A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

#MTF2022
3–5 MAY
in
BARCELONA

PROGRAMME

www.themedtechforum.eu
as per April 29, 2022

WELCOME INTRODUCTION

Dear participants, Dear speakers, Dear sponsors,

After a successful digital edition of the MedTech Forum 2021, we are pleased to inform you that we will see each other in person at the MedTech Forum 2022. The next edition of the Forum will be held on 3-5 May at the Barcelona International Convention Centre (CCIB).

This year's programme will offer onsite networking, plenary & parallel sessions and exhibition. But even more, the sessions in the plenary room will be broadcasted so remote participants can attend part of the programme. In the meantime, I invite you to revisit the 2019 and 2021 editions in our Archives.

See you in Barcelona and thank you for your ongoing support,

Best regards,

Serge Bernasconi
Chief Executive Officer
MedTech Europe

LIVE STREAMING

PROGRAMME AT A GLANCE

3 MAY 2022

BANQUET ROOM — 18:00-21:00 OPENING RECEPTION & COCKTAIL DINNER

4 MAY 2022

ROOM 111+112	ROOM 113	ROOM 133+134	ROOM 118+119
09:00-09:30 OPENING Welcome & Introduction			
09:30-10:20 PLENARY CEO #nofilter			
10:30-11:20 PARALLEL SESSION The best kept secret of Procurement in healthcare	10:30-11:20 PARALLEL SESSION Conducting R&D while navigating through an increasingly complex privacy landscape in Europe and beyond	10:30-11:20 PARALLEL SESSION Happy (almost) birthday to the IVD Regulation!	10:30-11:20 PARALLEL SESSION Data Governance in a Patient Pathway: unlocking the value of digital solutions by Johnson & Johnson
11:20-12:00 NETWORKING BREAK			
12:00-12:50 PARALLEL SESSION Take off for the €2.4 Billion European Innovative Health Initiative Partnership	12:00-12:50 PARALLEL SESSION The European Health Data Space: the nuts and bolts	12:00-12:50 PARALLEL SESSION EU Regulation on HTA: Enabler or Barrier for Access to Medical Technology Innovation?	12:00-12:50 PARALLEL SESSION Value of medical technologies contributing to resilient & innovative health systems by IQVIA
12:50-14:15 NETWORKING LUNCH			
13:20-14:10 SPONSORED SESSION From ESG talk to action by BCG	13:20-14:10 SPONSORED SESSION Regulatory Modernization: State of Industy and MedTech Leader Perspectives by Veeva MedTech	13:20-14:10 SPONSORED SESSION Right First Time: Delivering Complex Products in a Complex World successfully by Dassault	13:20-14:10 SPONSORED SESSION EU market assessment: key trends and opportunities in Medical Devices and Digital Health by Guidehouse
14:15-15:05 PARALLEL SESSION We see fragmentation today – but the future is EUDAMED	14:15-15:05 PARALLEL SESSION Putting data to work: accelerating the recovery from the pandemic by ResMed	14:15-15:05 PARALLEL SESSION How does EU money flow into recovery: lessons learned from national recovery plans	14:15-15:05 ASK THE EXPERTS IN ROOM 131+132
15:15-16:05 PARALLEL SESSION #MoveYourInnovation	15:15-16:05 PARALLEL SESSION Product liability in Europe: A fraying system? by FDB	15:15-16:05 PARALLEL SESSION Harmonising global labelling requirements Going back to basics - what really needs to go on the label?	15:15-16:05 PARALLEL SESSION Towards Greater Sustainability in Healthcare: The Journey so Far
16:05-16:40 NETWORKING BREAK			
16:40-17:30 PLENARY CEO #nofilter			
17:30-18:00 PLENARY Programme Highlights			
18:00-19:30 NETWORKING COCKTAIL			

5 MAY 2022

ROOM 111+112	ROOM 113	ROOM 133+134	ROOM 118+119
09:00-09:50 PLENARY Keynote speaker			
10:00-10:50 PARALLEL SESSION Pandemic preparedness: Is Europe ready for the next pandemic?	10:00-10:50 PARALLEL SESSION European alignment of digital health assessment by Alira Health co-hosted by EIT Health	10:00-10:50 PARALLEL SESSION From Code to culture	10:00-10:50 PARALLEL SESSION International data transfers: health data considerations
10:50-11:20 NETWORKING BREAK			
11:20-12:10 PARALLEL SESSION The rise and rise of China's medtech market changing landscape of the global medical technology industry and the global market	11:20-12:10 PARALLEL SESSION Trustworthy artificial intelligence in healthcare	11:20-12:10 PARALLEL SESSION MDR implementation: 24 months until May 2024	11:20-12:10 PARALLEL SESSION Empowering Independent Patient Advocacy by Edwards Lifesciences
12:20-13:10 PARALLEL SESSION How does the future look like for Medical Technologies' contribution to a Sustainable Transition in Healthcare?	12:20-13:10 PARALLEL SESSION Is Europe still attractive for the medtech industry?	12:20-13:10 PARALLEL SESSION Integrating start-ups in the industrial innovation ecosystem	12:20-13:10 SPONSORED SESSION MedTech in Digital Health - How to succeed with a Digital Health Portfolio in Europe by ZS
13:10-14:30 NETWORKING LUNCH			
13:30-14:20 SPONSORED SESSION Sustainability – new net-zero frontier or the boy who cried wolf? by McKinsey	13:30-14:20 SPONSORED SESSION Transparency, Effects on HCP Engagement by IQVIA	13:30-14:20 SPONSORED SESSION Reducing UDI confusion for regulatory affairs teams by Rimsys	13:30-14:20 SPONSORED SESSION A new horizon for circularity in MedTech by Deloitte
14:30-15:20 PLENARY CEO #nofilter			
15:20-15:50 PLENARY Programme Highlights			
15:50-16:00 PLENARY Conclusions			

A MedTech Europe event
The MedTech Forum
bringing HealthTech stakeholders together

THE MEDTECH FORUM OFFERS YOU THE OPPORTUNITY TO JOIN SELECTED SESSIONS ONLINE.

Register on The MedTech Forum website and select "online participation".

HOW TO JOIN US ONLINE?

REGISTER
Register on the MedTech Forum website: www.themedtechforum.eu

CONNECT
Don't forget your password and meet us on 4 May at 9:00 CET!

WHAT CAN YOU EXPECT?

LIVESTREAMING
Access to selected sessions* in live streaming
*Please check the official programme

ASK QUESTIONS
During sessions, speakers and moderators will be available to answer your questions on the platform.

RELIVE THE EVENT
Access presentations and videos on-demand until 4 June 2022.

TUESDAY 3 MAY

18:00-21:00 | BANQUET ROOM

OPENING RECEPTION & COCKTAIL DINNER

Veeva MedTech

WEDNESDAY 4 MAY

09:00-09:30 | ROOM 111+112

WELCOME AND INTRODUCTION

Moderator:

- Ingmar DE GOOIJER (Healthcare industry observer)

Speaker:

- Serge BERNASCONI (CEO, MedTech Europe)

09:30-10:20 | ROOM 111+112

CEO #NOFILTER

Global leaders from the field of medical devices, diagnostics and digital health will join the discussion and speak openly about the latest trends, challenges and opportunities they are facing.

Moderator:

- Ingmar DE GOOIJER (Healthcare industry observer)

Speakers:

- Pierre BOULUD (Chief Operating Officer – Executive Vice President Clinical Operations, bioMérieux)
- Marc JULIEN (Co-CEO, Diabeloop)
- Rich LESSER (Global Chair, Boston Consulting Group (BCG))
- Stefan WOLF (CEO, The Binding Site)

10:30-11:20

ROOM 111+112

THE BEST KEPT SECRET OF PROCUREMENT IN HEALTHCARE

The session will discuss how value-based innovation procurement contributes to resilient and sustainable healthcare in Catalunya. It will highlight what is needed to reap the benefits of innovative ways of procuring from both a healthcare provider as well as an industry perspective and will also discuss the COVID-19 lessons learned.

Moderator:

- Richard CHARTER (Vice-President, Medtech Market Access, Europe & Asia-Pacific, Alira Health)

Speakers:

- Ion ARRIZABALAGA (Health Innovation Project Manager, Agency for Health Quality and Assessment of Catalonia (AQUAS))
- Ramon MASPONS BOSCH (Chief Innovation Officer, Agency for Health Quality and Assessment of Catalonia (AQUAS))

ROOM 113

CONDUCTING R&D WHILE NAVIGATING THROUGH AN INCREASINGLY COMPLEX PRIVACY LANDSCAPE IN EUROPE AND BEYOND

Digital technology is opening opportunities for all players in the healthcare sector but it also creates specific challenges for medtech companies in particular. In the past, medtech companies typically relied on a highly regulated and lengthy research and development (R&D) phase focused on the launch of an end product. Today, in view of the digital/connected products, in addition to this regulatory framework, there is another challenge, which is the need to navigate the privacy regulations around the world when conducting R&D for software-based solutions. The session aims at discussing this particular privacy thorn in the R&D phase of digital products and brainstorm on potential solutions, ranging from regulatory harmonisation to the development of sector-specific standards or codes of conduct.

Moderator:

- Veronique BROKKE (Lead Privacy Counsel, Philips)

Speakers:

- Peter BLENKINSOP (International Pharmaceutical & Medical Device Privacy Consortium (IPMPC), Secretariat)
- Efstathia GKIKA (Associate General Counsel – Privacy, Cybersecurity & Digital EU Data Privacy Office, Baxter Healthcare)
- Kristof VAN QUATHEM (Counsel, Covington)

10:30-11:20

ROOM 133+134

HAPPY (ALMOST) BIRTHDAY TO THE IVD REGULATION!

The IVD Regulation will fully apply in just 20 days after the MedTech Forum. Is the IVD sector prepared and will all diagnostics remain available to patients and healthcare systems? What are the main challenges for the new system which remain and how can these be addressed? It is expected that most IVDs will still need certification and that many implementation challenges will remain. How can all stakeholders ensure the long-term success of the new regulatory system?

Moderator:

- Oliver BISAZZA (Director General - Industrial Policies, MedTech Europe)

Speakers:

- Christa COBBAERT (Head of Department of Clinical Chemistry and Laboratory Medicine at LUMC, Leiden; Chair of the European Federation of Laboratory Medicine Task Force on European Regulatory Affairs; Vice-chair of the International Federation of Clinical Chemistry Scientific Division Executive Committee; Chair of the European Federation of Laboratory Medicine Working Group on Test Evaluation; LUMC Leiden University; European Federation of Laboratory Medicine)
- Anna HALLERSTEN (Director - Head Regulatory Policy Europe, Roche)
- Catherine HOLZMANN (IVDMD Department Manager, GMED Notified Body)
- Carmen RUIZ-VILLAR FERNANDEZ-BRAVO (Head of Medical Devices Department, Spanish Agency for Medicines and Medical Devices (AEMPS))

ROOM 118+119

DATA GOVERNANCE IN A PATIENT PATHWAY: UNLOCKING THE VALUE OF DIGITAL SOLUTIONS - PRACTICAL PERSPECTIVES OF A PATIENT, GOVERNMENT, HEALTHCARE PROVIDER AND THE INDUSTRY

Johnson & Johnson MEDTECH

Digital Innovation is transforming healthcare across the patient journey and ultimately improves patient experiences and outcomes. The policy landscape and practices addressing digital healthcare across Europe is fragmented and changing - both at the hospital, country and regional levels. Key discussions and decisions about data regulation and policy, including common understanding across healthcare ecosystem and within hospitals, taking shape now, will impact how healthcare data is treated and used in the future. To realise a full potential of digital solutions provided by MedTech and enable the use of data along the continuum of care, while respecting all privacy rules, there is a need to tackle real and perceived issues around the data governance

The purpose of the session is to share perspective on data governance challenges from patient's, policymaker's, provider's and industry's perspective as well as to share best practice that can pave the way for more consistent approach and better implementation of solutions that have the power to transform the way that care is delivered.

Moderator:

- Karolina MACKIEWICZ (Director Innovation, ECHAlliance)

Speakers:

- Ana CASTELLANOS (Project Manager, Spanish Platform of Patients' Organisations)
- Lisa Ann HILL (Managing Director, Johnson & Johnson MedTech Spain)
- Julio MAYOL (Director of Innovation, Hospital Clinico San Carlos)
- Jordi PIERA JIMÉNEZ (Director of the Digital Health Strategy Office, Catalan Health Service)

11:20-12:00 **NETWORKING BREAK**

12:00-12:50

ROOM 111+112

TAKE OFF FOR THE €2.4 BILLION EUROPEAN INNOVATIVE HEALTH INITIATIVE PARTNERSHIP

The Innovative Health Initiative kicks off in January 2022. The objective of the €2.4 billion IHI partnership is to create an EU-wide health research and innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations. IHI brings together diverse stakeholders (universities, companies large and small, and other health stakeholders) in collaborative projects that address disease areas where there is a high burden on patients and/or society. In IHI cross-sectoral projects involve the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area.

Moderator:

- Patrick BOISSEAU (Director General - Strategic Initiatives, MedTech Europe)

Speakers:

- Philippe CLEUZIAT (Senior Director, R&D Department, Open innovation & partnerships, bioMérieux)
- Christoph MOORE (Senior Manager Portfolio, Strategy & Alliances, Medical Science Liaison & Grant Office / Staff Office EMEA, Fresenius Medical Care)
- Matthias MÜLLENBORN (Vice President Study Programmes, Patients & Partnerships, Global Chief Medical Office, NovoNordisk)
- Peter SCHROEER (Vice President Regulatory Affairs EMEA and Canada, Johnson & Johnson)
- Fanny VAN DER LOO (Director Public Affairs | Edwards Lifesciences | Health | EU | EMEA, Edwards Lifesciences)

ROOM 113

THE EUROPEAN HEALTH DATA SPACE: THE NUTS AND BOLTS

The European Health Data Space reflects a compelling vision to integrate Europe's national and regional health data systems. It has also put Europe's national and regional health systems on the spot, and shown that there are significant variations in digitalisation as well as untapped data reservoirs and potentials for data transfers and use. This session will focus on the "nuts and bolts" of data use and re-use, and explore the efforts and resources still required to make the EHDS a reality.

Moderator:

- Petra WILSON (Senior Adviser, FTI Consulting, Managing Director, Health Connect Partners)

Speakers:

- Mario JENDROSSEK (European affairs lead, French Health Data Hub)
- Samrend SABOOR (Head of ehealth and Patient Management, Siemens Healthineers)
- Louisa STÜWE (eHealth Project Lead, Ministère des solidarités et de la santé)

12:00-12:50

ROOM 133+134

EU REGULATION ON HEALTH TECHNOLOGY ASSESSMENT: ENABLER OR BARRIER FOR ACCESS TO MEDICAL TECHNOLOGY INNOVATION?

Following several years of impasse, the member states - supported by the European Commission- proposed a new law, now accepted by the three European institutions. Driven by the member states and financed by the European Commission, joint work will be done on methodologies, scientific advice and assessments defined in an annual workplan. This new regulation will recognise the specificity of medical technologies and a dedicated governance is expected, but implementation over the next 3 years will define the true impact. The MedTech Forum Panel discussion brings together representatives of member states, of the newly formed heads of agencies group involved in HTA, of the European Commission, of the medical technology industry, and of patients to provide insight of the current line of thinking on what to expect in coming years of activities under this new regulation. A preferred way forward by MedTech Europe members will also be shared.

Moderator:

- Yves VERBOVEN (Senior Adviser - External Consultant, MedTech Europe)

Speakers:

- Piedad FERRE DE LA PEÑA (Technical Advisor, Subdirectorate General for the SNS Services Portfolio and Compensation Funds, Ministry of Health, Spain)
- Flora GIORGIO (Deputy head of Unit, DG SANTE Directorate-General for Health and Food Safety, European Commission)
- Andrea RAPPAGLIOSI (Vice president Public Affairs, EMEA, Canada, LATAM, Edwards Lifesciences)
- Olaf WINKLER (BV Med)

ROOM 118+119

VALUE OF MEDICAL TECHNOLOGIES CONTRIBUTING TO RESILIENT & INNOVATIVE HEALTH SYSTEMS

IQVIA MEDTECH

Healthcare across the world has been challenged and transformed in multiple ways by the covid pandemic. The efficiency, resilience and capacity for innovation of healthcare ecosystems have been put to the test. The efficiency and throughput, the time needed for innovation and a need to increase robustness (e.g. of procurement, funding, treatment quality) of healthcare providers can seemingly be in opposition to each other. How can MedTech industry help maximize across all dimensions? In this session we will 1) position MedTech as a catalyst for sustainable change in healthcare, 2) identify how medical technologies can help "create time" for innovation while increasing efficiency and resilience of healthcare and 3) identify prerequisites for a successful translation of innovation into value for healthcare systems. We will focus on cutting-edge digital technologies and brainstorm about how they will impact healthcare. We shall address the following questions: How do medical technologies help increase both robustness and throughput of healthcare systems? What digital technologies can be expected to contribute most? What type of innovation with focus on efficiency and resilience in the primary care setting - can be facilitated by MedTech? How can public and private stakeholders work together to build future-proof digital healthcare infrastructure? What will that future look like across all stakeholders?

Speakers:

- John Lee ALLEN (Managing Partner, RYSE Asset Management)
- Razvan IONASEC (CTO Healthcare, Amazon Web Services, EMEA)
- Aleksandar PETROVIC (Principal, Consulting and Services, IQVIA MedTech)
- Kevin VAN DOOREN (Global lead Market Access & Reimbursement - Connected Care, Philips)

12:50-14:15 **NETWORKING LUNCH**

13:20-14:10

ROOM 111+112

FROM ESG TALK TO ACTION

BCG

The time for talk is over; markets and customers are demanding and rewarding action. Learn how companies are taking tangible action to address ESG challenges, driving patient access, delivering value-based healthcare and making rapid progress on the path to net zero.

Speakers:

- Greg FISCHER (BCG)
- Götz GERECKE (BCG)
- Katharina TILLMANNS (Head of Sustainability, Sartorius)
- Elia TZIAMBAZIS (Managing Director & Partner, BCG)

ROOM 113

REGULATORY MODERNIZATION: STATE OF INDUSTY AND MEDTECH LEADER PERSPECTIVES

Veeva MedTech

With rapidly evolving regulatory and market demands, compliance teams are constantly under pressure to do more with less, requiring a fundamental shift in operations, systems, and processes. So what is the current state of regulatory modernization across the industry? A recent survey of nearly 100 global device and diagnostics organizations gathered insights to understand better the industry's progress towards unifying regulatory operations. The results yield interesting insights. While 56 percent of global medtech companies have begun modernizing regulatory operations, the industry is behind in digital transformation compared to the life sciences industry overall. In most areas, we still see medtech companies using manual processes, disconnected data, and siloed systems that are neither scalable nor flexible. During this presentation we will share the key findings and discuss perspectives with industry leaders, as well as providing recommendations for modernizing and transforming regulatory to ensure compliance and increase speed to market.

Speaker:

- Annemien PULLEN (Senior Director Strategy Europe, Veeva MedTech)

13:20-14:10

ROOM 133+134

RIGHT FIRST TIME: DELIVERING COMPLEX PRODUCTS IN A COMPLEX WORLD SUCCESSFULLY

Regulations are increasing, supply chains are stressed – yet the healthcare industry delivered at unprecedented speed and scale during the pandemic.

We will discuss how Virtual Twins can boost your product development cycles whilst ensuring highest quality – cost effectively.

Virtual Twin close the loop from design to engineering, they connect requirements to the systems under development and thus support your validation and quality control through traceability as well as virtual testing. Virtual Twin allow you to manage the complexity associated with new product features that are driven by digital and data.

We will show how we not only facilitate multi-physics simulations of your products, but also how we can include patients using some of our technology.

You will learn about

- **Reducing Device Development Time and Cost** by systematically adopting Virtual Testing in place of Physical Testing
- **Expanding Innovation Bandwidth** using Process Automation and Democratization to empower experts and non-experts alike
- **Improving Device Safety and Effectiveness** by assessing device performance with realistic validated Virtual Human models
- **Meeting all Performance, Quality, and Compliance Requirements** using a Model-Based Systems Engineering approach
- **Reducing Risk of Expensive Late-Stage Design Modification** through visibility to all the right data at the right time
- **Optimizing Component Sourcing and Streamline New Part Introduction** using Standard Component Management

Speaker:

- Barbara HOLTZ (Life Sciences Value Expert, Dassault Systemes)

ROOM 118+119

EU MARKET ASSESSMENT: KEY TRENDS AND OPPORTUNITIES IN MEDICAL DEVICES AND DIGITAL HEALTH

The role of Med Tech in advanced therapeutic drug/device combination products and how Med Tech can play a pivotal role in commercial success. There is a need for companies developing advance therapies that require a device/ procedure for administration to deal with the logistics, physician engagement/training and support necessary to minimize disruption. How does Med Tech become a partner-of-choice? How do you scale globally?

Speaker:

- Karla ANDERSON (Partner Life Sciences, GuideHouse)

14:15-15:05

ROOM 111+112

WE SEE FRAGMENTATION TODAY - BUT THE FUTURE IS EUDAMED

Today it is already possible to register your company, economic operators and your products in the new centralised EU medical devices database, EUDAMED. However, EUDAMED exists today together with scattered national databases. It can be costly and confusing for manufacturers and other economic operators to navigate the EU 26 countries national notification and registration rules. What is the situation? Is there a solution and a possible way forward?

Moderator:

- Kevin TAYLOR (Associate Director Regulatory Affairs Digital Capabilities, Johnson & Johnson)

Speakers:

- Ronald BOUMANS (Program Manager, European Regulatory Affairs, EMERGO)
- Mary GRAY (Associate Director EU MDR UDI, Johnson & Johnson)
- Carmen RUIZ-VILLAR FERNANDEZ-BRAVO (Deputy Director, Medical Devices Department, AEMPS, Spanish Agency of Medicines and Medical Products)

ROOM 113

PUTTING DATA TO WORK: ACCELERATING THE RECOVERY FROM THE PANDEMIC

ResMed
Changing lives with every breath

As hospitals and healthcare systems are grappling with the challenges of the Covid19 pandemic including workforce burnout, patient backlogs and resource shortages, the pandemic has also shown a way out: going digital. This session showcases how better use of health data in digital health solutions are essential for healthcare systems to address these challenges. Improved access and use of health data can assist healthcare professionals, empower patients and citizens, address economic challenges and help with prevention, diagnosis, management and therapy of diseases, thus driving productivity and efficiency, and improving outcomes and patients' quality of life. If there is a silver lining in the pandemic, it could be a legacy of embracing data use and digital health.

Moderator:

- Petra WILSON (Senior Adviser, FTI Consulting, Managing Director, Health Connect Partners)

Speakers:

- Andrew HUXTER (VP Northern Europe & Growth Markets EMEA, ResMed)
- Tapani PIHA (Special adviser at SITRA (Finnish innovation fund), with the Ministry of Social Afffairs & Health, and FIPRA International, SITRA)
- Janne RASMUSSEN (Chief Consultant on IT Systems, Team Manager & DPO at MedCom, Member of Board of Directors & Treasurer at EHTEL)
- Piet-Heijn VAN MECHELEN (Honorary Chairman of Dutch Apnea Association (ApneuVereniging) policy advisor and international representative, Dutch Apnea Association (ApneuVereniging))

14:15-15:05

ROOM 133+134

HOW DOES EU MONEY FLOW INTO RECOVERY: LESSONS LEARNED FROM NATIONAL RECOVERY PLANS

The aim of the Recovery and Resilience Facility is to mitigate the economic and social impact of the coronavirus pandemic and make European economies and societies more sustainable, resilient and better prepared for the challenges and opportunities of the green and digital transitions. But how does it work? Who is proposing? Who is deciding? How medtech companies can access to it? Come and listen to some practical national examples.

Moderator:

- Jakob WEGENER FRIIS (Deputy Head of Cabinet, Cabinet Gentiloni, Commissioner for Economy, European Commission)

Speaker:

- Gonzalo ARÉVALO (DG for Research Planification, Ministry of Science and Innovation)
- Luis CAMPO (President & CEO Iberia GE Healthcare, GE Healthcare)
- Sharon HIGGINS (Director of Membership & Sectors, IBEC)

ROOM 131+132

ASK THE EXPERT: BEST PRACTICES AND SOLUTIONS FOR DEALING WITH COMPLEX SITUATIONS DURING MDR CONFORMITY ASSESSMENT PROCEDURES

Hogan Lovells

The purpose of this session would be to discuss best practices for dealing with potential obstacles during the conformity assessment procedure: e.g. disagreement with the notified body, delay in the review, lack of information from the notified body on the status of the application, insufficient clinical evidence to support a specific indication, gap in certification between MDD and MDR. Practical ways to deal with these obstacles will be discussed.

Speaker:

- Fabien ROY (Partner, Hogan Lovells)

ASK THE EXPERT: ARTIFICIAL INTELLIGENCE/MACHINE LEARNING BASED SOFTWARE AS A MEDICAL DEVICE

Hogan Lovells

In this session expert and participants will review the regulatory status quo for AI medical devices, identify current problems to certify self-learning or black box AI and explore potential pathways. The session will also discuss where the journey is heading in the future in terms of the coming EU Artificial Intelligence Act.

Speaker:

- Arne THIERMANN (Partner, Hogan Lovells)

14:15-15:05

ASK THE EXPERT: THE IMPLICATIONS OF US FDA'S HARMONIZATION OF THE QUALITY SYSTEM REGULATION WITH ISO 13485

Lachman CONSULTANTS
Experience. Excellence.™

The US Food and Drug Administration published their much-anticipated proposed rule (PR) to amend the Quality System Regulation (QSR) (21 CFR Part 820) on 2/23/2022, after four years in the works. This proposed rule does not only impact US manufacturers but all manufacturers with product in the US market.

FDA argues that the amendment to the QSR will result in bringing new medical devices to the market more quickly and reduce the burden on medical device providers by creating a single quality system structure for those already adhering to both ISO 13485 and Part 820.

The PR plans to adopt ISO 13485 by reference. FDA provides a table in the PR indicating where it believes that ISO and the current requirements under Part 820 are substantially similar. The proposal includes maintaining some aspects of 820 and ISO, obsoletion, addition, clarification, and revision.

This discussion will include understanding the nuances of the PR, how the final rule will and will not change FDA's inspection activities and programs and highlight how manufacturers in the US market already will need to adjust should the PR be made final. This is also a great opportunity for those who are not in the US market but plan to enter to understand the current mindset of FDA in medical device regulation

Speaker:

- Ricki CHASE (Vice President, Combo Products/Medical Device Technologies and Analytical Sciences, Lachman Consultant Services, Inc)

ASK THE EXPERT: ACCELERATE THE DIGITAL TRANSFORMATION OF REGULATORY AFFAIRS, QUALITY, CLINICAL AND SAFETY TOWARDS BECOMING STRATEGIC AND DATA-DRIVEN ORGANIZATIONS.

NNIT
We make a mark

With the concurrent challenges of resource-intensive requirements, life-cycle management and investment pressure the need for digital transformation of RA, Quality, Clinical and Safety is inevitable and cannot be ignored. You can't afford costly mistakes and loss of data.

When viewing the digital transformation from a business perspective, it becomes evident that you can take ownership of your data and enable the realization of business value through emerging technologies such as Artificial Intelligence and Machine Learning and implementation of solutions supporting further growth.

This emphasizes the need for a clear strategic direction to steer the whole organization through the change journey of digital transformation.

Speaker:

- Niels BUCH LEANDER (Global Head of Regulatory Affairs, NNIT)

14:15-15:05

ASK THE EXPERT: MARKET SIZE, SHARE AND GROWTH. ARE YOU STILL GUESSING?

MedTech Europe from diagnosis to cure | Market Data

Real data, Trusted service, Informed decisions

Information is power. Medical technology companies need to stay on top of the latest trends impacting their business. Informed decisions require up-to-date market data from a trusted service.

MedTech Europe's Market Data experts deliver unrivalled information, tailored to companies' portfolio and geographic needs. In this session you will discover the gold standard of market size, share and dynamics information for the medical devices and in-vitro diagnostics industry.

Speaker:

- Christian MANOIU (Director Market Data, MedTech Europe)

15:15-16:05

ROOM 111+112

#MOVEYOURINNOVATION

#MoveYourInnovation session is dedicated to those who are contemplating innovation and want to understand how they can contribute, innovate through the advice and examples of those already onto the rollercoaster and enjoying the ups and the downs of innovation journey. #Join us!

Moderator:

- Julie RACHLINE (CEO, LallianSe & Braintale)

Speakers:

- Nils REIMERS (Director Research & Development, Government Affairs and Market Access, Stryker)
- Marc MARTINELL (CEO, Minoryx)

15:15-16:05

ROOM 113

PRODUCT LIABILITY IN EUROPE: A FRAYING SYSTEM?

faegre drinker

This session is structured as follows:

- Discuss the evolution of Product Liability in the medtech space in the EU, as illuminated by US developments and practice trends as points of comparison (10 minutes);
- Set the table with the current proposals and discussion points of the European Commission (10 minutes);
- Open discussion with the panel to explore on the following (30 minutes):
- Considerations and questions regarding the Product Liability Directive in the EU;The new EU Collective Redress Directive on Consumer Class actions, its implementation in EU Member States, and interplay with GDPR;
- Upcoming European product safety regulation, as well as how MDR & IVDR are addressing liability issues;
- Implications for various member states, each with their own laws, interpretations, and implementation strategies;
- Discovery in the US as it compares to EU and proposed regulations in the EU;
- Lessons learned from mass torts and class actions in the US, and past rulings of the European Court of Justice; and
- Other related topics, such as the interplay of liability-related considerations with artificial intelligence in the EU.

Moderator:

- Teresa GRIFFIN (Partner, Faegre Drinker Biddle & Reath LLP)

Speakers:

- Mark BEAMISH (Policy officer, European Commission)
- Philipp SCHMIDT (Senior Legal Counsel EMEA, Zimmer Biomet)
- Agnes SZOBOSZLAI (Senior Legal Counsel, Philips)
- Michael ZOGBY (Partner, Faegre Drinker Biddle & Reath LLP)

15:15-16:05

ROOM 133+134

HARMONISING GLOBAL LABELLING REQUIREMENTS GOING BACK TO BASICS - WHAT REALLY NEEDS TO GO ON THE LABEL?

Medical devices label contains information targeted at the user to help communicate key information for safe and effective use of the device. Increasingly, regulators mandate local country information e.g., importers, to be added to product's label. Changes to labelling are often not only costly but they can be challenging to implement from a practical perspective. Greater efforts to promote a harmonised approach to medical devices labelling are needed. This session is going to explore various perspectives touching on what are the principles of medical devices' labelling, what information is key to be on the medical device's label, why are updates to product label's difficult to implement, and what can be done to promote harmonisation of labelling requirements at the global level.

Moderator:

- Emmet DEVEREUX (Director, Government and Regulatory Affairs, Cook Medical EMEA Group Limited)

Speaker:

- Robert DURGIN (Vice President, Regulatory Affairs Global Policy, Johnson & Johnson)
- Jesus RUEDA RODRIGUEZ (Director General Strategies, Special Projects & International Affairs, MedTech Europe)

ROOM 118+119

TOWARDS GREATER SUSTAINABILITY IN HEALTHCARE : THE JOURNEY SO FAR

This panel discussion will focus on how the industry is working to improve the sustainability performance of healthcare products. Speakers invited will talk about their experience and open the discussion on limits and obstacles encountered on their sustainability journey. The panel offers a unique opportunity to exchange ideas with industry experts throughout the value chain.

Moderator:

- Valerie RAMPI (Senior Manager, Environment and Sustainability, MedTech Europe)

Speakers:

- Ole GRØNDHAL HANSEN (project Manager, PVCMed Alliance)
- Vincent STONE (Technical and Environmental Affairs Senior Manager, VinylPlus)
- Laurens VAN HOUTE (Manager Surgical Department, Medisch Spectrum Twente)

16:05-16:40

NETWORKING BREAK

16:40-17:30

ROOM 111+112

CEO #NOFILTER

Global leaders from the field of medical devices, diagnostics and digital health will join the discussion and speak openly about the latest trends, challenges and opportunities they are facing.

Moderator:

- Ingmar DE GOOIJER (Healthcare industry observer)

Speakers:

- Birgitte DE VET (Vice-President - Medical Segment, Materialise)
- Mick FARRELL (CEO, ResMed)
- Thomas SCHINECKER (CEO, Roche Diagnostics)

17:30-18:00

ROOM 111+112

PROGRAMME HIGHLIGHTS

OLYMPUS

Join us live - onsite or online - and watch the news of the day. The MedTech Forum main moderator will be joined on stage by several speakers to run you through the highlights of the programme.

18:00-19:30

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09:00-09:50

ROOM 111+112

KEYNOTE SPEAKER

10:00-10:50

ROOM 111+112

PANDEMIC PREPAREDNESS: IS EUROPE READY FOR THE NEXT PANDEMIC?

Medical technologies have played a crucial role in the management of the COVID19 pandemic, through the provision of personal protective equipment, diagnostics tests, respiratory support equipment as well as injectables for vaccines. Companies worked around the clock to adapt to multiple production and distribution challenges, with high costs. What practices have medtech companies introduced and incorporated? A second lesson from these past two years is that pandemic preparedness is a crucial pillar of public health policies. Infectious disease threats know no borders, and dangerous pathogens that circulate are a risk everywhere. Europe must be better prepared to predict, prevent, detect, assess and effectively respond to pandemics in a highly coordinated fashion. To this end, the European landscape has significantly changed, with for example the introduction of a new Authority for Public health Emergency Preparedness and Response (HERA), as well as new roles for EMA and the ECDC. What did our sector learn from this crisis? Does the EU now have fully fit structures and instruments for the future? In short, is Europe ready for the next pandemic?

Moderator:

- Jessica IMBERT (Senior Manager Government Affairs & Public Policy, MedTech Europe)

Speakers:

- Martyna GIEDROJC (Director of International Public Affairs and Professional Relations Europe, Cepheid)
- Annalisa TESSAROLO (Policy Officer, DG for Internal Market, Industry, Entrepreneurship and SMEs - Europan Commission)
- Félix UEDELHOVEN (Head of Government Affairs & Policy Europe, GE Healthcare)

ROOM 113

EUROPEAN ALIGNMENT OF DIGITAL HEALTH ASSESSMENT

AliraHealth CO-HOSTED BY EIT Health

Co-funded by the European Union

Funding and reimbursement of digital health technologies have been a critical barrier to their adoption. Some European countries and regions have broken new ground in developing dedicated funding programmes to support digital health innovation, often starting in the domain of personal connected health or mHealth. How can fragmentation be avoided? This session convenes digital health policymakers from several European countries to discuss the potential and limits of European coordination.

Moderator:

- Richard CHARTER (Vice-President, Medtech Market Access, Europe & Asia-Pacific, Alira Health)

Speakers:

- Cristina BESCOS (Director of Innovation, EIT Health)
- Louisa STÜWE (eHealth Project Lead, Ministère des solidarités et de la santé)
- Elena TORRENTE (Digital Health Development Deputy Director. Head of DKV Innolab for Digital Health, DKV)

10:00-10:50

ROOM 133+134

FROM CODE TO CULTURE

The discussion in this session will focus on how codes of conduct, in particular in medtech, are evolving and how trade associations can further support companies in the compliance journey, for example with the development of specific standards to make the principles being translated into companies practices, in particular for smaller companies that do not necessarily have the necessary resources.

Moderator:

- Anne-Sophie BRICCA (Terumo BCT)

Speakers:

- Signe ELBAEK (Chief Compliance Officer, Moelnycke)
- Stephen NGUYEN-DUC (Global Head of Ethics&Compliance GEHC PDx, GE)
- Peter DIENERS (Regional Managing Partner Germany, Clifford Chance)

ROOM 118+119

INTERNATIONAL DATA TRANSFERS: HEALTH DATA CONSIDERATIONS

This session aims at highlighting the critical role international data transfers play in healthcare, review the current legal landscape, and discuss possible pathways forward. Globally, data localization has become a significant trend, with important consequences for the medtech industry. The discussion will start by briefly outlining the concerns of various stakeholders and the rationale for many of these localization requirements. Then it will focus on how cross border data flows, particularly in an era of digital health and telemedicine, advance patient care, and how they contribute to research, eliminating bias, monitoring device performance, and in a broader sense advancing medicine in the digital age. While specific new European legal initiatives aim to create better conditions for cross-border health data flows within Europe, transfers between Europe and other jurisdictions are fundamentally necessary to carry out appropriate and high-quality research, safety monitoring, and digitally supported patient care and treatment. The panel will then brainstorm on how to overcome broadly framed transfer restrictions.

Moderator:

- Thomas SCHUMACHER (Vice President, VP Chief Legal Counsel, Data and Privacy Medtronic, Medtronic)

Speakers:

- David PELOQUIN (Partner, Ropes & Gray)
- Hannah BRACKEN

10:50-11:20

NETWORKING BREAK

11:20-12:10

ROOM 111+112

THE RISE AND RISE OF CHINA'S MEDTECH MARKET CHANGING LANDSCAPE OF THE GLOBAL MEDICAL TECHNOLOGY INDUSTRY AND THE GLOBAL MARKET

China is becoming an increasingly important market for medical technologies. While the growth in many sectors of the economy is slowing, China's medical technology market and industry continue to grow. The medtech sector has been identified among the key priorities of China's industrial policy for the coming years. In 2021, China published a detailed plan to foster its domestic medtech industry, promoting "dual-circulation" objectives of reducing the country's reliance on foreign suppliers and expanding exports of domestic products. Overall, the policy environment especially in public procurement has been challenging for foreign medtech companies to gain access to the Chinese market. At the same time, China's bilateral trade in medical technologies went from a deficit of €1.3 bn in 2019 to a €5.2 bn surplus in 2020. What does China's industrial policy and the growth of Chinese industry mean for the future of the global medical technologies market? Can the European medtech industry remain competitive not just in China but in third countries and even in the EU? Join us for an exciting panel discussion to explore these and many other questions in depth.

Moderator:

- Trevor GUNN (Vice President International Relations, Medtronic, Chair, International Affairs Committee, MedTech Europe)

Speakers:

- Christian CLARUS (Director Government Affairs | Global Government Affairs & Market Access, B. Braun)
- Fredrik ERIXON (Director, European Centre for International Political Economy (ECIPE))
- Max J. ZENGLEIN (Chief Economist, Mercator Institute for China Studies (MERICS))

ROOM 113

TRUSTWORTHY ARTIFICIAL INTELLIGENCE IN HEALTHCARE

Medical technologies powered by artificial intelligence and machine learning can save lives, generate efficiencies, and help address the crisis in the healthcare workforce. But for it to be accepted and trusted by citizens, patients and healthcare systems alike, it needs to be appropriately regulated. This session will explore paths to regulating AI in different regions of the world.

Speakers:

- Susanna AUSSO (Head of the Artificial Intelligence Program, Fundació TIC Salut Social)
- Philip HAYWOOD (Policy Analyst, OECD)
- Erik VOLLEBREGT (Partner, Axon Lawyers)

11:20-12:10

ROOM 133+134

MDR IMPLEMENTATION: 24 MONTHS UNTIL MAY 2024

In May 2022, the Medical Devices Regulation (MDR) will have been in full application for almost one year. Despite the COVID-19 pandemic, some positive progress was achieved however today the slow and piecemeal MDR implementation is still seriously holding back industry and other stakeholders to complete transition in a timely fashion. In this session, current and foreseen challenges will be analysed with a view to discuss and suggest ways on how to best solve them.

Moderator:

- Marc-Pierre MÖLL (CEO, Bundesverband Medizintechnologie (BVMed))

Speakers:

- Anna Eva AMPELAS (Head of Unit - SANTE.DDG1.B.6, European Commission - Directorate General for Health and Food Safety - Medical devices, Health Technology Assessment)
- Li FELLÄNDER-TSAI (EFORT President 2021/2022, EFORT)
- Thierry SIRDEY (Competent Authority for Medical Devices (CAMD) - Executive Committee Co-Chair, CAMD)
- Graeme TUNBRIDGE (SVP Global Regulatory and Quality, Medical Device, BSI Group (Notified Body))

ROOM 118+119

EMPOWERING INDEPENDENT PATIENT ADVOCACY

Edwards

This session aims to demonstrate that patient groups can make a difference in improving the conditions for patients within healthcare systems and that the MedTech industry has a role and a responsibility to support this. Yet, patient advocacy is still a relatively new area within the MedTech sector and our industry can learn a lot from the pharmaceutical world and patient groups. The panelists in this session, who stem from varied backgrounds, will provide concrete examples to showcase what we can do collectively to lead the way in independent patient advocacy.

Moderator:

- Michael GEORGE, Edwards Lifesciences

Speakers:

- Teresa GLYNN (Development Executive, Global Heart Hub)
- Annabell MERKLIN (Edwards Lifesciences)
- Mai-Lise NGUYEN (Roche)

12:20-13:10

ROOM 111+112

HOW DOES THE FUTURE LOOK LIKE FOR MEDICAL TECHNOLOGIES' CONTRIBUTION TO A SUSTAINABLE TRANSITION IN HEALTHCARE?

Considering the challenges on the way to more sustainable healthcare in a context of growing societal expectations, how can the medical technology sector overcome obstacles identified on its journey to improve its sustainability performance?

The speakers will focus on how technologies can overcome some of the obstacles currently faced by the healthcare sector to achieve more "safe and sustainable chemicals and materials by design". They will also make recommendations to the medical technology industry for improving their record.

Moderator:

- Valerie RAMPI (Senior Manager, Environment and Sustainability, MedTech Europe)

Speakers:

- Ole GRØNDHAL HANSEN (project Manager, PVCMed Alliance)
- Renata JOVANOVIC (Partner, Deloitte Consulting Germany)
- Vincent STONE (Technical and Environmental Affairs Senior Manager, VinylPlus)
- Laurens VAN HOUTE (Manager Surgical Department, Medisch Spectrum Twente)

12:20-13:10

ROOM 113

IS EUROPE STILL ATTRACTIVE FOR THE MEDTECH INDUSTRY?

The environment for accessing the European market is now changing very significantly and rapidly. The implementation of the new Medical Device and In Vitor Diagnostics regulations, the GDPR regulation, the HTA EU cooperation regulation, Brexit, are among some of the critical changes which are potentially transforming the attractiveness of the European market. Some say Europe is or will shortly become the last place to introduce innovation in the world while a few years ago it was the first place to benefit from innovations. Nevertheless, Europe continues to offer an area of the world with the biggest demand for Medical Technologies with a population of over 400 million, an ageing population, skillful and strongly educated healthcare actors, engineers, chemists, social medicine with access for most and still strong economies with high purchasing powers. The panel will discuss and balance the growing challenges of access to the European market vs it still demand attractiveness. Conclusions might quite surprising.

Moderator:

- Ingmar DE GOOIJER (Healthcar industry observer)

Speakers:

- Serge BERNASCONI (CEO, MedTech Europe)
- Sjaak DECKERS (Venture Partner, NLC / CEO, Microsure)
- Christophe DUJARDIN (Vice-President - Managing Director Europe, Stryker)
- Alexander SOCARRAS (Executive Vice President – Head of EMEA Diagnostics, Siemens Healthcare Diagnostics Products)

12:20-13:10

ROOM 133+134

INTEGRATING START-UPS IN THE INDUSTRIAL INNOVATION ECOSYSTEM

As seen from Europe, there is an abysm between medtech companies and start-ups to perform R&I together. But both types of companies can meet and actively interact together at the regional and local scale which is more favourable for practical interactions. A roundtable will put together panellists representing key stakeholders like start-ups, global companies, healthcare organisations, investors, and public administration, will introduce: successful initiatives, identify critical factors, good practices, and investments for successful R&I.

Moderator:

- Sergio MUNOZ (FENIN)

Speakers:

- Izabel ALFANY (EIT Health)
- Yves BAYON (Medtronic)
- Mariá GONZÁLEZ MANSO (CEO, TUCUVI)
- Furio GRAMATICA (Director of Innovation, Fondazione Don Gnocchi)
- Madjid HIHI (Deputy Director - Scientific affairs & partnerships, CEA-LETI/Clinatec)

ROOM 118+119

MEDTECH IN DIGITAL HEALTH - HOW TO SUCCEED WITH A DIGITAL HEALTH PORTFOLIO IN EUROPE

ZS

The session will highlight how to think about, and execute on, a portfolio by focusing on key elements medical technology companies need to get right: thinking holistically about devices, software, and data along the patient journey; mapping out routes to market; proving value and having an organisational design that supports a digital health portfolio.

Moderator:

- Lukas GRABNER (Associate Partner, ZS)

Speakers:

- Florian LANGE (Director of Digital Health Solutions EMEA, Abbott)
- Katrin PUCKNAT (President, ResMed Germany)
- Alexandra TOADER (Management Consultant, ZS)

13:10-14:30

NETWORKING LUNCH

13:30-14:20

ROOM 111+112

SUSTAINABILITY – NEW NET-ZERO FRONTIER OR THE BOY WHO CRIED WOLF?

McKinsey & Company

Business sustainability has become a strategic imperative in MedTech, driven by pressure across stakeholders. Despite this, MedTech's ESG rating is lower than almost all other industries. Unlocking value creation requires assessing sustainability performance across metrics that matter and embedding them in the Company DNA. Today we will explore the trends in this space and where we have seen leaders in MedTech forge the sustainability path forward.

Speakers:

- Karsten DALGAARD (Senior Partner, McKinsey & Company)
- Gayane GYURJYAN (Partner, McKinsey & Company)
- Judy KRUSZEWSKI (Chief Executive, Sancroft)
- Robert WESTERDHAL (Director and co-founder, Material Economics)

ROOM 113

TRANSPARENCY, EFFECTS ON HCP ENGAGEMENT

IQVIA MEDTECH

Ensuring accurate data and meeting industry code and legal requirements across countries is key to MedTech business. Having all HCP and HCO spend in a single repository provides companies added value beyond transparency obligations and provides an effective means to improve transparency operations, compliance audits and monitoring.

Speakers:

- Nicolas ALBARRACIN (Senior Legal Counsel - Compliance & Privacy), (Merck)
- Dario GHOUDOUSSI (Sr. Dir. Commercial Compliance & Quality Solutions, IQVIA)

ROOM 133+134

REDUCING UDI CONFUSION FOR REGULATORY AFFAIRS TEAMS

Rimsys

The introduction of new UDI requirements in the EU MDR/IVDR regulations has fueled an increased focus by regulatory affairs teams. However, Europe is not the only region that is adding UDI requirements for medical technology products. Countries around the world from Brazil to South Korea have implemented some aspects of UDI. While UDI and other product labeling information have typically been maintained separately from other regulatory information, the growing complexity of supporting multiple markets is introducing compliance challenges. Companies can't treat it simply as an operational or supply chain process.

This session will help to simplify UDI complexity by exploring requirements across several major markets, including the types of devices that are covered and the expected implementation timelines. We?ll also explore new ways that RA teams can get a better handle on UDI information by managing it alongside product registrations, certificates, manufacturing site licenses, and other regulatory information.

Attendees will learn: Which products will be impacted by new UDI rollouts Data requirements and issuing entities for different regions How to curate "universal" UDI data for reuse across submissions.

Speaker:

- James GIANOUTSOS (CEO, Rimsys)

13:30-14:20 | ROOM 118+119

A NEW HORIZON FOR CIRCULARITY IN MEDTECH

Deloitte.

With sustainability high on everyone's agenda, the move toward circularity is inevitable. But what does it mean for the MedTech sector? From the value chain challenges & opportunities to the impact of the regulatory environment, and insights into the application of circular business models, we will explore aspects of circularity in MedTech.

Speakers:

- Javier COLÁS FUSTERO (Industry expert, Spain)
- Michel DE RIDDER (Partner, Quality and Compliance, Deloitte Risk Advisory, Belgium)
- Carlo GIARDINETTI (Consulting Sustainability lead, Deloitte, Switzerland)
- Aline LAUTENBERG (General Counsel - Director Legal & Compliance, MedTech Europe Belgium)
- Pieter SAUWENS (Director, Strategy, Analytics and M&A, Monitor Deloitte, Belgium)

14:30-15:20 | ROOM 111+112

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Global leaders from the field of medical devices, diagnostics and digital health will join the discussion and speak openly about the latest trends, challenges and opportunities they are facing.

Moderator:

- Ingmar DE GOOIJER (Healthcare industry boserver)

Speakers:

- Kevin LOBO (Chairman and Chief Executive Officer, Stryker)
- Ashley MCEVOY (Executive Vice President and Wolrdwide Chairman, Medical Devices, Johnson & Johnson)
- Rob TEN HOEDT (Executive Vice President & President EMEA & APAC, Medtronic and Chairman MedTech Europe)

15:20-15:50 | ROOM 111+112

PROGRAMME HIGHLIGHTS

OLYMPUS

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15:50-16:00 | ROOM 111+112

CONCLUSIONS

Moderator:

- Ingmar DE GOOIJER (Healthcare industry observer)

Speakers:

- Serge BERNASCONI (CEO, MedTech Europe)
- Rob TEN HOEDT (Chairman, MedTech Europe)

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Room 131 + 132

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