

#MTF2024
22–24 MAY
VIENNA

In cooperation with



LISAvienna life science austria

www.themedtechforum.eu

Programme as of March 21, 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

22 MAY 2024

22 IVIAT 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	08:30-09:30 WELCOME COFFEE					
09:30-09:45 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 SPONSORED 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 Women's health Sponsored by Hologic	10:40-11:30 ASK THE EXPERT		
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 How can we make Value Based Healthcare happen?	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		
EXHIBITION AREA	12:50-14:00 LUNCH BREAK					
14:00-14:50 PARALLEL SESSION Never again – Pandemic Preparedness for MedTech	14:00-14:50 SPONSORED SESSION On the power of regional medtech innovation ecosystems: Austria at a glance Sponsored by AUSTROMED/LISAvienna	14:00-14:50 SPONSORED 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		
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 Transition to the IVD Regulation	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	16:20-17:10 PARALLEL SESSION	16:20-17:10 PARALLEL SESSION	16:20-17:10 PARALLEL SESSION	16:20-17:10 ASK THE EXPERT		
Unlocking the transformative potential of GenAi Sponsored by McKinsey	Global market focus: CHINA	Alignment of device data driven by EUDAMED – what are the possibilities?	Learn from the best: some IHI winners sharing their experiences	Understanding the IVDR QTEC Group		
17:20-18:00 PLENARY CEO #nofilter						
EXHIBITION AREA	18:00-19:30 NETWORKING RECEPTION SPO	NSORED BY SIEMENS				

24 IVIAY	2024								
ST	STRAUSS LEHAR 1		L	EHAR 2	LE	HAR 3 & 4	SCH	UBERT 1	
EXHII	BITION AREA	08:00-08:30	WELCOME COFFEE						
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	care Transformation: rs, Shifting Mindsets		and implementing sed agreements		the value of medical gy in cancer care		nedtech and beyond – ould this work?	IHI: 50 min to	quit being a dummy

STRAUSS	LEHAR 1	LEHAR 2	LEHAR 3 & 4	SCHUBERT 1	
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09:30-10:20 SPONSORED SESSION Why generative AI? Co-organised by Deloitte	09:30-10:20 PARALLEL SESSION Managing Health data: From policy to practice	O9:30-10:20 SPONSORED SESSION Spotlight on innovative Start ups: How to collaborate Co-organised by LISAvienna	09:30-10:20 SPONSORED SESSION Capacity-Enhancing Innovation: the enabler for resilient healthcare systems? Co-organised by Edwards	Data-Driven Content Management - Navigating the complexities of documentation compliance RWS Group	
EXHIBITION AREA	10:20-10:50 NETWORKING BREAK				
10:50-11:40 PARALLELSESSION Unlocking Efficiency & Governance in the MDR and IVDR Maze	10:50-11:40 SPONSORED SESSION HCP safety and Security Sponsored by Stryker	10:50-11:40 PARALLEL SESSION Regulation on HTA A new reality for Access to Innovation in Europe	Building a Secure and Resilient Digital Healthcare Ecosystem: Reality or Utopia? Sponsored by Flex	10:50-11:40 ASK THE EXPERT	
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 SPONSORED SESSION Innovative Payment Schemes Assessed: Unveiling similarities and pathways for improvement Sponsored by Alira Health	11:50-12:40 ASK THE EXPERT	
EXHIBITION AREA	12:40-13:40 LUNCH BREAK				
13:40-14:30 PARALLEL SESSION Supply chains – our Achilles heel?	13:40-14:30 SPONSORED SESSION Circularity4Health: Driving EU Action for Net-Zero Health Systems Sponsored by Philips	13:40-14:30 SPONSORED SESSION Generative Al workshop Sponsored by BCG	13:40-14:30 PARALLEL SESSION Patient Engagement – a business imperative for Medtech?	13:40-14:30 ASK THE EXPERT	
14:40-15:30 PARALLEL SESSION Real world data – a game changer for the Medtech Industry?	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 Fostering and embracing Corporate Sustainability in your Governance	14:40-15:30 ASK THE EXPERT It is a small world after all: MedTech Europe's partners in research	
15:40-16:30 PARALLEL SESSION Global regulatory matters: reliance in practice	15:40-16:30 PARALLEL SESSION	15:40-16:30 PARALLEL SESSION European Alignment on Digital Health Assessment	15:40-16:30 PARALLEL SESSION	15:40-16:30 ASK THE EXPERT	
16:30-16:50 PLENARY Conclusions				A MacRein Europa sewit The MedTech Forum bringing Health Tech stakeholders together	

WEDNESDAY 22 MAY

18:30-22:00

WELCOME COCKTAIL RECEPTION



VIENNA CITY HALL



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



08:30-09:30

WELCOME COFFEE

09:30-09:45

STRAUSS

OPENING KEY NOTE

SPEAKER:

• Oliver BISAZZA (CEO, MedTech Europe)

09:45-10:30

STRAUSS

CEO #NOFILTER

SPEAKERS:

- Oliver BISAZZA (CEO, MedTech Europe)
- Bronwyn BROPHY (CEO, Vitrolife Group)
- Katarzyna MAZUR-HOFSAESS (Care Enablement, Fresenius Medical Care)
- Tom POLEN (CEO, 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.

SPEAKER:

Michel MARBOEUF (Stryker)

HAR

CYBER RESILIENCE OF EUROPEAN HEALTHCARE: READINESS OF THE SECTOR



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 (Reed Smith)

EHAR 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.



10:40-11:30

LEHAR 3 & 4

WOMEN'S HEALTH

HOLOGIC®

SPEAKER:

Jose YEBRA (General Manager Europe South, Hologic)

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:

- Daphne DERNISON (Philips)
- Carlos GOUVEA (Moderator, CBDL)

HAR 1

HOW CAN WE MAKE VALUE BASED HEALTHCARE HAPPEN?

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.

EHAR 2

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

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?

LEHAR3 & 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 (Vice President, MedTech Cloud)

12:50-14:00

LUNCH BREAK



14:00-14:50

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?

EHAR

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.

EHAR 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.

SPEAKERS:

- Oliver BISAZZA (CEO, MedTech Europe)
- Koen SEGERS (Deloitte)
- Pascal WAUCQUEZ (Head of Europe & Middle East Region, bioMérieux)
- Gavin WOOD (Company Group Chairman, Johsnon / Johnson MedTech)

LEHAR3 & 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, crossvendor device communication and how its adoption can promote scalability in medical device development and maintenance.

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



14:00-14:50

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



📚 p†c Deloitte.

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

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.

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.

EHAR 2

TRANSITION TO THE IVD REGULATION

The expert panel will discuss the state of the transition and its impact for industry, notified bodies and other actors. As EU Reference Laboratories soon will be designated for the first time, the panel will dive into the implications for the class D IVDs they will cover.

SPEAKERS:

- Rana CHALHOUB (Regulatory Affairs Director, Mecomed)
- Anna HALLERSTEN (Head Regulatory Policy Europe, Roche Diagnostics)
- Christian HARWANEGG (Chief Executive Officer, Maro Array Diagnostics)
- Ortwin SCHULTE (German Federal Ministry of Health)

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 (Partner, Faegre Drinker Biddle & Reath LLP)

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



15:00-15:50

CHUBERT 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.

15:50-16:20

NETWORKING BREAK

16:20-17:10

McKinsey & Company

STRA

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)

UNLOCKING THE TRANSFORMATIVE POTENTIAL OF GENAI

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?

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



16:20-17:10

EHAR 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 (Edwards)
- Nathalie VIRAG (Distinguished Scientist | Global Technology and Innovation Bakken Fellow, Technical Fellow Medtronic, Medtronic)

SCHUBERT

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
- Anna SCHADE

17:20-18:00

TRAUSE

CEO #NOFILTER

MODERATOR:

• Sue SAVILLE (Health Event Facilitator)

SPEAKERS:

- Oliver BISAZZA (CEO, MedTech Europe)
- Urmi RICHARDSON (President EMEA, Thermo Fischer)

18:00-19:30

XHIBITION AREA

NETWORKING RECEPTION







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.

EHAR 1

08:00-08:30

WELCOME COFFEE

08:30-09:20

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.

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.

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.

E-LABEL FOR MEDTECH AND BEYOND - HOW COULD THIS WORK?

Johnson & Johnson Med Tech

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.

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.

SPEAKER:

Hugh LAVERTY (Head of Scientific Operations, IHI)

SCHUBERT

LEHAR 3 & 4



09:30-10:20

TRAUS

WHY GENERATIVE AI?

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 of Life Sciences Practice, Deloitte)

SPEAKERS:

- Aditya KUDUMULA (Partner of Life Sciences Practice, Deloitte)
- Sofia PALMIERI (Researcher, Ghent University)

HAR 1

MANAGING HEALTH DATA: FROM POLICY TO PRACTICE

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.

EHAR 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:

LISAvienna

- Tamara GEBERT (CSO and Co-Founder, brightmind.ai)
- Hugh LAVERTY (Head of Scientific Operations, IHI)
- Tamás PETROVICS (CEO and Co-Founder, XUND,)
- Josef SCHABAUER (Member of the Board of Directors Austromed, Austromed)
- Nayeli SCHMUTZ (Chief Medical Officer & Co-founder, PIPRA AG)

LEHAR3 & 4

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



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.



09:30-10:20

SCHUBERT

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

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.

LEHAR 1

HCP SAFETY AND SECURITY

*s*tryker

LEHAR 2

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 lastest intelligence, a panel of the key actors will tell you.

SPEAKER:

- Maya MATTHEWS (European Commission)
- Marco MARCHETTI (Co-Chair, AGENAS, Italy)

LEHAR3 & 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.



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?

EHAR

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, Abbott Vascular)
- Oliver Bisazza, CEO, MedTech Europe

HAR 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.

SPEAKER:

• Richard HOLBOROW (BSI Group)

HAR3 & 4

INNOVATIVE PAYMENT SCHEMES ASSESSED: UNVEILING SIMILARITIES AND PATHWAYS FOR IMPROVEMENT

AliraHealth

Traditional reimbursement frameworks, often struggle to integrate newly approved technologies. Innovative Payment Schemes are a key mechanism for timely access to innovative medical technologies and procedures. This session will present the analysis and assessment of the 16 IPS in Europe.

12:40-13:40

LUNCH BREAK



13:40-14:30

TRAUS

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.

EHAR 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.

HAR₂

GENERATIVE AI WORKSHOP

BCG

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 (CEO, Global Heart Hub)
- Anca TOMA (Executive Director, European Patients' Forum)

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?

- Dipak KALRA (President, The European Institute for Innovation through Health Data)
- Amra RACIC (Senior Director Government Strategy, MedTech at Veeva)

14:40-15:30

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 (BD)
- Mario PLEBANI (President, EFLM)

HAR ;

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:

- Sylvy DA ROCHAS DIAS (Expert panel, EMA)
- Flora GIORGI
- Maya MATTHEWS (European Commission)

HAR3 &

FOSTERING AND EMBRACING CORPORATE SUSTAINABILITY IN YOUR GOVERNANCE

Explore the Corporate Sustainability Due Diligence Directive's influence on the medical technology sector, understand its requirements, and learn strategies for effective compliance and adaptation.

ASK THE EXPERT: IT IS A SMALL WORLD AFTER ALL: MEDTECH EUROPE'S PARTNERS IN RESEARCH

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.

SCHUBERT 1



15:40-16:30

STRAUSS

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)

LEHA

HAR 2

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.

FHAP 2 &

STRAUSS

15:40-16:30

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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