



A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

#MTF2024
22-24 MAY
VIENNA

In cooperation with



www.themedtechforum.eu

Programme

as of April 23, 2024

WELCOME INTRODUCTION



**Dear participants, Dear speakers,
Dear sponsors,**

MedTech Europe is delighted to have hosted a successful MedTech Forum. This year's Forum has highlighted just how innovative the medical technology sector is, and how much it contributes to patients and healthcare systems.

The medical technologies sector has a lot to offer – in the past years, we have had a deep and positive impact on the way healthcare is delivered. We are looking forward to the future – the future of our sector, the creativity and innovation power in Europe, and the role that our industry will have in transforming healthcare.

Medtech innovations offer needed solutions to Europe's challenges, but only if they can get through the European maze, and to the patients and healthcare systems that need them. It is paramount for Europe to put special attention to keep its historical attractiveness for our industry.

Best regards,

Oliver BISAZZA
Chief Executive Officer
MedTech Europe

PROGRAMME AT A GLANCE

22 MAY 2024

VIENNA CITY HALL

18:30-22:00 Welcome Cocktail Reception at the Vienna City Hall sponsored by LISAvienna and AUSTROMED

23 MAY 2024

STRAUSS	LEHAR 1	LEHAR 2	LEHAR 3 & 4	SCHUBERT 1
EXHIBITION AREA 08:30-09:15 WELCOME COFFEE				
09:15-09:40 OPENING Opening Key Note				
09:45-10:30 PLENARY CEO #nofilter				
10:40-11:30 PARALLEL SESSION MDR Sprint: Turbocharge Companies for a Smooth Transition	10:40-11:30 PARALLEL SESSION Cyber resilience of European healthcare: readiness of the sector Co-organised by ReedSmith	10:40-11:30 PARALLEL SESSION Successfully Navigating Exits and Financings in Tough Times	10:40-11:30 SPONSORED SESSION Europe is the most innovative continent when it comes to enhancing women's healthcare": really? Sponsored by Hologic	10:40-11:30 ASK THE EXPERT Clearing the Compliance Hurdles: Preparing for FDA Inspections HOGAN LOVELLS
EXHIBITION AREA 11:30-12:00 NETWORKING BREAK				
12:00-12:50 PARALLEL SESSION Localisation trend in the medtech industry	12:00-12:50 PARALLEL SESSION A Compass for Collaboration: Navigating Stakeholders' Roles in Transitioning To Value-Based Healthcare	12:00-12:50 PARALLEL SESSION Towards an EU Cardiovascular Health Plan - The Role of MedTech Industry	12:00-12:50 SPONSORED SESSION Rethinking Innovation: Driving Organizational Value from the Inside Out Sponsored by Veeva MedTech	12:00-12:50 ASK THE EXPERT Promotion of medical devices in the EU and interactions with healthcare professionals HOGAN LOVELLS
EXHIBITION AREA 12:50-14:00 LUNCH BREAK				
14:00-14:50 PARALLEL SESSION Regulation on HTA - A new reality for Access to innovation in Europe	14:00-14:50 PARALLEL SESSION On the power of regional medtech innovation ecosystems: Austria at a glance Co-organised by AUSTROMED/LISAvienna	14:00-14:50 PARALLEL SESSION Uncovering Europe's Innovation Allure Co-organised by Deloitte	14:00-14:50 SPONSORED SESSION IEEE 11073: How the SDC Interoperability Standard will transform MedTech Products Sponsored by ZEISS	14:00-14:50 ASK THE EXPERT The Power of the Digital Thread: Weaving quality into product engineering DELOITTE / PTC
15:00-15:50 PARALLEL SESSION The Climate Crisis: our next Health Crisis?	15:00-15:50 PARALLEL SESSION Transforming the medtech procurement of innovations culture	15:00-15:50 PARALLEL SESSION IVDR state of transition - pulse check and outlook	15:00-15:50 PARALLEL SESSION Case Study Analysis: Navigating the Impact of New Product Liability rules for medtech Business and Regulatory Strategies	15:00-15:50 ASK THE EXPERT Market Data Surveys: unique insights for the medical device field
EXHIBITION AREA 15:50-16:20 NETWORKING BREAK				
16:20-17:10 SPONSORED SESSION Unlocking the transformative potential of GenAI Sponsored by McKinsey	16:20-17:10 PARALLEL SESSION Global market focus: CHINA	16:20-17:10 PARALLEL SESSION Alignment of device data driven by EUDAMED – what are the possibilities?	16:20-17:10 PARALLEL SESSION Learn from the best: some IH winners sharing their experiences	16:20-17:10 ASK THE EXPERT Understanding the IVDR QTEC Group
17:20-18:00 PLENARY CEO #nofilter				
EXHIBITION AREA 18:00-19:30 NETWORKING RECEPTION SPONSORED BY SIEMENS				

24 MAY 2024

STRAUSS	LEHAR 1	LEHAR 2	LEHAR 3 & 4	SCHUBERT 1
EXHIBITION AREA 08:00-08:30 WELCOME COFFEE				
08:30-09:20 PARALLEL SESSION Digital Healthcare Transformation: Breaking Barriers, Shifting Mindsets Co-organised by Ernst & Young	08:30-09:20 PARALLEL SESSION Designing and implementing value-based agreements	08:30-09:20 PARALLEL SESSION Recognizing the value of medical technology in cancer care	08:30-09:20 PARALLEL SESSION Digital label for medtech and beyond – how could this work? Co-organised by Johnson&Johnson Medtech	08:30-09:20 ASK THE EXPERT IHI: 50 min to quit being a dummy
09:30-10:20 PARALLEL SESSION Why generative AI? Co-organised by Deloitte	09:30-10:20 PARALLEL SESSION Navigating EU Regulations impacting use of health data in MedTech Co-organised by Faegre Drinker Biddle & Reath	09:30-10:20 PARALLEL SESSION Spotlight on innovative Start ups: How to collaborate Co-organised by AUSTROMED/ LISAvienna	09:30-10:20 SPONSORED SESSION Capacity-Enhancing Innovation: the enabler for resilient healthcare systems? Sponsored by Edwards	09:30-10:20 ASK THE EXPERT Data-Driven Content Management - Navigating the complexities of documentation compliance RWS Group
EXHIBITION AREA 10:20-10:50 NETWORKING BREAK				
10:50-11:40 PARALLEL SESSION Unlocking Efficiency & Governance in the MDR and IVDR Maze	10:50-11:40 SPONSORED SESSION Improving Healthcare Safety and Supporting Improved Care Deliver Sponsored by Stryker	10:50-11:40 PARALLEL SESSION Global regulatory matters: reliance in practice	10:50-11:40 SPONSORED SESSION Building a Secure and Resilient Digital Healthcare Ecosystem: Reality or Utopia? Sponsored by Flex	10:50-11:40 ASK THE EXPERT The impact on medical device reimbursement as part of the ongoing shift from inpatient to outpatient care in USA and Europe. Avania
11:50-12:40 PARALLEL SESSION EU Green Deal: challenges and opportunities for the medtech sector	11:50-12:40 PARALLEL SESSION Medtech Exodus: Reclaiming Europe's Innovation Edge	11:50-12:40 PARALLEL SESSION Global clinical evidence: challenges and opportunities of RWE sources	11:50-12:40 PARALLEL SESSION Innovative Payment Schemes in Europe: Updates, Reality, and Trends Co-organised by Alira Health	11:50-12:40 ASK THE EXPERT Transform your Post Market Surveillance with GenAI and Automation Smarteeva
EXHIBITION AREA 12:40-13:40 LUNCH BREAK				
13:40-14:30 PARALLEL SESSION Supply chains – our Achilles heel?	13:40-14:30 PARALLEL SESSION Circularity4Health: Driving EU Action for Net-Zero Health Systems Co-organised by Philips	13:40-14:30 SPONSORED SESSION Generative AI in Marketing Sponsored by BCG	13:40-14:30 PARALLEL SESSION Patient Engagement – a business imperative for Medtech?	13:40-14:30 ASK THE EXPERT Cybersecurity from business risk to competitive advantage Ernst & Young
14:40-15:30 PARALLEL SESSION Never again – Pandemic Preparedness for Medtech	14:40-15:30 PARALLEL SESSION IVDs, In house assays and Research Use Only products - how will be ecosystem change?	14:40-15:30 PARALLEL SESSION Joint Scientific Consultation - Evidence and Europe	14:40-15:30 PARALLEL SESSION	14:40-15:30 ASK THE EXPERT Standing on the shoulders of giants
15:40-16:20 PARALLEL SESSION Global regulatory matters: reliance in practice	15:40-16:20 PARALLEL SESSION	15:40-16:20 PARALLEL SESSION European Alignment on Digital Health Assessment	15:40-16:20 PARALLEL SESSION	15:40-16:20 ASK THE EXPERT
16:20-16:25 PLENARY Conclusions				

WEDNESDAY 22 MAY

18:30-22:00

VIENNA CITY HALL

WELCOME COCKTAIL RECEPTION



The LISAvienna and AUSTROMED host organizing team warmly welcomes you to The MedTech Forum in Vienna!

Join us for the Welcome Cocktail Reception at the Vienna City Hall, featuring informal networking, delightful Viennese cuisine, and the enchanting ambiance of the festival hall. We look forward to seeing you in Vienna, where a blend of rich cultural heritage and excellent business prospects awaits you!

Directions: Vienna City Hall, Lichtenfelsgasse 2, Feststiege 1, 1010 Vienna, Austria

THIS IS AN ECOEVENT, HOW TO GET THERE:



Metro: U2 (Schottentor/Ring), U3 (Volkstheater/Ring)



Tram: 1, 71, D, U2Z (Rathausplatz/Burgtheater), 2 (Parliament)



Cycle: Cycle paths nearby, bicycle parking available, bike rental station at Rathauspark

THURSDAY 23 MAY

08:30-09:15

WELCOME COFFEE

09:15-09:40

STRAUSS

OPENING KEY NOTE

SPEAKER:

- Oliver BISAZZA (CEO, MedTech Europe)

09:45-10:30

STRAUSS

CEO #NOFILTER

MODERATOR:

- Sue SAVILLE (Health Event Facilitator)

SPEAKERS:

- Bronwyn BROPHY (CEO, Vitrolife Group)
- Katarzyna MAZUR-HOFSAESS (CEO Care Enablement & Member of the Management Board, Fresenius Medical Care)
- Thomas EDWARD Pole JR (Chairman of the Board, CEO and President, BD)

10:40-11:30

STRAUSS

MDR SPRINT: TURBOCHARGE COMPANIES FOR A SMOOTH TRANSITION

This practical panel session will address the immediate challenges faced by stakeholders during the transition to the MDR and will focus on short-term, actionable solutions designed to alleviate the hurdles hindering SMEs and bigger companies from navigating this regulatory shift smoothly.

MODERATOR:

- Miroslav PALAT (CEO, CzechMed)

SPEAKERS:

- Michel MARBOEUF (Senior Director Global Regulatory policy & intelligence, Stryker)
- Alexey SHIRYAEV (Global Head of Clinical and Regulatory Affairs, Team-NB)

10:40-11:30

LEHAR 1

CYBER RESILIENCE OF EUROPEAN HEALTHCARE: READINESS OF THE SECTOR

ReedSmith
Driving progress
through partnership

Against the backdrop of COVID-19, geopolitical strains and the recent ENISA threat landscapes (both for healthcare in May 2023, and for the general state of cybersecurity in November 2023), healthcare is increasingly becoming a priority target for State and non-state actors, as well as a lucrative target for would-be cyber-criminals. The panel would bring together stakeholders from across the sector, as well as a cybersecurity agency expert, to discuss the cyber-readiness of the European healthcare sector.

MODERATOR:

- Cynthia O'DONOGHUE (Partner, Reed Smith LLP)

SPEAKERS:

- Martha DE CUNHA MALUF-BURGMAN (Director Regulatory Affairs Digital Health, Edwards Lifesciences)
- Alina URS (Senior Cyber Security Coordinator, National Cyber Security Directorate, Romania)

LEHAR 2

SUCCESSFULLY NAVIGATING EXITS AND FINANCINGS IN TOUGH TIMES

Despite a challenging environment for M&A and fundraising amidst an evolving EU regulatory landscape, this panel features strategics, investors and start-up CEOs who are doing deals in spite of these obstacles, and are here to share their strategies in achieving these goals.

MODERATOR:

- Stephen LEVIN (Editor-in-Chief, Market Pathways/Medtech Strategist)

SPEAKERS:

- Christoph MASSNER (Earlybird Venture Capital)
- Daniel O'MAHONY (Partner, Seroba Life Sciences)
- Daniel ROSE (Former CEO, LimFlow)

LEHAR 3 & 4

EUROPE IS THE MOST INNOVATIVE CONTINENT WHEN IT COMES TO ENHANCING WOMEN'S HEALTHCARE": REALLY?

HOLOGIC®

Is Europe leading in women's health innovation? As a new EU policy cycle approaches, policymakers should reflect on initiatives to prioritize women's health on the agenda. This entails fostering interaction with innovators, and Hologic is eager to address this critical issue for millions of EU women.

10:40-11:30

SCHUBERT 1

ASK THE EXPERT: CLEARING THE COMPLIANCE HURDLES: PREPARING FOR FDA INSPECTIONS

Hogan
Lovells

This interactive session will address strategies for preparing for and handling FDA inspections, response strategies, and compliance requirements. Topics will include common deficiencies identified in FDA inspections and developing an effective remediation plan.

SPEAKER:

- Michael S. HEYL (Partner Global Regulatory, Hogan Lovells)

11:30-12:00

NETWORKING BREAK

12:00-12:50

STRAUSS

LOCALISATION TREND IN THE MEDTECH INDUSTRY

This session will be an opportunity to discuss various ways countries are going about localisation policies, to what extent localisation of manufacturing actually improves access to medical supplies and what makes companies tick when it comes to investment decisions, whether or not to localise their production/presence in different markets.

SPEAKERS:

- Benish ASLAM (Manager Government Affairs and Market Access, Apacmed)
- Daphne DERNISON (Head Government and Public Affairs Europe, Philips)
- Carlos GOUVEA (Executive President, CBDL)

LEHAR 1

A COMPASS FOR COLLABORATION: NAVIGATING STAKEHOLDERS' ROLES IN TRANSITIONING TO VALUE-BASED HEALTHCARE

Health system transformation requires a multi-stakeholder approach, yet it remains unclear how e.g. providers, patients, payers and industry may support the transition. Panellists from the European Alliance for Value in Health will discuss what each stakeholder may contribute, and what is expected from the others.

MODERATOR:

- Casper PAARDEKOOPEL (Partner, Vintura & European alliance for Value in Health)

SPEAKERS:

- Stephanie FRIDD (Director Value Based Care, Philips)
- Rebecca STEELE (Manager Life Sciences, European alliance for Value in Health)

12:00-12:50

LEHAR 2

TOWARDS AN EU CARDIOVASCULAR HEALTH PLAN - THE ROLE OF MEDTECH INDUSTRY

The panel explores EU's response to rising cardiovascular disease, affecting 60M Europeans daily. Amid aging population and non-communicable diseases, how can the EU ensure equitable access to prevention, early detection, and treatment? How can MedTech foster sustainable change for CVD patients?

MODERATOR:

- Alexander OLBRECHT (Director Digital Health, MedTech Europe)

SPEAKERS:

- Birgit BEGER (CEO, European Heart Network)
- Neil JOHNSON (Executive Director, Global Heart Hub)
- Jean-Luc LEMERCIER (Corporate Vice President EMEACLA & JAPAC, Edwards Lifesciences)
- Franz WEIDINGER (European Society of Cardiology)

LEHAR 3 & 4

RETHINKING INNOVATION: DRIVING ORGANIZATIONAL VALUE FROM THE INSIDE OUT

Veeva MedTech

In a competitive, regulated medtech landscape, how can organizations innovate swiftly while ensuring patient safety? This session explores strategies with industry leaders, addressing barriers to innovation, leveraging tech for product availability monitoring, and streamlining operations for faster regulatory approvals.

SPEAKER:

- Annemien PULLEN (VP MedTech Cloud, Veeva Systems)

SCHUBERT 1

ASK THE EXPERT: PROMOTION OF MEDICAL DEVICES IN THE EU AND INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Hogan Lovells

This interactive session will address key challenges manufacturers may face in the EU when promoting their device at conferences, on their website or on social media and when interacting with healthcare professionals during clinical, scientific, and marketing activities.

SPEAKER:

- Fabien ROY (Partner Global Regulatory, Hogan Lovells)

12:50-14:00

LUNCH BREAK

14:00-14:50

STRAUSS

REGULATION ON HTA: A NEW REALITY FOR ACCESS TO INNOVATION IN EUROPE

For selected highly innovative technologies a Member States driven EU regulation is being implemented in 2024. The application of JSC start in 2025. JCA reports will be ready in 2026. To know how this impact your business and have the latest intelligence, a panel of the key actors will tell you.

SPEAKERS:

- Marco MARCHETTI (Vice Chair HTA Coordination Group / Direttore UOC HTA, Agenas)
- Maya MATTHEWS (Head of Unit, State of Health, European Semester, Health Technology Assessment, European Commission)
- Andrea RAPPAGLIOSI (Chair MedTech Europe HTA Committee, MedTech Europe)

LEHAR 1

ON THE POWER OF REGIONAL MEDTECH INNOVATION ECOSYSTEMS: AUSTRIA AT A GLANCE



Join this session to explore Austria's medtech sector and the reasons why Vienna plays a key role in the regional innovation ecosystem. Discover key companies, thriving SMEs, emerging start-ups, key players in academia, and funding opportunities and support structures driving innovation.

SPEAKERS:

- Alexander BIACH (Business Location Advocate, Vienna Chamber of Commerce)
- Veronika BINDER (CEO, Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH)
- Christian HARWANEGG (CEO, MacroArray Diagnostics GmbH)
- Anni KOUBEK (CEO, QMD Services)
- Bernhard WITTMAN (CEO, Sigmapharm Arzneimittel)

14:00-14:50

LEHAR 2

UNCOVERING EUROPE'S INNOVATION ALLURE

Deloitte.

Explore the draw of European medtech investments, and weigh its vast market and innovation prowess and stability, versus challenges like regulatory environment and bureaucracy. Discuss recommendations and gain insight into Europe's innovation edge, and prospects for a competitive future.

MODERATOR:

- Koen SEGERS (Senior Director, Deloitte)

SPEAKERS:

- Hubert GAMBS (Deputy Director-General DG GROW - Internal Market, Industry, Entrepreneurship and SMEs, European Commission)
- Stuart SILK (President Europe, Latin America, Canada & EEMEA, Stryker)
- Pascal WAUCQUEZ (Sr Vice President, Clinical Operations - Europe, Middle-East, Turkey, Russia (EME), bioMérieux UK Ltd)
- Gavin WOOD (Company Group Chairman, Johnson & Johnson MedTech EMEA)

LEHAR 3 & 4

IEEE 11073: HOW THE SDC INTEROPERABILITY STANDARD WILL TRANSFORM MEDTECH PRODUCTS



Medical device manufacturers must meet growing demands for integrated and sustainable healthcare applications. Explore the IEEE 11073 SDC standard for service-oriented, cross-vendor device communication and how its adoption can promote scalability in medical device development and maintenance.

SPEAKERS:

- Attila GAGYOR (Management Consultant Health Solutions, Carl Zeiss Digital Innovation GmbH)
- Leo LINDHORST (Head of Innovation Health Solutions, Carl Zeiss Digital Innovation GmbH)

SCHUBERT 1

ASK THE EXPERT: THE POWER OF THE DIGITAL THREAD: WEAVING QUALITY INTO PRODUCT ENGINEERING



Achieving regulatory compliance and business agility is a key challenge. A 'digital thread' along the product lifecycle can help automate compliance and manage risk end-to-end. Deloitte and PTC experts will discuss benefits of digital thread throughout design, manufacturing, service, and improvement.

15:00-15:50

STRAUSS

THE CLIMATE CRISIS - OUR NEXT HEALTH CRISIS?

Climate change increasingly impacts citizen's health. How can the medtech sector contribute to decarbonizing healthcare and what is needed for building resilient, sustainable healthcare systems? Speakers will share their views on how to prevent the climate crisis turning into a next health crisis.

SPEAKER:

- Véronique TORDOFF (Image-Guided Therapy Leader Europe, Philips)

LEHAR 1

TRANSFORMING THE MEDTECH PROCUREMENT OF INNOVATIONS CULTURE

How to overcome the barriers to procurement of innovations and to transform procurement culture into one that encourages added value for citizens and market innovation. Promoting innovation procurement through knowledge sharing, matchmaking, and influencing EU policy on innovation procurement.

SPEAKERS:

- Danny HAVENITH (Chairman / Director, MercurHosp)
- Carlos LARRAÑETA GÓMEZ-CAMINERO (Procure4health Community coordinator, Andalusian Public Health System)

LEHAR 2

IVDR STATE OF TRANSITION - PULSE CHECK AND OUTLOOK

The expert panel will discuss the current state of the IVDR transition: recent progress, challenges and impact on stakeholders. What do the latest learnings and time extensions mean for stakeholders now - and in the future?

MODERATOR:

- Anna HALLERSTEN (Head Regulatory Policy Europe, Roche Diagnostics)

SPEAKERS:

- Peter BISCHOFF-EVERDING (European Commission)
- Rana CHALHOUB (Regulatory Affairs Director, Mecomed)
- Christian HARWANEGG (CEO, MacroArray Diagnostics GmbH)
- Ortwin SCHULTE (Head of Unit/Ministerialrat, German Federal Ministry of Health)

15:00-15:50

LEHAR 3 & 4

CASE STUDY ANALYSIS: NAVIGATING THE IMPACT OF NEW PRODUCT LIABILITY RULES FOR MEDTECH BUSINESS AND REGULATORY STRATEGIES

Anticipate shifts in European regulatory landscape, aligning with U.S. litigation trends. Navigate proposed liability changes, safety regulations, environmental litigation, and pan-European class actions. Join the panel to strategize and discuss proactive measures for companies to prepare.

MODERATOR:

- Adrienne FRANCO BUSBY (Strategic Litigator and Advisor to Product Manufacturers, Faegre Drinker Biddle & Reath LLP)

SPEAKERS:

- Aline LAUTENBERG (General Counsel, MedTech Europe)
- Shuna MASON (Partner, CMS London)
- Simon NEILL (Senior Legal Director, Johnson & Johnson Law Department EMEA)

SCHUBERT 1

ASK THE EXPERT: MARKET DATA SURVEYS: UNIQUE INSIGHTS FOR THE MEDICAL DEVICE FIELD

Medical device sector is a very dynamic sphere, where it is of paramount importance to have reliable information to make strategic decisions. Please join this session to learn more about the Market Data team, uniqueness of our surveys and what we can offer to meet your information needs.

SPEAKER:

- Andras KÖRIZS (Manager Market Data, MedTech Europe)

15:50-16:20

NETWORKING BREAK

16:20-17:10

STRAUSS

UNLOCKING THE TRANSFORMATIVE POTENTIAL OF GENAI

McKinsey
& Company

GenAI is transforming MedTech, unlocking significant value through scale and productivity. How can you apply GenAI for growth, process simplification and efficiency gains? Join us to explore successful GenAI use cases and discuss the next steps for fast-tracking GenAI benefits for your organization.

LEHAR 1

GLOBAL MARKET FOCUS: CHINA

China is a vast and dynamic country with a rapidly growing economy, diverse cultures, and a significant global impact, especially when it comes to manufacturing, and healthcare. In this session, we will zoom in on the dynamics, trends, and unique opportunities shaping the landscape of medical technology in China and their impact beyond.

MODERATOR:

- Trevor GUNN (VP International Relations, Medtronic)

16:20-17:10

LEHAR 2

ALIGNMENT OF DEVICE DATA DRIVEN BY EUDAMED – WHAT ARE THE POSSIBILITIES?

There is an increasing need for medical device data: in patient medical records demanded by hospitals, in supply chain demanded by customers and in tenders and reimbursement demanded by regulators. How and when EUDAMED and UDI will play a role in supplying reliable information about devices?

SPEAKERS:

- Kevin TAYLOR (Director, Medical Device Interface, Global Regulatory Affairs, Johnson & Johnson Innovative Medicine)
- Lionel TUSSAU (Lead Healthcare, Bayard)

LEHAR 3 & 4

LEARN FROM THE BEST: SOME IHI WINNERS SHARING THEIR EXPERIENCES

Several MedTech Europe corporate members are partners in IHI consortia running medical research and innovation projects. They all share something: the transformation of an idea into a project that will soon advance the medical research and impact the healthcare system. Get inspired to be the next one!

MODERATOR:

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

SPEAKERS:

- Niklas BLOMBERG (Executive Director, Innovative Health Initiative (IHI))
- Christian MUEHLENDYCK (Scientific Partnerships Lead Europe, Middle East and Africa (EMEA) J&J MedTech, Johnson & Johnson)
- Fanny VAN DER LOO (Director Public Affairs, Edwards)
- Nathalie VIRAG (Senior Director Medtronic Global Technology and Innovation, Medtronic)

SCHUBERT 1

ASK THE EXPERT: UNDERSTANDING THE IVDR



Get the chance to ask your specific questions regarding a successful implementation of the IVDR and contact other IVD manufacturers. Learn from the experience from different projects and get the answers you need.

SPEAKERS:

- Diana HOHAGE (Senior QA/RA Manager, qttec services GmbH)
- Anna SCHADE (QA/ RA Manager, qttec services GmbH)

THURSDAY 23 MAY

17:20-18:00

STRAUSS

CEO #NOFILTER

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MODERATOR:

- Sue SAVILLE (Health Event Facilitator)
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SPEAKERS:

- Patrick MALANAPHY (Head of Life Science EMEA, Henkel AG & Co/ KGaA)
- Urmi PRASAD RICHARDSON (President EMEA, Thermo Fisher Scientific)

18:00-19:30

EXHIBITION AREA

NETWORKING RECEPTION



THE MEDTECH FORUM 2024 APP

The official MedTech Forum App will be available end of April 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

Interact and vote during the sessions with other on-site.

SHARE YOUR FEEDBACK

Use the app to leave your comments about the sessions.

08:00-08:30 **WELCOME COFFEE**

08:30-09:20

STRAUSS

DIGITAL HEALTHCARE TRANSFORMATION: BREAKING BARRIERS, SHIFTING MINDSETS



This discussion explores the crucial transition to digital transformation in healthcare and the necessary adaptations in incentives and perspectives to enhance patient care. Leveraging insights from industry leaders, we analyse existing obstacles and past failures and present practical solutions. Additionally, we examine how recent legislation can revolutionise healthcare through comprehensive digitalisation, fostering innovation, streamlining processes, and enhancing patient satisfaction.

MODERATOR:

- Miroslav PALAT (CEO, CzechMed)

SPEAKERS:

- Michael FORISCH (Global Head of Digital Quality and Regulatory, Roche)
- Pascal VERDONCK (Prof MedTech & Chair Maria Middelares Hospital, Ghent University)

LEHAR 1

DESIGNING AND IMPLEMENTING VALUE-BASED AGREEMENTS

A value-based agreement is a reimbursement model that links payment for an intervention (medical device or service) to the achievement of predefined outcomes. The session will discuss the barriers to application and how to overcome together with a framework supporting companies considering VBAs.

SPEAKERS:

- Jonathan PEARSON-STUTTARD (Head of Health Analytics & Partner, LCP Health Analytics)
- Rebecca SLOAN (Senior Market Access Specialist, LCP Health Analytics)

08:30-09:20

LEHAR 2

RECOGNIZING THE VALUE OF MEDICAL TECHNOLOGY IN CANCER CARE

The adoption of medical technologies has been lacking behind, despite significantly affecting patient outcomes and benefiting healthcare systems across the care continuum. Recognizing their value can enable equal patient access, sustainable funding and advance Europe's cancer care commitment.

MODERATORS:

- Katalin ERSEK (Access & Policy Lead EMEA-LATAM, Roche Diagnostics)
- Francesco FLORINDI (EMEA Strategic Partnerships Manager Predictive Genomics, Thermo Fisher Scientific)

SPEAKERS:

- Ivana CATTANEO (Chair of the EFPIA (European Federation of Pharmaceutical Industries and Associations) Oncology Platform, Executive Director Therapeutic Area Advocacy and Precision Medicine - Novartis)
- Richard PRICE (Head of Policy, European Cancer Organisation)
- Bettina RYLL (Founder, The Melanoma Patients Network Europe and Member of the Cancer Mission Board)

LEHAR 3 & 4

DIGITAL LABEL FOR MEDTECH AND BEYOND – HOW COULD THIS WORK?

Johnson & Johnson
MedTech

Labels have become overcrowded in recent years with information unrelated to identification, handling and safety of the medical device. This session will explore how an e-label concept could help manage this challenge and whether there is a potential for future regulatory acceptance.

MODERATOR:

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

SPEAKERS:

- Shekhar NAMBI (Director, Digital Identification and Traceability, Johnson & Johnson)
- Vincenzo RENDA (Director Single Market & Digital Competitiveness, DIGITALEUROPE)

08:30-09:20

SCHUBERT 1

ASK THE EXPERT: IHI: 50 MIN TO QUIT BEING A DUMMY

By participating in IHI projects, MedTech Europe corporate members can access EC funding for cross-sectorial research and innovation that associate SMEs, global companies and public partners in pharma, medtech and biotech. The session will explain how to proceed and what are the benefits.

MODERATOR:

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

SPEAKERS:

- Hugh LAVERTY (Head of Scientific Operations, Innovative Health Initiative (IHI))
- Christian MUEHLENDYCK (Scientific Partnerships Lead Europe, Middle East and Africa (EMEA) J&J MedTech, Johnson & Johnson)
- Fanny VAN DER LOO (Director Public Affairs, Edwards)
- Nathalie VIRAG (Senior Director Medtronic Global Technology and Innovation, Medtronic)

09:30-10:20

STRAUSS

GenAI: ARE WE MAXIMISING THE VALUE OF GENAI TO ENABLE PATIENT-CENTRIC SOLUTIONS?

Deloitte.

This session will discuss the transformative journey and prerequisites required to support the pivotal shift from generative AI being applied to enhance internal processes and functions to external usage, enabling patient-centric solutions.

MODERATOR:

- Ben DESMET (Partner - Deloitte Life Sciences Practice, Deloitte)

SPEAKERS:

- Aditya KUDUMULA (Partner of Life Sciences Practice, Deloitte)
- Katarzyna MARKIEWICZ-BARREAU (Market Intelligence Lead, Philips)
- Sofia PALMIERI (Researcher, Ghent University)

LEHAR 1

NAVIGATING EU REGULATIONS IMPACTING USE OF HEALTH DATA IN MEDTECH



Explore current health data policies, from EU laws (EHDS, AI Act, cybersecurity) to global medtech challenges. Delve into how regulators and companies manage conflicting interests. Discover tools for navigating privacy regulations, harmonizing policies, and fostering innovation in this concise, dynamic session.

SPEAKER:

- Mary DEVLIN CAPIZZI (Moderator, Faegre Drinker Biddle & Reath - IPMPC Secretariat)

09:30-10:20

LEHAR 2

SPOTLIGHT ON INNOVATIVE START UPS : HOW TO COLLABORATE



Explore start-ups' views on collaborating with large firms and major customers in social insurance. Gain insights from successful SMEs sharing experiences in R&D partnerships, product development, and sales collaborations. In addition, learn more about sought-after future partners.

SPEAKERS:

- Tamara GERBERT (Co-Founder and Head of strategy, Brightmind.AI GmbH)
- Tamás PETROVICS (CEO and Co-Founder, XUND)
- Bernhard REDL (CEO, edupression.com powered by SOFY GmbH)
- Josef SCHABAUER (Member of the Board of Directors Austromed, Austromed)
- Nayeli SCHMUTZ (Chief Medical Officer & Co-founder, PIPRA AG)

LEHAR 3 & 4

CAPACITY-ENHANCING INNOVATION: THE ENABLER FOR RESILIENT HEALTHCARE SYSTEMS?



Edwards

Amidst critical healthcare workforce shortages, hospitals face capacity challenges, necessitating innovation in processes, technology, and mindset. With the Belgian Presidency prioritizing an EU health workforce strategy, the MedTech Industry must foster consensus on innovation's role in addressing shortages. This session explores reconciling urgent care needs with workforce gaps, defining the industry's role, and initiating mindset shifts for sustainable change.

SCHUBERT 1

ASK THE EXPERT: DATA-DRIVEN CONTENT MANAGEMENT - NAVIGATING THE COMPLEXITIES OF DOCUMENTATION COMPLIANCE



Meeting complex regulatory requirements for Medical and In Vitro Diagnostics Device Manufacturers, especially with Eudamed, is crucial. Incomplete submissions and disorganized technical documentation cause common delays in market approval. This presentation delves into a data-driven, componentized content management approach, ensuring consistency, and expediting documentation for device registration.

SPEAKER:

- André SCHLOTZ (Vice President Global Automotive and Manufacturing Solutions, RWS Group)

10:20-10:50

NETWORKING BREAK

10:50-11:40

STRAUSS

UNLOCKING EFFICIENCY & GOVERNANCE IN THE MDR AND IVDR MAZE

From fostering agile governance structures to streamlining operations, reducing bottlenecks, simplifying approval processes and establishing clearer guidelines, our panelists will brainstorm on actionable recommendations aimed at shaping more efficient and future ready MDR and IVDR regulatory frameworks.

MODERATOR:

- Olga VAN GROEL-LAWLOR (Senior Global Regulatory Intelligence & Advocacy Manager, Boston Scientific)

SPEAKERS:

- Tom MELVIN (Academia)
- John O'DEA (CEO, Palliare)
- Graeme TUNBRIDGE (Senior Vice President Global Regulatory and Quality, Medical Devices, BSI)

LEHAR 1

HCP SAFETY AND SECURITY

stryker

Healthcare delivery in Europe faces unprecedented challenges, as observed with the continuing struggles with backlogs, and long-term healthcare staff fatigue. This has led to hospital facing rising recruitment and retention challenges and increasing HCP demonstrations, demanding better working conditions. This session will explore these challenges and the solutions industry can support.

SPEAKER:

- Sherieta MISERIELAL-BOEDHOE (Director, Marketing Medical Acute Care & sage, Stryker)

LEHAR 2

GLOBAL REGULATORY MATTERS: RELIANCE IN PRACTICE

Strong regulatory capacity is essential for a well-functioning healthcare system and implementation of reliance practices has been a topic of growing interest internationally. In this panel discussion, we are going to explore examples of reliance and discuss what it takes to facilitate reliance in practice.

MODERATOR:

- Rana CHALHOUB (Regulatory Affairs Director, Mecomed)

SPEAKERS:

- Jasjit BAVEJA (Associate Director, Policy, Ph.D., MTAA)
- Flora GIORGIO (Head of Unit, European Commission)

10:50-11:40

LEHAR 3 & 4

BUILDING A SECURE AND RESILIENT DIGITAL HEALTHCARE ECOSYSTEM: REALITY OR UTOPIA?



Today, medical devices are accelerating their growth into a digital ecosystem that facilitates continuous data exchange between patients and healthcare providers. A group of experts will explore how the industry is managing the complexity of this ecosystem and discuss patient readiness for technology adoption, as well as cybersecurity implications.

MODERATOR:

- Alexander OLBRECHT (Director Digital Health, MedTech Europe)

SPEAKERS:

- Daniele FAZIO (VP Business Development, Flex)
- Mark STOESZ (General Manager Enterprise Solutions, GE HealthCare International Region)

SCHUBERT 1

ASK THE EXPERT: THE IMPACT ON MEDICAL DEVICE REIMBURSEMENT AS PART OF THE ONGOING SHIFT FROM INPATIENT TO OUTPATIENT CARE IN USA AND EUROPE.



SPEAKER:

- Stephen HULL (Senior Vice President, Avania Market Access)

11:50-12:40

STRAUSS

EU GREEN DEAL: CHALLENGES AND OPPORTUNITIES FOR THE MEDTECH SECTOR

As Europe's net zero transformation is fully on, each sector has to contribute. What challenges and opportunities does the medical technology sector face in the transition? Is Circularity fact or fiction? How to succeed in the transition to more sustainable materials and chemicals? What should a Green Deal 2.0 look like?

LEHAR 1

MEDTECH EXODUS: RECLAIMING EUROPE'S INNOVATION EDGE

In this session, our panel will dissect the MDR and IVDR challenges that have inadvertently triggered an outflow of innovation from Europe's vibrant ecosystem and discuss potent solutions and reforms aimed at steering medical technology innovation back to the heart of Europe.

SPEAKERS:

- Samih AL MAWASS (Divisional Vice President, EMEA (Europe, Middle East & Africa), Vascular, Abbott Vascular)
- Oliver BISAZZA (CEO, MedTech Europe)
- Alan FRASER (BioMedAlliance)
- Céline SAINT OLIVE BAQUE (CEO, NORAKER - Innovative Biomaterials)

11:50-12:40

LEHAR 2

GLOBAL CLINICAL EVIDENCE: CHALLENGES AND OPPORTUNITIES OF RWE SOURCES

In this session we plan to explore different approaches to collecting clinical evidence for medical devices worldwide. Specific focus will be given to the opportunities and challenges of Real World Evidence (RWE), particularly how it could be leveraged for the MDR.

SPEAKERS:

- Philip DESJARDINS (Partner, Arnold & Porter)
- Nataliya DEYCH (Vice President Regulatory Affairs, Edwards Lifesciences)
- Richard HOLBOROW (Global Head of Clinical Compliance, BSI)
- Donal O'CONNOR (Clinical Manager Medical Devices, Health Products Regulatory Authority (HPRA))

LEHAR 3 & 4

INNOVATIVE PAYMENT SCHEMES IN EUROPE: UPDATES, REALITY, AND TRENDS



Traditional reimbursement schemes struggle to incorporate innovation. Alternatively, innovative payment schemes (IPS) can provide timely patient access to innovative medical technologies and procedures. This panel will discuss the latest updates on the 17 main European IPS and share stakeholders' perspective on their current implementation.

SCHUBERT 1

ASK THE EXPERT: TRANSFORM YOUR POST MARKET SURVEILLANCE WITH GENAI AND AUTOMATION



Post Market Surveillance, such as complaint handling, adverse event reporting and regulatory reports have gotten burdensome, complex and a lot more visible with MDR and IVDR. Some of these functions are also extensions of customer service. Join us to see real world examples of how MedTech companies have applied modern AI and automation to transform post market surveillance.

SPEAKER:

- Plarent YMERI (CEO, Smarteeva)

12:40-13:40

LUNCH BREAK

13:40-14:30

STRAUSS

SUPPLY CHAINS – OUR ACHILLES HEEL?

The MedTech sector has some of the most complex supply chains of any sector both by their breadth and by their depth. Numerous examples of supply chain failures have occurred recently, leading to disruptions in the sector but new paradigms in resilience and robustness of supply chains are emerging.

SPEAKER:

- Mark STOESZ (General Manager Enterprise Solutions, GE HealthCare International Region)

13:40-14:30

LEHAR 1

CIRCULARITY4HEALTH: DRIVING EU ACTION FOR NET-ZERO HEALTH SYSTEMS **PHILIPS**

70% of global emissions are tied to material handling and use while extraction and consumption are growing at almost unprecedented rates. This session will discuss the opportunities of circular business models to improve people's health and well-being, the barriers to and enablers of more circular, resilient health systems and concrete policy needs.

LEHAR 2

GENERATIVE AI IN MARKETING **BCG**

Join Jochen Tham, CMO at ZEISS Meditech, and experts from BCG for an immersive workshop on GenAI in marketing. Learn to craft campaigns with GenAI, enhancing creativity and efficiency, and gain insights from a leading marketing executive on how to scale AI and evolve the marketing operating model.

SPEAKERS:

- Lisa HARTMANN (Principal, BCG)
- Jan-Frederik JERRATSCH (Managing Director & Partner, BCG)
- Jochen THAM (Head of Digital Customer Experience, CARL ZEISS)

LEHAR 3 & 4

PATIENT ENGAGEMENT – A BUSINESS IMPERATIVE FOR MEDTECH?

Recent trends in IHI, HTA and R&D have made patient engagement both an obligation and a commercially astute initiative for MedTech.

This session will bring together industry and patient group leaders to look at Patient Engagement in healthcare.

SPEAKERS:

- Patrick BOISSEAU (Director General of Industry Strategic Initiative, MedTech Europe)
- Neil JOHNSON (Executive Director, Global Heart Hub)
- Anca TOMA (Executive Director, European Patients' Forum)

SCHUBERT 1

ASK THE EXPERT: CYBERSECURITY FROM BUSINESS RISK TO COMPETITIVE ADVANTAGE



On the backdrop of the ever-increasing focus on Cybersecurity in MedTech from a regulatory and risk perspective, join us in this interactive session to explore a different angle – Cybersecurity through the lens of your customers and how to leverage Cybersecurity to gain a competitive edge in the market.

SPEAKER:

- Cristian DUMITRESCU (Cybersecurity Partner, Ernst & Young)

14:40-15:30

STRAUSS

REAL WORLD DATA – A GAME CHANGER FOR THE MEDTECH INDUSTRY?

Explore opportunities and challenges for the use of Real-World Data (RWD) for the development of medical technologies. How does the European Health Data Space act as an enabler? What are the challenges that innovators face?

SPEAKERS:

- Dipak KALRA (President, The European Institute for Innovation through Health Data)
- Erika MOSOR (Researcher, Medical University of Vienna: Section for Outcomes Research, Center for Medical Data Science)
- Christian MUEHLENDYCK (Scientific Partnerships Lead Europe, Middle East and Africa (EMEA) J&J MedTech, Johnson & Johnson)
- Amra RACIC (Senior Director Government Strategy, MedTech at Veeva Systems)

LEHAR 1

IVDS, IN HOUSE ASSAYS AND RESEARCH USE ONLY PRODUCTS - HOW WILL BE ECOSYSTEM CHANGE?

This session examines the state of the diagnostic market in Europe, considers its strongest trends and where the sector will evolve in the future. Its panelists will discuss their perspectives on the status and outlook for lab developed tests, CE-marked IVDs and the research pipeline.

SPEAKERS:

- Daniela DELLEDONNE (Vice President & General Manager, EMEA, BD Life Sciences – Biosciences)
- Daniel WHITE (VP Sales CDS, France, Iberia, UK and FAS EMEA, Cepheid)

LEHAR 2

JOINT SCIENTIFIC CONSULTATION - EVIDENCE AND EUROPE

Innovation likely to be subject to joint clinical assessment, has an opportunity to undergo a parallel expert panel – joint HTA Joint Scientific Consultation (JSC). A panel of Expert Panels MDR/IVDR, Notified Bodies, Member States JSC representative and the European Commission.

SPEAKERS:

- Sylvie DA ROCHAS DIAS (Head of Office, expert panels and group office, EMA)
- Richard HOLBOROW (Global Head of Clinical Compliance, BSI)

LEHAR 3 & 4

14:40-15:30

SCHUBERT 1

ASK THE EXPERT: STANDING ON THE SHOULDERS OF GIANTS

Learn more about MedTech Europe's new membership category that supports SMEs and startups to navigate the different EU funding programmes for research and innovation and gives them the opportunity to join research and innovation activities at MedTech Europe and IHI projects from the industry side.

SPEAKERS:

- Patrick BOISSEAU (Director General, Strategic Initiatives, MedTech Europe)
- Christopher BREYEL (Executive Director Member Relations & Services, MedTech Europe)

15:40-16:20

STRAUSS

NEVER AGAIN – PANDEMIC PREPAREDNESS FOR MEDTECH

During the COVID-19 pandemic many heroic efforts were made by health systems, including MedTech companies at the heart of the crisis. So how is the MedTech sector preparing for the next pandemic? Global commitments are being discussed but in practice will we be ready when the next pandemic comes?

LEHAR 1

EUROPEAN ALIGNMENT ON DIGITAL HEALTH ASSESSMENT

Securing reimbursement and funding for digital health solutions has been a barrier to their adoption. Can we harmonise their evaluation across Europe? This session convenes experts in digital health for discussions on the potential and limitations of coordinating efforts at the European level.

LEHAR 2

SPEAKERS:

- Katarzyna MARKIEWICZ-BARREAU (Market Intelligence Lead, Philips)
- Uta-Maria OHNDORF (General Manager, Roche Diagnostics Austria)
- Louisa STÜWE (Project Director, Digital Health Delegation, French Ministry of Health)

LEHAR 3 & 4

16:20-16:25

STRAUSS

CONCLUSIONS

SPEAKER:

- Oliver BISAZZA (CEO, MedTech Europe)

ASK THE EXPERT

WHAT?

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

WHERE?

SHUBERT 1

WHEN?

23 and 24 May

HOW?

In a breakout room with one expert and a maximum of 20 participants. Seats are allocated on a first come first served basis, be on time!



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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