an external environment that offers much promise, but also poses significant challenges
- Driving a closed-loop system that feeds benefit-risk insights from clinical and post-marketing environment into product development
- Leveraging regulatory grade real-world data and evidence to inform predefining analysis, post-marketing safety surveillance and label expansions

8.40 – 9.10 CET

PLENARY

ELIN FROSTEHAV
President, Acute Care Therapies
Getinge

LEVERAGING CUTTING-EDGE TECHNOLOGIES FOR NEXT-GENERATION DEVICE DESIGNS

- Enabling cost-efficiency, rapid market entry and user-friendly devices through streamlined design processes
- Embracing agile principles in the design phase to enable quick iterations and responsiveness to user feedback
- Prioritizing user needs and preferences throughout the entire design process to ensure user-friendly devices
- Utilizing virtual prototyping and 3D modeling for rapid product development
- Fostering collaboration among designers, engineers and clinicians to drive adoption and improving patient outcomes

9.15 – 9.50 CET

WORKSHOPS

PRODUCT DEVELOPMENT

STRATEGIC PRODUCT LIFECYCLE MANAGEMENT: EMPOWERING SUCCESS THROUGH DIGITALIZATION AND DATA-DRIVEN STRATEGIES

- Leveraging digitalisation and data analytics to drive informed decision-making across product stages
- Implementing risk-based approaches in lifecycle management to identify and mitigate potential hazards
- Utilising real-world data for ongoing product improvement
- Implementing agile systems that adapt to changing requirements
- Up-skilling and re-skilling teams for a modern workforce

QUALITY & REGULATORY

DIVING INTO THE NEW CYBERSECURITY REQUIREMENTS UNDER MDR REQUIREMENTS

- Illustrating the importance of preventing malicious intrusions or unauthorised modifications of device software and firmware
- Making sense of the overlapping requirements surrounding cybersecurity medical devices
- Exploring MDRs approach to cybersecurity requirements and which regulations are new
- Extending existing risk management methods to cover the new requirements while also adopting new methods

9.55 – 11.15 CET

REFRESHMENTS, NETWORKING, AND PRE-ARRANGED 1-2-1 MEETINGS

11.20 – 11.50 CET

SESSIONS

PRODUCT DEVELOPMENT

FELIX WANDEL
VP, Robotics and Technology, EMEA
Zimmer Biomet

INNOVATING ROBOTICS AND DIGITAL PRODUCT DEVELOPMENT IN THE MEDICAL DEVICE LANDSCAPE

- Integrating cutting-edge technology into the digital product development process for innovative medical solutions
- Navigating regulatory and safety considerations in the dynamic field of robotics and digital healthcare products
- Utilising AI algorithms to optimise medical device design and performance
- Envisioning the future landscape of healthcare through the intersection of robotics, technology, and digital product development

QUALITY & REGULATORY

EMMA WRIGHT, PH.D.
EVP, Regulatory Affairs and Quality Assurance and Chief Medical Officer
Mölnlycke

A CUSTOMER CENTRIC APPROACH TO STRATEGY: ETHNOGRAPHY IN ACTION

- Embracing customer-centricity throughout the entire product lifecycle
- Identifying and understanding customer needs through ethnographic research
- Applying the health economic concept of value to prioritize outcomes within resource constraints
- Examining challenges in the wound care sector during the transition from innovation to patient care
- Demonstrating how a customer-centric approach can lead to enhancements in patient outcomes in the healthcare industry

11.55 – 12.30 CET

WORKSHOPS

PRODUCT DEVELOPMENT

AMPLIFYING INNOVATION AND EFFICIENCY THROUGH EXTERNAL PARTNERSHIPS

- Exploring the risks and benefits to contract manufacturing for medical devices
- Reducing capital investment and production costs through outsourcing
- Streamlining the manufacturing process for faster time-to-market
- Ensuring transparency and collaboration with external partners
- Navigating cultural and regulatory aspects for successful collaborations
- Leveraging specialized expertise for complex medical device production

QUALITY AND REGULATORY

SIMPLIFYING COMPLIANCE THROUGH REGULATORY PLATFORMS

- Staying up to date with the latest changes in regulations and those in the pipeline
- Organising and managing all compliance-related documents in a centralised
- Leveraging risk assessments to ensure cyber security
- Minimising delays and expediting product launches by streamlining compliance processes

12.35 – 13.20 CET

PANEL DISCUSSION

CLAIRE GOURICHON
VP and Head, Corporate QA/RA
Straumann Group

SUSANA DE AZEVEDO WÄSCH, PH.D.
VP, Quality Management and Regulatory Affairs and Medical Affairs
Ypsomed

FREDERIQUE PEDRETTI-ABEL
VP, International Quality
Becton Dickinson

LINA KARLSSON, PH.D.
EVP, Business Area Antiseptics
Mölnlycke

ANGELA MAIN
SVP, Global Chief Compliance Officer and Associate General Counsel, Asia Pacific
Zimmer Biomet

ISABELLE FOURTHIN, M.D.
VP, Medical Affairs
Baxter

WOMEN IN LEADERSHIP

- What's one leadership lesson you've learned in your career?
- As a leader, what has been the most significant barrier in your career?
- How do you and your organisation empower the next generation of skilled professionals?
- What is the best piece of advice you've received from leadership?
- What advice would you give to the next generation of leaders?

13.20 – 14.20 CET

LUNCH & LEARN ROUNDTABLE DISCUSSIONS AND OPEN SEATING LUNCH

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Choose from:

ESTHER GERTEIS
VP, Medical and Regulatory Affairs
TRiCares GmbH

POST-MARKET SURVEILLANCE AND MEDICAL DEVICE REPORTING IN AN SME ENVIRONMENT

ELLEN LAAS
CEO
PlantTec Medical

EXPLORING STRATEGIC MEDICAL DEVICE DEVELOPMENT AS A KEY CONCERN FOR MANUFACTURERS

RICHARD WILLMANN, PH.D.
VP, R&D, Image-Guided Therapy Systems
Philips

MEET THE SPEAKER: LEVERAGING DATA ANALYTICS AND REAL-WORLD EVIDENCE

AXEL KORT
VP, Global Manufacturing Engineering and Service Technologies
Fresenius Medical Care

DESIGN FOR MANUFACTURING: BRIDGING THE GAP BETWEEN INNOVATION AND PRODUCTION EFFICIENCY

JOHN LEAMY
VP, Quality Systems and Digital Services
Johnson & Johnson

UTILISING GENAI TO TRANSFORM QUALITY MANAGEMENT SYSTEMS AND REGULATORY COMPLIANCE/INTELLIGENCE

STRENGTHENING MEDICAL DEVICE CYBERSECURITY: STRATEGIES FOR A RESILIENT DEFENSE

14.25 – 15.10 CET

PANEL DISCUSSION

LENA HAGMAN
COO
XVIVO

STAVIT COHEN
SVP, Research and Development
Momentis Surgical

TZACHI RAFAELI
VP, R&D
Insightec

JOHN POWER
CEO and Founder
Aerogen

EWEN NORTHWOOD, PH.D.
Chief R&D Officer
Eakin Healthcare

DIANA HEINRICHS
CEO and Founder
Lindera GmbH

NAVIGATING INNOVATION AND CHALLENGES IN MEDICAL DEVICE DEVELOPMENT FOR SMES

- Discussing the inherent challenges facing small- to mid-sized medical device companies during the product development journey
- How innovation serves as a cornerstone for SMEs to seize unique opportunities in a competitive landscape
- Navigating the intricate landscape of new European regulations and their implications
- Involving patient perspectives in prototype design and how it contributes to improved medical devices
- Examining the transformative shift towards patient-centric approaches and its impact on medical device development strategies

15.15 – 15.45 CET

PRODUCT DEVELOPMENT SPOTLIGHT

ROOM 1

ALIND SAHAY
VP, Research and Development
Pentax, a Hoya Corporation

HARNESSING AI'S POWER TO REVOLUTIONISE MEDICAL DEVICE DEVELOPMENT

- Reducing physical iterations with AI driven virtual prototypes
- Tailoring medical devices to individual patient needs to ensure customized care
- Monitoring device performance post-launch by facilitating early detection of defects
- Accelerating data analysis to help researchers identify potential breakthroughs faster and more efficiently
- Utilising AI driven algorithms to enable medical devices to provide more accurate and timely diagnosis

ROOM 2

BEATE HANSON, M.D.
Chief Medical Officer
Convatec

CHARTING THE FUTURE OF MEDICAL DEVICES TO DRIVE INNOVATION

- Unveiling ConvaTec's commitment to pioneering medical devices that prioritize improved patient experiences and outcomes
- Forging successful collaborations to elevate clinical standards
- Balancing cutting-edge technology with a human touch, ensuring medical devices resonate with patient needs
- Harnessing the power of data analytics and AI in medical devices to enhance diagnostic accuracy and treatment personalization

15.50 – 16.35 CET

PANEL DISCUSSION

MARION GULLSTRAND
EVP, HR and Sustainability
Arjo

SABINE KRUMMEL-MIHAJLOVIC
VP, HR
Stryker

GUILLAUME JULIEN
VP, Global Talent Acquisition, Leadership Development and HR Analytics
Getinge

JOHN LEAMY
VP, Quality Systems and Digital Services
Johnson & Johnson

DIVERSITY, EQUITY AND INCLUSION

- How do you define diversity and inclusion in an ever-changing work environment?
- How can organisations tap into the power of diverse perspectives and experiences?
- What has influenced your thinking around DEI and motivated you to get involved in being an advocate for change?
- What successful outcomes has your organisation realised from diversity initiatives or best practices?

16.35 – 16.45 CET

CHAIR'S CLOSING REMARKS

PRODUCT DEVELOPMENT

KENDRA HILEMAN, PH.D.
VP and Head, Instrumentation R&D
Alcon

QUALITY & REGULATORY

FREDERIQUE PEDRETTI-ABEL
VP, International Quality
Becton Dickinson