A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

#MTF2023

30 MAY – 1 JUNE

DUBLIN

In cooperation with Irish Medtech Association Ibec

PROGRAMME

www.themedtechforum.eu

as of May 22, 2023

WELCOME INTRODUCTION

Dear participants, Dear speakers, Dear sponsors,

This year's MedTech Europe's annual conference will be held from 30 May to 1 June 2023 at the Convention Centre Dublin (CCD).

We are now busy with the preparation of the event in which you'll find a programme offering an optimal balance between plenary sessions, parallel sessions, ask the expert roundtables and networking breaks. In addition, the sessions in the plenary room will be broadcasted so remote participants can attend part of the programme.

We will also adopt a new concept for the exhibition and networking area allowing for improved interaction between participants.

We're looking forward to welcoming you to Dublin and we thank you in advance for your support.

Best regards,

Oliver BISAZZA
Chief Executive Officer
MedTech Europe

LIVE STREAMING

PROGRAMME AT A GLANCE

30 MAY 2023

09:30-17:30 MEDTECH MEETING OF MINDS CONFERENCE, HOSTED BY THE IRISH MEDTECH ASSOCIATION

LEVEL 3 — 18:00-21:00 The MedTech Forum Opening reception & cocktail dinner sponsored by Siemens

31 MAY 2023

THE LIFFEY	LIFFEY HALL 1	LIFFEY HALL 2	LIFFEY MEETING ROOM 2	LIFFEY MEETING ROOM 3
08:30-09:30 WELCOME COFFEE				
09:30-09:45 OPENING Welcome & Introduction				
09:45-10:30 PLENARY CEO #nofilter				
10:40-11:30 PARALLEL SESSION MoveYourInnovation#2	10:40-11:30 PARALLEL SESSION Where and how can we make the transition to the IVD Regulation more efficient, predictable and timely?	10:40-11:30 PARALLEL SESSION Data sharing transforms our healthcare systems *How the EHDS can fullfil its goal and transform patient's lives*	10:40-11:30 PARALLEL SESSION From ESG Talk to Action - Reducing MedTech's Impact on our Planet By BCG	
11:30-12:00 NETWORKING BREAK				
12:00-12:50 PARALLEL SESSION Taking the 'Risk' out of 'Risk Sharing Agreements': Leveraging RWE to Connect Regulatory, Innovative Funding Models, and Product Adoption By Alira Health	12:00-12:50 PARALLEL SESSION Digital Twin in healthcare is making headway	12:00-12:50 PARALLEL SESSION Medical Devices Regulation (MDR): What does the future hold for healthcare systems and patients?	12:00-12:50 PARALLEL SESSION Advancing towards carbon-free healthcare with Circular Economy: ready for the journey? By Flex	
12:50-14:00 LUNCH BREAK				
14:00-14:50 PARALLEL SESSION Building a cyber-capable healthcare system in the face of digital instability By ReedSmith	14:00-14:50 PARALLEL SESSION Innovative Payment Schemes (IPSs) in Europe: springboard for innovation?	14:00-14:50 PARALLEL SESSION Sustainability: emerging opportunities and challenges for the Medical Technology Sector	14:00-14:50 PARALLEL SESSION Leveraging the Medical Device Regulations (MDR) for Commercial Success: 3 Strategies for Value-driven Sales By Value Connected	
15:00-15:50 PARALLEL SESSION Europe's Search for Renaissance By Ibec	15:00-15:50 PARALLEL SESSION Final countdown to the European Medical Devices Database – Is your business ready?	15:00-15:50 PARALLEL SESSION Europe's investment in Scientific Advice and Joint Scientific Consultations as part of new regulations MDR/IVDR/ HTA-R, new pieces of the puzzle!	15:00-15:50 PARALLEL SESSION Value Creation in MedTech through the Eyes of an Investor By McKinsey	15:00-15:50 ASK THE EXPERT Please refer to the pages 15 and 16
15:50-16:20 NETWORKING BREAK				
16:20-17:10 PARALLEL SESSION A new era in robotic-assisted surgery: Present and future	16:20-17:10 PARALLEL SESSION GDPR: Mission complete! By Faegre Drinker Biddle and Reath	16:20-17:10 PARALLEL SESSION Global impact of EU MDR/IVDR	16:20-17:10 PARALLEL SESSION Streamlining Regulatory Operations: Industry trends & Innovations By Veeva Medtech	
17:20-18:00 PLENARY CEO #nofilter				

EXHIBITION HALL — 18:00-19:30 Networking reception sponsored by Olympus

1 JUNE 2023

THE LIFFEY	LIFFEY HALL 1	LIFFEY HALL 2	LIFFEY MEETING ROOM 2	LIFFEY MEETING ROOM 3
08:00-09:00 WELCOME COFFEE				
09:00-09:40 PLENARY Keynote speaker				
09:50-10:40 PARALLEL SESSION The potential of artificial intelligence in healthcare - How the AI Act could become the deciding factor for transforming healthcare By Roche	09:50-10:40 PARALLEL SESSION Global public health: towards achieving universal health coverage	09:50-10:40 PARALLEL SESSION Manufacturing the future: Navigating change, sustaining growth By Ibec	09:50-10:40 PARALLEL SESSION MedTech innovation: addressing healthcare system inefficiencies and workforce constraints By Edwards	09:50-10:40 ASK THE EXPERT Please refer to the page 23
10:40-11:10 NETWORKING BREAK				
11:10-12:00 PARALLEL SESSION Irish founder-led enterprises transforming healthcare globally By Ibec	11:10-12:00 PARALLEL SESSION Time for a sustainable transition within the medtech sector By Siemens	11:10-12:00 PARALLEL SESSION Implementation of HTA Regulation at full speed – what's up and will countries use it?	11:10-12:00 PARALLEL SESSION Breaking down barriers: Towards global convergence of medical device regulations	
12:10-13:00 PARALLEL SESSION Europe's sleepwalking towards a US litigation culture By Faegre Drinker Biddle & Reath	12:10-13:00 PARALLEL SESSION Interoperability in practice - What are the MedTech Industry's costs for not becoming interoperable?	12:10-13:00 PARALLEL SESSION The critical role of Procurement in healthcare to unlock Value Based Health Care – transforming public procurement from a transactional- into a value-based approach	12:10-13:00 PARALLEL SESSION Ethical use of Data in AI	
13:00-14:00 NETWORKING LUNCH				
14:00-14:50 PARALLEL SESSION Navigating supply chain challenges By KPMG	14:00-14:50 PARALLEL SESSION One year in: The Innovative Health Initiative leads to its first successful and collaborative European projects	14:00-14:50 PARALLEL SESSION	14:00-14:50 PARALLEL SESSION 510(K): Industry Landscape and Challenges By Lachman Consulting	
15:00-15:50 PLENARY CEO #nofilter				
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 31 May at 9:30 GMT!

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 1 July 2023.

TUESDAY 30 MAY

09:30-17:30

THE AUDITORIUM

MEDTECH MEETING OF MINDS CONFERENCE, HOSTED BY THE IRISH MEDTECH ASSOCIATION

You are invited to Ireland in advance of the MedTech Forum to participate in the Irish Medtech Association's Meeting of Minds Digital Health Conference, 29 & 30 May, Dublin Convention Centre.

Ireland's medtech sector is over 100 years in the making and is recognised as a top five global hub. Understand how Ireland has built this ecosystem and is actively preparing for the next phase in its evolution.

Hosted by the Irish Medtech Association, through the conference and the social programme, you will meet the Irish network, including; industry leaders, senior academics, key opinion leaders, government officials, regulators and more.

Comprising:

- Innovation through the ages: The story of how Ireland became a success in global medtech will be told at the historic world-famous Long Room Library at Trinity College Dublin.
- The future of healthtech: How Ireland's highly connected cross-sectoral ecosystem is preparing.
- Unveiling a world's first global future skills roadmap for health technology: 'The Future Skills Needs in Digital Health 2026' report.
- Getting ahead of EU and international regulations: How Ireland is shaping policy.
- Scaling innovation to reach patients: Ireland's thriving founder-led ecosystem.
- A national dialogue on the European Health Data Space with EIT Health.

With 25 expert speakers, this unmissable event will also offer valuable networking opportunities with the irish ecosystem. Irish Medtech Association are delighted to be the cooperation partner for The MedTech Forum 2023.

Full programme and tickets, visit the link https://www.medtechmeetingofminds.ie/

18:00-21:00

LEVEL 3

THE MEDTECH FORUM OPENING RECEPTION & COCKTAIL DINNER

SIEMENS Healthineers

WEDNESDAY 31 MAY

08:30-09:30 **WELCOME COFFEE**

09:30-09:45 THE LIFFEY

WELCOME AND INTRODUCTION

Moderator:

- Sue SAVILLE (Health Event Facilitator)

Speakers:

- Oliver BISAZZA (CEO, MedTech Europe)

09:45-10:30 THE LIFFEY

CEO #NOFILTER

Global leaders from European medical technology manufacturers will join the discussion and speak openly about the latest trends, challenges and opportunities they are facing.

Moderator:

- Sue SAVILLE (Health Event Facilitator)

Speakers:

- Bronwyn BROPHY (Incoming CEO, Vitrolife)
- Jeremy EAKIN (Chief Executive Officer, Eakin Healthcare)
- Toni SCHROFNER (Chief Officer Medical Division & Member of the Executive Board, Dräger)

10:40-11:30 THE LIFFEY

MOVEYOURINNOVATION#2

Agile, strategic, opportunistic, value-generating innovations: how to navigate and collaborate. A "How to session" to implement an innovative mindset and culture, with a specific focus on time. Time management, scheduling, expectation and understanding are different in start-ups and global companies despite their cooperation to deliver innovation to the patient and the healthcare systems. How to manage it?

This non-conventional, open panel discussion will offer an interactive approach, testimonies and examples.

Moderator:

- Julie RACHLINE (President, LallianSe)

Speakers:

- Enrique CLAVEROL-TINTURE (Head of the Medical Technologies Programme, European Innovation Council, European Commission)
- John MACNAMARA (VP R&D, Medtronic)
- Maeve MCGRATH (Head Healthcare Innovation, Roche)

10:40-11:30

LIFFEY HALL 1

WHERE AND HOW CAN WE MAKE THE TRANSITION TO THE IVD REGULATION MORE EFFICIENT, PREDICTABLE AND TIMELY?

This session will consider where we can increase Notified Body capacity to support the implementation of the IVD Regulation system. Can we simplify the complexity and reduce the time of conformity assessment and other major Notified Body activities? What role should regulators, Notified Bodies, manufacturers and other stakeholders play?

Moderator:

- Megha IYER (Director, Global Strategic Regulatory Affairs, Thermo Fisher Scientific)

Speakers:

- Flora GIORGIO (Acting Head of Unit of DG Sante D3, European Commission)
- Kira MEYEROVICH (Manager RA Advocacy, BD Life Sciences)
- Andreas STANGE (Senior Vice President MHS regulatory & quality, TÜV SÜD)

LIFFEY HALL 2

DATA SHARING TRANSFORMS OUR HEALTHCARE SYSTEMS - HOW THE EHDS CAN FULLFIL ITS GOAL AND TRANSFORM PATIENT'S LIVES

Innovative Payment Schemes are a key mechanism to guarantee the timely access of European patients to innovative value-adding medical technologies and procedures. A mapping conducted by MedTech Europe end of 2022 has demonstrated the existence of 21 IPSs in 8 of the 32 European countries scoped for this project. This session will offer you the possibility to learn more about IPSs in general and about two of them in particular (Funding Mandate in England and the Early Coverage framework for innovative DMDs in France) by interacting with those who manage them in their respective countries.

Moderator:

- Wim VANDENBERGHE (Partner, ReedSmith)

Speakers:

- Ronan CAHILL (Professor of Surgery, University College Dublin)
- Marjolijn KLAVER (VP Strategy and Market Development, Johnson & Johnson)
- Jelena MALININA (Data Director, EURORDIS)

10:40-11:30 LIFFEY MEETING ROOM 2

FROM ESG TALK TO ACTION - REDUCING MEDTECH'S IMPACT ON OUR PLANET

BCG

We impact the planet in many more ways beyond carbon. The MedTech industry drives significant impact in carbon but also beyond, especially in product and packaging waste including single use products. The focus on MedTech's waste impact is growing, and regulations are starting to tighten. This creates a challenge to MedTech players, but many are using the push to gain competitive advantage. Learn from BCG and experts from Medtronic and GSK what a world class nature and circularity strategy looks like, how to measure your company's impact, identifying the key levers, and getting going on reducing the impact in partnership with customers and suppliers … for the benefit of all of us.

Moderator:

- Elia TZIAMBAZIS (Europe, Middle East & South America Lead for Climate & Sustainability in Healthcare, Managing Director & Partner, The Boston Consulting Group)

Speakers:

- Armida GIGANTE (Senior Manager Sustainability Western Europe, Medtronic)
- Renata SCOFIELD (Senior Sustainability Director, GSK)
- Charline WURZER (Central Europe Lead for Climate & Sustainability in Healthcare, Partner, The Boston Consulting Group)

11:30-12:00 **NETWORKING BREAK**

12:00-12:50 THE LIFFEY

TAKING THE 'RISK' OUT OF 'RISK SHARING AGREEMENTS': LEVERAGING RWE TO CONNECT REGULATORY, INNOVATIVE FUNDING MODELS, AND PRODUCT ADOPTION

AliraHealth

Innovative funding models and risk sharing agreements in MedTech have been identified as a key enabler for Medical Technology introduction post CE mark. However conventional Regulatory evidence generation is not fit-for purpose for risk sharing agreements and holistic reimbursement. There is often a disconnect of 'value' at product introduction through to full-scale product adoption. This session will provide a concrete roadmap to link evidence generation for MedTech across the product life-cycle: from regulatory approval, to reimbursement and adoption. Technologies focused on will include Robotic Surgery, Advanced Diagnostics and high risk implantable devices.

Moderator:

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

Speakers:

- Rossana ALESSANDRELLO (Value-based Procurement Director, Agència de Qualitat i Avaluació Sanitàries de Catalunya (AQuAS))
- Rachele BUSCA (Director, HTA and Real-World Evidence EMEACLA, Edwards Lifesciences)
- Federico CALADO (Vice President, Global Real-World Solutions, Alira Health)

12:00-12:50

LIFFEY HALL 1

DIGITAL TWIN IN HEALTHCARE IS MAKING HEADWAY

The Digital Twins concept is no more science fiction; it has many real-life applications too. This technology allows the creation of a virtual representation of a physical object or system. A digital twin is a digital replica of a businesses' tools, people, processes, and systems. The healthcare systems use Digital Twins to build digital representations of healthcare data, such as hospital environments, lab results, human physiology, etc., through computer models. Data that covers the individual, population traits, and environment are used to construct virtual twins.

Moderator:

- Adrian IONESCU (Professor at Swiss Federal Institute of Technology Lausanne, EPFL Ecole Polytechnique Fédérale de Lausanne)

Speakers:

- Ger JANSSEN (Department head AI, Data Science & Digital Twin, Philips)
- Marco MARSELLA (Head of Unit DG for Communications Networks, Content and Technology, European Commission)
- Alexander MEYER (Professor, Deutsches Herzzentrum der Charité)
- Nathalie VIRAG (Distinguished Scientist, Corporate Technology and Innovation, Medtronic)

LIFFEY HALL 2

MEDICAL DEVICES REGULATION (MDR): WHAT DOES THE FUTURE HOLD FOR HEALTHCARE SYSTEMS AND PATIENTS?

The Medical Device Regulation (MDR) was published in 2017 with a transition period of 3(4) years to ensure a smooth transition from the old Directives to the modernised rules of the MDR. More than six years after the publication of the MDR, despite huge investments and efforts to comply, stakeholders still face many challenges with the implementation of the new system.
To safeguard the continuity of patient care across Europe and the world, a package of legal and non-legal solutions has been introduced by the legislators over the past months.
Are these solutions enough to avoid medical devices disappearing from the market? Can Europe win back its historical place as the geography of choice for new device launches? What are the next steps envisaged by EU regulators?

Moderator:

- John Kilmartin (Vice President Regulatory Affairs Coronary & Renal Denervation, Medtronic)

Speakers:

- Flora GIORGIO (Acting Head of Unit, European Commission - Directorate-General for Health and Food Safety DG Santé D3)
- Lorraine NOLAN (Chief Executive, Health Products Regulatory Authority)
- Christelle RATIGNIER-CARBONNEIL (Director General French National Agency for the Safety of Medicines and Health)
- Royth VON HAHN (Senior Vice President Global Head of Medical & Health Services, TÜV SÜD Product Service Division)

12:00-12:50 LIFFEY MEETING ROOM 2

ADVANCING TOWARDS CARBON-FREE HEALTHCARE WITH CIRCULAR ECONOMY: READY FOR THE JOURNEY?

The medical technology sector is responding to the call for a greater focus on sustainability.
The sum of each equipment manufacturer's ESG actions has created momentum within the industry and improved the sustainability outlook overall.
But with growing environmental sensitivity, momentum in this area can mean competitive advantage for those who sustain it.
Circular Economy solutions for medical equipment offers an opportunity to accelerate sustainability and reduce your environmental impact significantly.
This translates as thoughtful selection of environmentally friendly or sustainable raw materials; clever design to enable easy assembly and disassembly; manufacturing for durability to extend the life of the product, and development of new business models to support the case for refurbishment and reuse.
To discuss the challenges and benefits of embracing a circular path, we've assembled a group of experts who will openly share their experience and insights on the emerging trends in sustainable product design and manufacturing in the healthcare industry.

Moderator:

- Jesus RUEDA RODRIGUEZ (General Director of Strategies, Special Projects & International Affairs, MedTech Europe)

Speakers:

- Christian CLARUS (Global Government Affairs & Market Access, B. Braun)
- Daniele FAZIO (VP Business Development, Flex Health Solutions)
- Ffion JACKSON (Global Lead Sustainable Chemicals, Siemens Healthineers)
- Niels SOERENSEN (Head Global Procurement, Roche Diabetes)

12:50-14:00 **NETWORKING LUNCH**

14:00-14:50

THE LIFFEY

BUILDING A CYBER-CAPABLE HEALTHCARE SYSTEM IN THE FACE OF DIGITAL INSTABILITY

ReedSmith
Driving progress through partnership

In November 2022, the EU Agency for Cybersecurity (ENISA) published the 2022 Cybersecurity Threat Landscape. The report follows the European Commission's proposed Cyber Resilience Act, a regulation aimed at shoring up the cybersecurity of connected digital products. This case reflects a trend of legislative interventions reinforcing the European digital space. However, recent cybersecurity breaches (including notorious cyberattacks on the Irish Department of Health and the Health Service Executive) show that European healthcare systems remain dangerously exposed to the evolving threat landscape. This session aims to discuss the European cybersecurity threat landscape, particularly in relation to health, including possible legislative and non-legislative methods to bolster the security, safety and trust of healthcare delivery.

Moderator:

- Asélle IBRAIMOVA (Counsel, ReedSmith)

Speakers:

- Neil O'HARE (Group CIO & Professor of Health Informatics, Children's Health Ireland & University College Dublin (UCD))
- Chris TYBERG (Chief Information Security Officer, Abbott)

LIFFEY HALL 1

INNOVATIVE PAYMENT SCHEMES (IPSS) IN EUROPE: SPRINGBOARD FOR INNOVATION?

Innovative Payment Schemes are a key mechanism to guarantee the timely access of European patients to innovative value-adding medical technologies and procedures. A mapping conducted by MedTech Europe end of 2022 has demonstrated the existence of 21 IPSs in 8 of the 32 European countries scoped for this project.

This session will offer you the possibility to learn more about IPSs in general and about two of them in particular (Funding Mandate in England and the Early Coverage framework for innovative DMDs in France) by interacting with those who manage them in their respective countries.

Moderator:

- Rachele BUSCA (Director, HTA and Real-World Evidence EMEACLA, Edwards Lifesciences)

Speakers:

- Daniel BAMFORD (Deputy Director, Medtech and Digital, Innovation, Research and Life Sciences, NHS England)
- Oleg BORISENKO (Director, MTRC (MedTech Reimbursment Consulting))
- Louisa STÜWE (Ministry of Health and Prevention, France)

14:00-14:50

LIFFEY HALL 2

SUSTAINABILITY: EMERGING OPPORTUNITIES AND CHALLENGES FOR THE MEDICAL TECHNOLOGY SECTOR

European healthcare systems are increasingly expected to serve not only patients but also the planet. What does this mean for the ecological and social footprint of medical technology manufacturers, their technologies, and their evolving missions? Join this high-level panel to hear directly from industry leaders about their sustainability journey to date.

Moderator:

- Oliver BISAZZA (CEO, MedTech Europe)

Speaker:

- Samih AL MAWASS (Divisional Vice President, EMEA (Europe, Middle East & Africa), Abbott Vascular)
- Sophie DUTILLOY (President International Vision Care Franchise, Alcon)
- Urmi PRASAD RICHARDSON (EMEA President, Thermo Fisher Scientific)
- Stuart SILK (President EMEA, Latin America, Canada, Stryker)

LIFFEY MEETING ROOM 2

LEVERAGING THE MEDICAL DEVICE REGULATIONS (MDR) FOR COMMERCIAL SUCCESS: 3 STRATEGIES FOR VALUE-DRIVEN SALES

ValueConnected

Join our Medical Technology Forum session to learn how commercial and market access teams can use the Medical Device Regulations (MDR) as a powerful tool to drive sales and maximize results. In this interactive session, we will explore three key strategies that medical technology companies can use to leverage the MDR to their advantage.

Firstly, we will discuss how the MDR can be used to leverage value messages, which can help medical technology companies articulate their products' unique benefits and value to key stakeholders. Secondly, we will examine how medical technology companies can transform technical features into unique value messages that resonate with their target audience. Finally, we will explore how the MDR process can take marketing collateral to a whole new level, helping medical technology companies to create compelling and effective marketing materials that drive sales.

Don't miss this opportunity to learn how the MDR can be used to drive commercial success in the medical technology industry. Join us for an engaging and informative session that will leave you with actionable insights and strategies for success.

Moderator:

- Eric HAUSCHILD (Director of Business Development EMEA, ValueConnected)

Speakers:

- Ciska JANSSENS-BÖCKER (Director of Clinical Marketing, ValueConnected)
- Ernesto NOGUEIRA (CEO and Founder, ValueConnected)

15:00-15:50

THE LIFFEY

EUROPE'S SEARCH FOR RENAISSANCE

Irish Medtech Association
Ibec

The continent of Europe is going through its perennial turbulence and predictions of its global demise abound. Whilst the war on Ukraine, uncontrolled migrant inflows, high price inflation from energy security of supply concerns and an aging population are significant challenges, there are many economic and social opportunities emerging from technological progress in the continent's global lead to pivot towards digitisation and greening of production and consumption. Medical technologies are at the vanguard of the potential renaissance for Europe but many impediments remain.

This keynote address will set out the contemporary economic conditions facing businesses globally from historically tight labour markets, significant wage growth, decades' high consumer price inflation and tightening of monetary policy correcting the extended period of low interest rates. The post pandemic recovery continues to disrupt existing business delivery channels with the advent of concerns for sustainability of economic, social and environmental models becoming existential. The governance of this disruption will require social cohesion, a strength of the often maligned European Social model.

The so-called ESG Agenda (with its focus on environmental, social & governance) may well be the defining agenda of this century. The address will contrast how Europe in taking a coordinated global lead on these issues with other global blocks and how it may be best placed to succeed if it can amend short-term impediments like European Union Medical Devices Regulations.

Moderator:

- Jude WEBBER (Financial Correspondant, The Financial Times)

Speaker:

- Danny MCCOY (CEO, Ibec)

LIFFEY HALL 1

FINAL COUNTDOWN TO THE EUROPEAN MEDICAL DEVICES DATABASE – IS YOUR BUSINESS READY?

With one year left until the European database on medical devices, EUDAMED, becomes fully functional, this session provides an interactive discussion on EUDAMED system & stakeholder readiness from various perspectives including manufacturers, service providers, Notified Bodies and the European Commission. We will discuss EUDAMED transparency considerations and provide an opportunity for the audience to ask the experts their own questions. Join our interactive panel to get the latest EUDAMED insights!

Moderator:

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

Speakers:

- Orla DALY (Policy & Legal Officer, European Commission, DG SANTE Unit D.3 - Medical Devices)
- John O'SULLIVAN (Industry Engagement Officer, Medical Devices, NSAI Certification (National Standards Authority of Ireland - Notified Body))
- Lionel TUSSAU (Healthcare Market Unit , Global Lead, Atrify)
- Olga VAN GROL-LAWLOR (Manager Global Regulatory Intelligence & Advocacy, Boston Scientific)

15:00-15:50

LIFFEY HALL 2

EUROPE'S INVESTMENT IN SCIENTIFIC ADVICE AND JOINT SCIENTIFIC CONSULTATIONS AS PART OF NEW REGULATIONS MDR/IVDR/ HTA-R, NEW PIECES OF THE PUZZLE!

The new EU Regulation on HTA introduced an interplay and new tasks for the MDCG, NB, expert panels of the MDR, and IVDR. For the Health Technology Developers, data submission to the notified bodies is listed as part of the dossier to submit for joint clinical assessments. Within the recitals of the HTA-R, it is acknowledged that the new regulation should not interfere with the MDR and IVDR and be distinct. We will bring together a panel of key actors as European commissions units responsible for the MDR/IVDR, respectively the HTA-R, the MDCG, the EMA unit overseeing the expert panels, the NB, the Member States HTA Coordination group representative to take stock of current views on concrete implementation and check&balances of the interplay.

The session aims to open the dialogue to foster the set-up of a well-defined and agreed framework of interplay. With this a starting point, we will seek further discussions with the involved actors and report back at the next MedTech Forums ahead of the final implementation in January 2025.

Moderator:

- Yves VERBOVEN (Senior Adviser, MedTech Europe)

Speakers:

- Flora GIORGIO (Acting Head of Unit, European Commission - Directorate-General for Health and Food Safety DG SANTE D3 : Medical products and innovation)
- Richard HOLBOROW (Head of Clinical Compliance, BSI)
- Maya MATTHEWS (Acting Director, Head of Unit, HTA, uropean Commission - Directorate-General for Health and Food Safety DG SANTE C : Digital, EU4Health and Health Systems Modernisation)
- Andrea RAPPAGLIOSI (Senior Vice President Market Access, Public Affairs & Communication EMEA, Canada and LATAM, Edwards LifeSciences)
- Michael VOGL (Medical Device Specialist - Expert Panels ad Groups Office, European Medicines Agency – EMA)

LIFFEY MEETING ROOM 2

VALUE CREATION IN MEDTECH THROUGH THE EYES OF AN INVESTOR

McKinsey & Company

MedTech outperformed the S&P 500 nearly twofold from 2012 to 2019, but investor skepticism has returned since then and performance has stalled with TSR growing at 3% CAGR from 2019 – 2022 compared to 21% CAGR from 2012 – 2019. Can we continue to copy the tried and tested recipe from the last decade or do we need to change how we think about value creation? During our session, we will explore the main challenges for value creation in the next decade and how we can think out of the box to create value.

Speaker:

- Karsten DALGAARD (Senior Partner, McKinsey & Company)

15:00-15:50

LIFFEY MEETING ROOM 3

ASK THE EXPERT: BEST PRACTICES TO AVOID CHALLENGING SITUATIONS DURING CONFORMITY ASSESSMENT PROCEDURES UNDER THE MDR AND IVDR

Hogan Lovells

During this interactive session, attendees will have the opportunity to learn about best practices to successfully go through conformity assessment procedures under the MDR and IVDR. This will include discussions about how to prepare the conformity assessment, how to maintain good working relationship with its notified body at all time and avoid delays or surprises during the review.

Speaker:

- Fabien ROY (Partner, Hogan Lovells)

ASK THE EXPERT: POWERED BY MEDTECH: THE TRUE DRIVERS OF GLOBAL PRECISION MEDICINE

KPMG

"Precision medicine" to the pharmaceutical industry is the answer to what their most competitive offerings are and will be. But precision medicine is not driven by drugs, its driven by the MedTech industry. MedTech supplies the diagnostics, platforms, services, and IT to fuel discovery to commercialization of precision medicine for the pharma industry, and the M&A and alliances between MedTech and Pharma are fundamental to the development and delivery of precision medicine worldwide. Join us in a panel with luminaries from pharma and MedTech to discuss the precision medicine ecosystem and how to navigate its new frontier on a global Scale.

Speaker:

- Kristin POTHIER (Global and US Healthcare and Life Sciences Deal Advisory and Strategy Leader, KPMG)

ASK THE EXPERT: REGULATING DIGITAL HEALTH - DEMYSTIFYING SAMD AND ITS IMPACT ON MEDTECH

HUMA

Don't miss the opportunity to join Rudolf Wagner, who leads Huma's Quality Assurance & Regulatory Affairs, alongside Alex Gilbert, Vice President of MedTech, for an insightful discussion on how regulated frameworks for Software as a Medical Device can contribute to the development of distinctive companion apps. This session is designed to be interactive and promises to provide valuable insights from the team behind the first disease agnostic Class IIb SaMD.

Speakers:

- Alex GILBERT (Vice President MedTech, HUMA)
- Rudolf WAGNER (Quality Assurance & Regulatory Affairs, HUMA)

15:00-15:50

ASK THE EXPERT: THE CHANGING WORLD OF EVIDENCE: HOW TO THRIVE IN BOTH EU AND US MARKETS

Hull Associates LLC
MARKET ACCESS

This small group session will review the emerging evidence requirements for innovator products in both EU markets and the USA with key strategies for companies to integrate the right strategies into their early stage product planning.

Speaker:

- Stephen HULL (Founder and President, Hull Associates LLC)

15:50-16:20

NETWORKING BREAK

16:20-17:10

THE LIFFEY

A NEW ERA IN ROBOTIC-ASSISTED SURGERY: PRESENT AND FUTURE

Robotic surgery, also called robot-assisted surgery, allows doctors to perform many types of complex procedures with more precision, flexibility and control than is possible with conventional techniques. Robotic surgery is usually associated with minimally invasive surgery. It is also sometimes used in certain traditional open surgical procedures. The last few years have seen an acceleration in the use of surgical robotics. It has been an exciting period for the surgical teams launching and expanding their robotic-assisted surgery (RAS) programmes. 2023 is likely to see increased demand for RAS around the world. What are the challenges ahead of this deployment of RAS? How we can expand the type of procedures we are able to offer via RAS even further? How to harness the power of data to know their progress in each procedure type? The increasing activity in surgical robotics will drive increased demand for training. How to train a growing number of surgical trainees?

Moderator:

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

Speakers:

- Mathieu BADARD (VPGM Joint Replacement, Europe, Stryker)
- Dirk BARTEN (Sr VP & GM EU Commercial & Marketing, Intuitive Surgical)
- Rocco DE BERNARDIS (WW President Robotic Programme, Johnson & Johnson)
- Richard JANSEN (Senior Director Surgical Robotics Sales, Medtronic)

16:20-17:10

LIFFEY HALL 1

GDPR: MISSION COMPLETE!

faegre drinker

On May 25, 2023, the General Data Protection Regulation (GDPR) will celebrate its 5th Anniversary. When the GDPR was adopted, its supporters foretold that it would bring a new era of harmonised data protection rules and enforcement throughout the EU. It would end purely administrative compliance requirements like data processing registrations in favor of genuinely holding organisations accountable for their data protection practices. This panel will explore, five years on, whether the GDPR has accomplished these objectives, with a focus on how the medical technology industry has been impacted by the GDPR, the challenges that are keeping medtech data protection officers awake at night, and the direction of interpretation and enforcement.

Moderator:

- Peter BLENKINSOP (Partner, Faegre Drinker)

Speakers:

- David MURPHY (Assistant Commissioner, Irish Data Protection Commission)
- Aoife O'ROURKE (Director, European Data Protection Officer, Cook Medical)
- Chantal VETS (Senior Legal Director, Privacy Global Program Leader, Medtronic)

LIFFEY HALL 2

GLOBAL IMPACT OF EU MDR/IVDR

The transition to the EU MDR and IVDR will have an impact on access to markets around the world. The concept of CE-marking, well established in the EU, is used in many countries outside Europe to support medical devices' registrations. This session will address the global impact of the EU regulations and solutions to maintain access to international markets. Join us for an exciting panel discussion to explore how leading medtech manufacturers are managing the impact on their international registrations and addressing the questions posed by regulatory authorities outside the EU.

Moderator:

- Emmett DEVEREUX (Director of Government and Regulatory Affairs EMEA, COOK Medical EMEA Group and Chair of the International Group at MedTech EU, Abbott Cook Medical EMEA Group)

Speakers:

- Philippe AUCLAIR (Senior Director Regulatory Strategy, Abbott)
- Rana CHALHOUB (Regulatory Affairs Director, Mecomed)
- Peter SCHROEER (Director Europe, Quality Systems & Regulatory Affairs, Johnson & Johnson

16:20-17:10

LIFFEY MEETING ROOM 2

STREAMLINING REGULATORY OPERATIONS: INDUSTRY TRENDS & INNOVATIONS

Veeva MedTech

With rapidly evolving regulatory and market demands, medtech companies are under pressure to do more with less, requiring a fundamental shift in operations, systems, and processes. Our annual benchmark study found that while 54% are moving towards harmonized processes, the medtech industry lags behind in digital transformation compared to the life sciences.

In this session, we'll examine the study findings, including year-over-year progress. We'll also share insights for optimizing processes and leveraging technology to ensure compliance in light of EU MDR, IVDR, UDI, and eSTAR.

Additionally, we will hear from Dominik Reterski, Corporate Vice President, Quality Assurance and Regulatory Affairs, about how Teleflex is streamlining global processes, centralizing operations, and transforming corporate culture to drive efficiency and an attractive work environment.

Speakers:

- Charlene BOUMARD (Director, Regulatory Strategy, MedTech EU, Veeva MedTech)
- Dominik RETERSKI (Corporate Vice President, Quality Assurance/Regulatory Affairs, Teleflex)

17:20-18:00

THE LIFFEY

CEO #NOFILTER

Global leaders from the field of medical technology manufacturers will join the discussion and speak openly about the latest trends, challenges and opportunities they are facing.

Moderator:

- Sue SAVILLE (Health Event Facilitator)

Speakers:

- Chris LLEWELLYN (Senior Partner, Global Head of Life Sciences, McKinsey & Company)
- Rob TEN HOEDT (Executive Vice President and President, Global Regions, Medtronic and Chair of MedTech Europe)
- Alexander SOCARRÁS (Executive Vice-President, Head of Global Commercial, DX Laboratory Solutions , Siemens Healthineers)

18:00-19:30

NETWORKING RECEPTION

OLYMPUS

THE MEDTECH FORUM 2023 APP

The official MedTech Forum App will be available a few days before the Forum and only for registered participants.

Download the app to maximise your time and experience during the event!

CONNECT WITH THE COMMUNITY

Start a conversation using direct messages and use this opportunity to network with your peers. Meet them in the exhibition hall at the booth of your choice.

EXHIBITORS DIRECTORY

Discover all the exhibitors and locate them on the map.

CREATE YOUR PERSONALISED AGENDA

Add your sessions of interest to My Programme and receive notifications before they begin.

INTERACT DURING SESSIONS

Ask questions and vote during the sessions with other on-site and online participants.

ONLINE PARTICIPATION

People attending the event online will be able to chat with the on-site attendees.

SHARE YOUR FEEDBACK

Use the app to leave your comments about the sessions.

THURSDAY 1 JUNE

08:00-09:00 **WELCOME COFFEE**

09:00-09:40 THE LIFFEY

KEYNOTE SPEAKER

Moderator:

- Sue SAVILLE (Health Event Facilitator)

Speaker:

- Major General Tim HODGETTS (Surgeon General, Defence Medical Services, Ministry of Defence (MOD))

09:50-10:40 THE LIFFEY

THE POTENTIAL OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE - HOW THE AI ACT COULD BECOME THE DECIDING FACTOR FOR TRANSFORMING HEALTHCARE

Roche

Artificial Intelligence (AI) in healthcare holds the promise to improve patient outcomes and healthcare systems. It can also tackle many healthcare challenges, including workforce shortages, healthcare financing and improving or even saving patients' lives. With the launch of the AI Act, the EU has the potential to lead this area by building an advanced and fit-for-purpose regulatory environment and ensuring greater patient trust. While the proposed legislation will determine how and if new AI-enabled medical technologies will be placed on the market and reach patients, it begs the question of where AI-enabled medical technology is actually changing healthcare for the better on the ground and if the AI Act would become a hurdle or accelerator to the transformation.

Moderator:

- Eliza SLAWTHER (Senior Writer, Medtech Insight)

Speakers:

- Giovanni BRIGANTI (Chair of Artificial Intelligence and Digital Medicine, University of Mons, Belgium)
- Corinne DIVE-RECLUS (Global Head of Lab Insights Business, Roche)
- Torie ROBINSON (CEO & Founder, Epilepsy Sparks)
- Andrzej Jan RYS (Director for health systems, medical products and innovation, European Commission)

09:50-10:40

LIFFEY HALL 1

GLOBAL PUBLIC HEALTH: TOWARDS ACHIEVING UNIVERSAL HEALTH COVERAGE

Achieving universal health coverage (UHC) is one of the 2030 Sustainable Development Goals and a strategic priority for the World Health Organization. In this session, the panelists will explore how medical technology and trade policy can support the goal of achieving the UHC. The discussion will cover the challenges and opportunities in the global health policy landscape and how to overcome them. The panel will also discuss examples of successful policies and initiatives and the importance of cross border trade and public-private partnerships. The session will explore how UHC can become a reality and how medical technologies and trade can help in achieving it.

Moderator:

- Trevor GUNN (Medtronic)

Speakers:

- Dana FAGER (Medical Technologies, Supply Chain, and Health Data Analyst, United States Department of Commerce)
- Jesús RUEDA RODRÍGUEZ (Director General Strategies, Special Projects & International Affairs, MedTech Europe)

LIFFEY HALL 2

MANUFACTURING THE FUTURE: NAVIGATING CHANGE, SUSTAINING GROWTH

Irish Medtech Association Ibec

The manufacturing sector employed over 29 million people in the EU in 2020, across 2 million enterprises [Eurostat 2020]. The European Commission's industrial strategy aims to ensure that European industry can lead the way as it embarks on a transition towards climate neutrality and digital leadership to make the EU industry more competitive globally. Protecting Europe's manufacturing competitiveness is an imperative, as the impact of 'limping from one crisis to the next' unveils real challenges such as raw materials shortages, logistics, and supply chains breaking down; regional supply chains being resorted to, and reshoring. And yet, throughout these hurdles, manufacturing continues to shine as the star performer in Ireland's considerable economic success, with Ireland's level of employment in high-technology manufacturing, as a share of total employment, now the highest in the EU, with 29% of manufacturing jobs in high technology sectors. This panel of experts will discuss some of the current challenging facing global manufacturing competitiveness and how the sector is responding through business model innovation, capital and technology investment, talent development and strategic partnerships. The role of policy in shaping the future EU manufacturing competitiveness will also be discussed.

Moderator:

- Sharon HIGGINS (Executive Director, Membership and Sectors, Ibec)

Speakers

- Gary HARNETT (Vice-president of Partnership and External Supply for Janssen Global Supply Chain)
- Sean GAYER (Vice President, Operations, Boston Scientific)
- Ann O'CONNELL (Irish Medtech Skillnet Manager)
- Brendan SHEPPARD (CEO, Smart Factory)

09:50-10:40

LIFFEY MEETING ROOM 2

MEDTECH INNOVATION: ADDRESSING HEALTHCARE SYSTEM INEFFICIENCIES AND WORKFORCE CONSTRAINTS

Edwards

Where COVID-19 already hugely disrupted our lives, our hospitals, and our healthcare systems, today we are facing the next challenge for our healthcare systems: the unprecedented shortages of healthcare workers, and huge capacity strains of hospitals.

The World Health Organization (WHO) recently warned that without immediate action the health and care workforce gaps in our region could spell disaster. 40% of medical doctors are close to retirement in 1/3 of countries in Europe and their places are simply not being filled. The hospital is no longer an attractive workplace, and Europe does not have a proper workforce planning in place.

And this has been exacerbated due to COVID-19, which added to burn-out, fatigue, stress of healthcare professionals. Professionals are leaving the profession, and patients are suffering from this every day.

Waiting lists to access care for example are now a reality throughout Europe, even in countries that did not have them in the past. And in the meantime, demand for care continues to grow as our population is ageing.

This session will look at how to reconcile the urgent and ever-growing need for care and treatment, with the growing gap in offer from healthcare workers, what the role for our innovative industry should be, and at what will it take to shift mind-sets and instigate sustainable change.

Moderator:

- Christelle SAINT-SARDOS (Edwards)

Speakers

- Daan LIVESTRO (Gupta Strategists)
- Máirín RYAN (Director of Health Technology Assessment & Deputy Chief Executive Officer)
- Steve THOMAS (Chair of Health Policy and Management - Trinity College Dublin)
- Andrea RAPPAGLIOSI (Senior Vice President Market Access, Public Affairs & Communication EMEA, Canada and LATAM, Edwards LifeSciences)

09:50-10:40 LIFFEY MEETING ROOM 3

ASK THE EXPERT: HEALTH DATA 2.0 – EUROPEAN HEALTH DATA SPACE, DATA ACT AND AI FROM A REGULATORY PERSPECTIVE

Hogan Lovells

In this session we will discuss how upcoming EU data governance legislation will impact data-driven health businesses. The EU Data Act and the European Health Data Space (EHDS) are key pillars of the European data strategy – far reaching data governance regulation beyond data protection.

Speaker

- Arne THIERMANN (Partner, Hogan Lovells)

ASK THE EXPERT: READY-SET-RE-SET: 2023 ORGANIC AND INORGANIC GROWTH AND PROFITABILITY IN MEDTECH

KPMG

Parts of the global MedTech industry thrived and others struggled to achieve their goals through the pandemic. This resulted in an uneven market with surpluses of cash for some companies and major cost cutting challenges for others, and some with both; necessitating a resetting of expectations and new creative options for both internal and external growth. From expansion in partnerships and alliances designed to serve the patient holistically without outright purchase, to "reintegration's" of companies who brought on new acquisitions too quickly to complete commercial transformation on a global scale. Join us in a panel with luminaries from across global MedTech to look at the hottest areas for growth, the data-driven trends and watch-outs, and the clinical, financial, and commercial success paths in the diagnostics, medical device, and digital technology of the future.

Speakers

- Steve SAPLETAL (National Advisory Leader, Life Sciences, KPMG US)
- Brian EGAN (Life Sciences Leader, KPMG Ireland)

ASK THE EXPERT: SUSTAINABLE AND TRANSPARENT SUPPLY CHAINS AND THE EMERGING REGULATORY LANDSCAPE

Deloitte.

Speakers

- Fearghal KEARNEY
- David RAKOWSKI (Partner, Deloitte)

10:40-11:10 **NETWORKING BREAK**

11:10-12:00

THE LIFFEY

IRISH FOUNDER-LED ENTERPRISES TRANSFORMING HEALTHCARE GLOBALLY

Irish Medtech Association Ibec

Founders play a vital role in thriving medtech ecosystems. They are the nuclei of innovation and progress. These businesses come in a lot of different shapes and sizes, from early-stage ventures to high-growth scaleups, to multinationals and curating the surrounding ecosystem required at each stage is fundamental for their success. Ireland's medtech ecosystem is over 100 years in the making, employing 45,000 people and the indigenous Irish medtech sector is a key component of Ireland's medtech cluster, with over 200 companies employing 6,500 people. These companies are world-class, highly innovative and dynamic, delivering complex technologies, products and services throughout the world. With the international financing and the funding environment tightening, four founders will share their unique experience of taking on risk, from starting, to scaling, to IPO and what is required from an ecosystem to encourage and support same.

Moderator:

- Sinead KEOGH (Head of Sectors and Director, Medtech & Engineering, Ibec)

Speakers:

- Kieran DALY (Co-founder and CTO, Health Beacon)
- Elizabeth MCGLOUGHIN (Co-founder and CEO, Tympany)
- Lucy O'KEEFE (Co-founder and CEO, CroiValve)
- Brian SHIELDS (CEO, Neurent Medical)

11:10-12:00

LIFFEY HALL 1

TIME FOR A SUSTAINABLE TRANSITION WITHIN THE MEDTECH SECTOR

SIEMENS Healthineers

We would like to use the opportunity of the Medtech Forum in Dublin to present the 'time for a sustainable transition' as a bridge between achieving sustainability objectives to protect the planet and avoiding scarcity and delay in innovation in the medtech sector.

At a time when the European Union has put sustainability as a core pillar of its actions, the medtech sector, fully supportive of such political directions, is nonetheless becoming more and more under pressure. Hindered by the complexity of their healthcare technologies, medtech companies face challenges in adapting to environmental regulatory changes, moving ahead on faster timelines than medical device vertical legislation allows for re-design.

In order to actively contribute to the EU long-terms goals in sustainability, the medtech sector has developed the so-called time for a sustainable transition project, an industry-wide position which asks to take into consideration the long the innovation cycle and life of medical devices, in order to provide sufficient time to develop new sustainable products.

Moderator:

- Jan AHLSKOG (Senior Director - Food, Industrials, Chemicals & Environment, Fipra)

Speakers:

- Tomris OZBEN (President, EFLM)
- Alexander SOCARRÁS (Executive Vice-President, Head of Global Commercial, DX Laboratory Solutions, Siemens Healthineers)
- Joel TICKNER (Executive Director, Green Chemistry and Commerce Council)
- Alexa TOOMEY (Head of Sustainability, Renewable Energy and Agtech, Enterprise Ireland)

11:10-12:00

LIFFEY HALL 2

IMPLEMENTATION OF HTA REGULATION AT FULL SPEED - WHAT'S UP AND WILL COUNTRIES USE IT?

While the implementation of the MDR and IVDR are in the final stage, an additional EU regulation on HTA is at the early stages of implementation but progressing well in finalising the structural and governance set-up of this member states driven regulation. Alongside this structural and decision-making implementation, a service contract was awarded to put forward methodologies and guidance to ensure a kick-start at the foreseen start of the application of this regulation in January 2025. The session will provide insights into how this new regulation will impact access to medical technologies once the hurdle of CE marking of a product is overcome. Speakers will discuss how leading countries seek to use this regulation, link it to their innovative access pathways and bring in patients' and healthcare professional voices. Ultimately from an industry perspective, it will be explored what can be done to adapt the assessment to the specificities of technologies and avoid it becoming an extra barrier and delaying access to innovation in Europe. The session will include a view from the European Commission, leading EU countries, industry and a comparison to UK market access.

Moderator:

- Yves VERBOVEN (Senior Adviser, MedTech Europe)

Speakers:

- Roisin ADAMS (NCPE)
- Judith FERNANDEZ (Deputy Director, International, HTA, HAS)
- Maya MATTHEWS (Acting Director, Head of Unit, HTA, uropean Commission - Directorate-General for Health and Food Safety DG SANTE C : Digital, EU4Health and Health Systems Modernisation)
- Andrea RAPPAGLIOSI (Senior Vice President Market Access, Public Affairs & Communication EMEA, Canada and LATAM, Edwards LifeSciences)
- Conor TELJEUR (Chief Scientist, HIQA)

11:10-12:00

LIFFEY MEETING ROOM 2

BREAKING DOWN BARRIERS: TOWARDS GLOBAL CONVERGENCE OF MEDICAL DEVICE REGULATIONS

Regulatory convergence and reliance accelerate access to medical technologies and strengthen the regulatory capacity for oversight of medical devices globally. The COVID-19 pandemic highlighted the value of international cooperation and reliance practices enabling easier access to medical devices that have been approved in countries with well-established regulatory frameworks. Even small differences in standards and technical regulations can lead to major differences in regulatory path for devices worldwide. In this panel discussion, regulators and industry experts will come together to explore the challenges and opportunities for convergence in medical device regulation and what role regional harmonisation and convergence platforms and initiatives, such as IMDRF and GHWP, can play in achieving it.

Moderator:

- Emmett DEVEREUX (Director of Government and Regulatory Affairs EMEA, COOK Medical EMEA Group and Chair of the International Group at MedTech EU, Cook Medical EMEA Group)

Speakers:

- Ali AL DALAAN (Vice Executive President, Medical Devices Sector, Saudi Food & Drug Authority)
- Anna HALLERSTEN (Director and Head Regulatory Policy Europe, Co-Chair MedTech Europe IVD Regulatory Affairs Committee, Roche Diagnostics International Ltd)
- Andrzej Jan RYS (Director for health systems, medical products and innovation, European Commission)
- Janet TRUNZO (Senior Executive Vice President, Technology & Regulatory Affairs, AdvaMed)

12:10-13:00

THE LIFFEY

EUROPE'S SLEEPWALKING TOWARDS A US LITIGATION CULTURE

faegre drinker

The current wave of regulatory activity at European level is creating a perfect storm that is causing Europe to sleepwalk towards a US-like litigation culture. A sharpening of liability laws, with the proposed drafts revising the Product Liability Directive and the AI Liability Directive strongly tipping in favour of consumers. The (uncoordinated) tightening of screws around horizontal and vertical safety regulations. The introduction of pan-European class actions and, last but not least, litigation funders are opening shops in several EU Members States incentivising a different consumer behaviour. These processes will result in an unavoidable increase in claims. The panel will discuss these developments and address what can still be done or should be done to avoid a US-like litigation culture coming to Europe.

Moderator:

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

Speakers:

- Carolyn BLAKE (European Policy Consultant, US Chamber of Commerce Institute for Legal Reform)
- David MORKAN (Director and Senior Counsel EMEA, Cook Medical)
- Simon NEILL (Assistant General Counsel, Johnson & Johnson)
- Susan WILSON (Director, Intellectual Property Policy, Intel)

12:10-13:00

LIFFEY HALL 1

INTEROPERABILITY IN PRACTICE - WHAT ARE THE MEDTECH INDUSTRY'S COSTS FOR NOT BECOMING INTEROPERABLE?

The healthcare sector is facing a high amount of pressure due to a declining workforce, strikes, growing administrative burdens, rising healthcare costs, and other reasons. For digital solutions to provide answers to these challenges they must work effectively without increasing the workload to an overburdened workforce. Therefore, medical technologies must be able to seamlessly communicate through enhanced interoperability. However, interoperability in the healthcare sector remains limited and a major obstacle to a digital transformation which may result in an incomplete understanding of an individual's or population's health needs, which can lead to poorer outcomes and higher costs from different perspectives.

It is then crucial to understand how interoperability will look in the future and how it can be achieved in Europe. Participants will discuss the needs of the healthcare sector, the hurdles to overcome to achieve an interoperable ecosystem, and future opportunities such as with the European Health Data Space (EHDS).

Moderator:

- Sabine DÖRHÖFER (Standard Domain Lead, Roche, Moderating in her capacity as co-chair of the interoperability working group,MedTech Europe)

Speakers:

- Roberto REALE (Technical Implementation Manager, Department for Digital Transformation, Italy)
- Julia SKAPIK (Chief Medical Information Officer for the National Association of Community Health Centers (NACHC))
- Michael WILKENING (Strategy and Business Development Medical Division, Dräger)

LIFFEY HALL 2

THE CRITICAL ROLE OF PROCUREMENT IN HEALTHCARE TO UNLOCK VALUE BASED HEALTH CARE - TRANSFORMING PUBLIC PROCUREMENT FROM A TRANSACTIONAL - INTO A VALUE-BASED APPROACH

European healthcare systems face significant challenges: how to match the increased demand for healthcare services with an increased lack of qualified staff and to improve patient outcomes while managing the total cost of care delivery. Although medical technologies may not be able to solve all of these challenges, they can certainly be part of the solution. Because of an overall traditional execution of the public procurement and tender process based on volume and price, too many of these technologies still need to be implemented, and the adoption of innovative medtech to be promoted. Needing a new procurement paradigm, MedTech Europe, together with BCG and EHPPA (European Health Public Procurement Association), engaged on a journey to move from volume-based procurement towards value-based procurement. During the session, the speakers will elaborate on how (public) procurement can unlock sustainable value-based health care systems across Europe.

Moderator:

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

Speakers:

- Richard CHARTER (Vice President Medtech Market Access - Europeé Asia Pacific, Alira Health)
- Praful MEHTA (CEO, Vamstar)
- Andrea RAPPAGLIOSI (Senior Vice President Market Access, Public Affairs & Communication EMEA, Canada and LATAM, Edwards LifeSciences)

12:10-13:00 LIFFEY MEETING ROOM 2

ETHICAL USE OF DATA IN AI

While European co-legislators are finalising their positions on the AI Act, data protection and other authorities are starting to issue AI, with a particular focus on fair and trustworthy AI. At the same time, MedTech companies cannot put their AI innovation projects on hold until the new regulatory framework is landed and the intersections with existing laws are fully clarified. In this session, we will discuss what factors and considerations MedTech companies can take into when building and implementing trustworthy AI applications, in addition to the known regulatory requirements.

Moderator:

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

Speaker:

- David MURPHY (Assistant Commissioner, Irish Data Protection Commission)

13:00-14:00 **NETWORKING LUNCH**

14:00-14:50 THE LIFFEY

NAVIGATING SUPPLY CHAIN CHALLENGES

KPMG

Recent events have shown that medical devices are extremely susceptible to disruptions in their supply chain. Medical devices are subject to strict regulatory requirements and at most times, supply chain disruptions are also going to have a regulatory impact. Manufacturers have had to deal with a fair share of supply chain challenges over the past three years. Shortages of key raw materials, logistics delays, sterilization constraints, labour challenges, the list goes on resulting in skyrocketing costs and delays. This session will explore how industry is dealing with the continuous and emerging supply chain challenges, how to increase the resilience of supply chains to withstand the future disruptions and what policy options would be helpful in managing supply chain issues.

Moderator:

- Roger VAN DEN HEUVEL (Partner, EMA Life Sciences Strategy Lead, KPMG)

Speaker:

- Laith ALTIMIME (President, SEMI Europe)
- Mike ANDERSON (Vice President Europe and APAC Operations, Stryker)

14:00-14:50

LIFFEY HALL 1

ONE YEAR IN: THE INNOVATIVE HEALTH INITIATIVE LEADS TO ITS FIRST SUCCESSFUL AND COLLABORATIVE EUROPEAN PROJECTS

The Innovative Health Initiative (IHI) is the EU's $2.4 billion public-private partnership to create an innovation ecosystem that facilitates the translation of scientific knowledge into tangible innovations. IHI implemented the first wave of consortia in 2023 and will continuously launch calls until 2027. Its mission is to bring together diverse academic and other public stakeholders for collaborative high-impact health projects with the biopharmaceutical, biotechnology and medical technology sectors, including companies active in the digital area. This session will focus on how medical technology companies can shape and join projects under IHI and share the experience of the IHI pioneers made at different stages of building IHI partnerships.

Moderator:

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

Speakers:

- Hugh LAVERTY (Executive Director, IHI)
- Christian MUELHENDYCK (IHI Lead JNJ MedTech, JnJ)
- Andrzej Jan RYS (Director for health systems, medical products and innovation, European Commission)
- Fanny VAN DER LOO (Director Public Affairs | Edwards Lifesciences | Health | EU | EMEA | CAN | LATAM, Edwards Lifescience)

LIFFEY HALL 2

LIFFEY MEETING ROOM 2

510(K): INDUSTRY LANDSCAPE AND CHALLENGES

Lachman CONSULTANTS (IRELAND) Experience. Excellence.™

The conversation will surround the rapid advancement of new technologies, the 510(k) process and post-market impact such as recalls and adverse trends, critical design factors and key considerations governing these products.

Moderator:

- Frances ZIPP (CEO, Lachman Consultants)

Speakers:

- Deanna ANDERSON (Senior Director, Lachman Consultants)
- Scott DECKEBACK (Manufacturing Data Integrity and Computer Validation, Lachman Consulting)
- Padraig MAGUIRE (Head of Quality & Regulatory Affairs, S3 Connected Health)
- John O'DEA (CEO, Palliare)

15:00-15:50

THE LIFFEY

CEO #NOFILTER

Global leaders from European medical technology manufacturers will join the discussion and speak openly about the latest trends, challenges and opportunities they are facing.

Moderator:

- Sue SAVILLE (Health Event Facilitator)

Speakers:

- Joe ALMEIDA (Chief Executive Officer, Baxter)
- Lisa EARNHARDT (Executive Vice President Medical Devices, Abbott)
- Mick FARRELL (CEO, ResMed)

15:50-16:00

THE LIFFEY

CONCLUSIONS

Moderator:

- Sue SAVILLE (Health Event Facilitator)

ASK
THE EXPERT

WHAT?

One expert addressing a specific topic and leading a roundtable discussion.

WHERE?

LIFFEY MEETING ROOM 3

WHEN?

31 May at 15:00
1 June at 9:50

HOW?

In a breakout room with one expert and a maximum of 12 participants. Seats are allocated on a first come first served basis, be on time!

A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

REGISTRATION

Rima Salama
Registration Coordinator
regist.medtechforum@europa-organisation.com

SPONSORSHIP TEAM

Natacha Roger
Dir. +33 5 34 45 50 76
sponsorship@themedtechforum.eu

Christopher Breyel
c.breyel@medtecheurope.org

www.themedtechforum.eu

MedTech Europe
from diagnosis to cure

EUROPA ORGANISATION
BY EUROPA GROUP