



A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together



23-25 JAN.
2018
—
The EGG
BRUSSELS

**FINAL
PROGRAMME**

WELCOME INTRODUCTION



Serge Bernasconi
Chief Executive Officer
MedTech Europe

Dear partners,

I'm pleased to announce that the MedTech Forum enters a new era in 2018!

At MedTech Europe, the voice of the in vitro diagnostics (IVD) and medical devices (MD) industry in Europe, we are reshaping our annual Forum with the ambition to make it 'THE' European medical technology event to be at or to be seen at for anyone involved in or with medical technology in Europe.

We also have the objective over the years to multiply by 5 the current number of participants. We will gradually enlarge the program to address a larger variety of topics - from very specialised to very general and from very specific to global but always with a multi stakeholders approach. We will also enlarge the target audience to a broader representation of our industry (which in total employs 650,000 people in Europe), patients, hospital representatives, service providers, suppliers, Scientific Societies, National Associations, policy-makers, Notified Bodies, consultants, Authorities, etc and we will create opportunities for SMEs, startups and investors. Last but not least, we will agglomerate over the years several of MedTech Europe events together.

To achieve our goals, we are working with a new partner – Europa Organisation - well-known and innovative experts in congress organization and development. Together with them, our sponsors, our supporters and the media, we will bring the MedTech Forum to the next level. MedTech Europe will ensure that your investment brings you the best outcome you are looking for.

See you in Brussels on 23-25 January 2018

TUESDAY 23 JANUARY

09:00-18:00 **MEDTECH EUROPE WORKING GROUPS**

For MedTech Europe members only

18:15-21:00 **WELCOME COCKTAIL & DINNER**

hosted by MedTech Europe Board

WEDNESDAY 24 JANUARY

08:45-09:15 **WELCOME COFFEE AND REGISTRATION**

09:15-09:45 **OPENING SESSION**

Plenary

Moderators:

- Serge BERNASCONI, CEO, MedTech Europe
- Ingmar DE GOOIJER

09:15-19:00 **EXHIBITION AND NETWORKING**

09:45-10:45 **CEO #NOFILTER**

Plenary

Global leaders from the field of medical devices, diagnostics and digital health have agreed to sit together and speak openly about the latest trends, challenges and opportunities they're facing. How are they coping with Brexit, the continuous pressure to innovate, service and low-cost models and what do they expect the next disruptive force to be? The audience will have the opportunity to ask direct questions that will be answered with #nofilter

Objectives:

- To understand the forces shaping the medtech industry
- To give audience members an opportunity for an unfiltered Q&A with industry leaders

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Elie LOBEL, CEO, Orange Healthcare
- Cécile REAL, Co-founder & CEO, Endodiag
- Herman VERRELST, CEO, Biocartis

10:45-11:30

IMPACT OF THE NEW IVD REGULATION ON THE INDUSTRY

Regulatory

The new EU Regulations were published in May 2017 and are intended to strengthen patient protection while fostering competitiveness and innovation. The IVD Regulation applies from May 2022 and is a substantial re-writing of the rulebook for industry. In this panel discussion between authorities, we explore the impact this Regulation is starting to have on IVD manufacturers and their supply chains.

Key questions to be addressed include:

- How are companies planning and budgeting for their new responsibilities?
- What are the main challenges that small, medium and large manufacturers foresee?
- To what extent does the new Regulation affect legacy products versus new innovations?
- What benefits do companies expect to derive from the new, modernized rules?

Moderator:

- Michel DE RIDDER, Partner, Deloitte

Speakers:

- Salvatore D'ACUNTO, Head of Unit Health Technology and Cosmetics, European Commission
- Simon RICHARDS, Vice-President, Regulatory Affairs EME and RCIS, Abbott
- John WILKINSON, Director of Devices, Medicines and Healthcare products Regulatory Agency

CONNECTING TO THE MEDICAL INTERNET OF THINGS

Digital developments

Patient-generated data from connected medical devices, apps and sensors are on the rise. This raises questions about how different devices and datasets will work together to support remote clinical decision-making and seamless patient experiences. The medical 'Internet of Things' system is growing and two experts from outside the traditional medtech industry (a chip manufacturer & a healthcare technology provider) will discuss the current state of play as well as opportunities and challenges for the future.

Objectives:

- To give an overview of the medical Internet of Things and its potential
- To elaborate on how to build the right foundation that creates a secure, reliable medical Internet of Things (from a hardware and services point of view)
- To give suggestions to the medtech industry on how to cope with the IoT

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Joseph FERNANDO, Principal Architect, IoT Vertical Markets
- David VASQUEZ, Director of International IoT Business Development, Verizon Enterprise Solutions

EUROPEAN COMMISSION AND MEDTECH INDUSTRY: THE POWER OF PARTNERSHIP

Business strategy

The European Commission will present different EU initiatives expected to influence access to innovation and awarding value for medical technologies, in an environment where health is a national competence. Among the most relevant initiatives expected to be presented are the EU Public Procurement Directive (DG Growth), Health System Performance and the EU cooperation on HTA (there will be a new EC legislative proposal by the end of January) (DG Sante). Besides providing an update on Commission activities, the presentations should trigger a discussion from a business perspective e.g. how these initiatives could influence the business in Europe in the next 5 years (e.g. facilitate exchange of knowledge and best practices, measure performance, change in attractiveness of Europe as first market to go to in a frame of better regulations, shift from price only driven to a value-based procurement, increase in number of assessments on medical devices, HTA as a potential tool to stimulate innovation, increased data requirements , investment).

Objectives:

- To discuss how the EU initiatives are impacting your business
- To present and deepen understanding of EU initiatives relevant to the medtech sector

Moderator:

- Hans MARTENS, Senior Advisor, European Policy Centre, Danish think tank Europa

Speakers:

- David BLANCHARD, Deputy Head of Unit in the Directorate in charge of Public procurement, Directorate-General for Industry, Single Market, Entrepreneurship and SME (DG GROW) of the European Commission
- Andrzej RYS, Health Systems and Medical products and Innovation Director, European Commission

SPOTLIGHT ON KOREA

International

The goal of the session is to provide an overview of the Korean market, with an overview of the key opportunities and hurdles which a MedTech company can expect when operating there specifically:

- Health Policies – what are the healthcare priorities in Korea? How do they influence the MedTech Sector, are there any opportunities or pitfalls there?
- Access to market – what is a reasonable expectation of the timeline to market in Korea for medical technologies? (To the moment when they can be used by patients). What are the major questions to be resolved along the way.
- Investment opportunities. How to use Korea as your Far East hub?
- Funding – Understanding the opportunities and issues related to working with the National Health Insurance Service. How is the value of innovation recognised in Korea? A brief review of the Value Appraisal Standard and the way pricing guidelines with evidence base are affecting the Korean market.

Moderator:

- Jesus RUEDA RODRIGUEZ, Director International Affairs, MedTech Europe

Speakers:

- So-Hyung JEONG, Assistant Manager Medical & Bio, KOTRA HQ
- Yoonjin LEE, Investment & Research Manager, KOTRA Brussels

NETWORKING BREAK

IMPACT OF THE NEW MEDICAL DEVICES REGULATION ON THE INDUSTRY

Regulatory

The new EU Regulations were published in May 2017 and are intended to strengthen patient protection while fostering competitiveness and innovation. The Medical Devices Regulation applies from May 2020 and substantially modernizes and builds on the existing rules. In this panel discussion between authorities, we explore the impact this Regulation is starting to have on medical devices manufacturers and their supply chains.

Key questions to be addressed include:

- How are companies planning and budgeting for their new responsibilities?
- What are the main challenges that small, medium and large manufacturers foresee?
- To what extent does the new Regulation affect legacy products versus new innovations?
- What benefits do companies expect to derive from the new, modernized rules?

Moderator:

- Michel DE RIDDER, Partner, Deloitte

Speakers:

- Erik HANSSON, Deputy Head, Health Technology and Cosmetics Unit of the DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) of the European Commission
- Rita PEETERS, Senior Director, Regulatory Affairs Policy and Intelligence EMEA, Johnson & Johnson
- John WILKINSON, Director of Devices, Medicines and Healthcare products Regulatory Agency

DIAGNOSTIC INFORMATION: AN UNPOLISHED JEWEL

Business strategy

Healthcare decision-makers rely on swift and accurate information to diagnose and treat patients. The diagnostics industry can be a key source of the medical information essential to optimising patient outcomes.

But is the full potential of diagnostics information being realised?

There is a unique opportunity to enhance the value of diagnostics if we are able to value information. Diagnostics companies have a jewel in their hands and they need to learn how to polish it.

Objectives:

- To provide an overview of stakeholders' perspectives of the value of diagnostic information.
- To use a series of examples and case studies to help attendees discover more about the Value of Diagnostic Information concept and opportunities to use it to demonstrate the value.

Moderator:

- Hans MARTENS, Senior Advisor, European Policy Centre, Danish think tank Europa

Speakers:

- Alex LEFEVRE, Head of Market Access and Medical Affairs, Roche Diagnostics Belgium
- Bernarda ZAMORA, Economist, The Office of Health Economics

GAMIFICATION IN MEDTECH - READY TO PLAY?

Business strategy

Improving healthcare is not only about developing better therapies, devices and diagnostics. Better outcomes can be achieved by keeping people motivated to follow prescribed treatment. Applied gaming can play a valuable role in this field.

In this session, two experts will discuss the different purposes and approaches of applied gaming in therapy, prevention, recovery and rehabilitation, diagnosis and treatment.

Jurriaan van Rijswijk has been an Applied Game Architect for 20 years and won the ICT Personality of the Year Award in the Netherlands in 2014. He develops game strategies and designs behaviour change interventions using clinically and scientifically-validated games - for which he has also won various awards. Hannah Rose Thomson holds an instrumental role at the multiple award-winning company Elvie, which specialises in turning "neglected" medical devices into "fashionable" gadgets that women want to use. Its first product, released a year ago, is a pelvic floor exercise tool that connects to a smartphone app to help women strengthen their muscles.

Objectives:

- To give an overview of the current and future state of play of gaming in healthcare in general and the (potential) role for the medtech industry
- To elaborate on the implications of gamification in the product development journey

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Hannah Rose THOMSON, Senior Manager, Health and Wellness, Elvie
- Jurriaan VAN RIJSWIJK, Chairman & Founder, Games for Health Europe Foundation

SME FINANCIAL SUPPORT MODELS: WHAT ALTERNATIVE ARE AVAILABLE FOR FOSTERING INNOVATION?

SMEs Track

This session will address key issues that SMEs are facing when it comes to financial support and innovation management. The different financing models available will be presented as well as practical ways to foster innovation.

BA Millenaar (CEO of NLC) will introduce an innovative perspective on fostering and bringing healthtech innovation to the market. NLC

- the European Healthtech Venture Builder
- brings science to life, and supports corporates as external incubation partner and co-creator of innovation. NLC actively scouts science-based inventions at leading academic research institutes, hospitals and corporates and transforms them into successful healthcare companies. NLC does not work as consultants, but as co-founder of such ventures. A small selection of the partnerships in place: Erasmus MC Rotterdam, TU Eindhoven, Fraunhofer, CSEM, DKFZ (German Cancer Research Centre), Philips, SanQuin (Dutch Blood Bank) and Boston Scientific. NLC also cooperates with R&D in unlocking in-house IP.

Moderator:

- Jane SUMMERFIELD, Counsel, Hogan Lovells

Speakers:

- Patrick BOISSEAU, VP Healthcare, CEATech
- Bert-Arjan MILLENAAR, Founder & CEO, NLC – The Healthtech Venture Builders

ADVANCED ANALYTICS IN MEDTECH:

Sponsored session

What healthcare can learn from Formula 1 - how machine learning has changed an industry and what are the implications for MedTech sponsored by McKinsey [McKinsey&Company](#)

Data and analytics capabilities have made a leap forward in recent years. The volume of available data has grown exponentially, more sophisticated algorithms have been developed, and computational power and storage have steadily improved

- while previously «boiling the ocean» seemed like a bad idea now is becoming possible and increasingly attractive as the new massive «kettle» has emerged. The convergence of these trends is fueling rapid technology advances and business disruptions
- which more and more impact healthcare. Our QuantumBlack CEO will share:
 - Their real life experiences how they have leveraged big data and machine learning to change the game in Formula 1
 - How do machine learning capabilities work and how can they help drive true business impact
 - Four angles on why the time is now - how these new technologies find more and more traction in healthcare (clinical trials, commercial, real world evidence) and how they could form the cornerstone to pushing MedTech forward on performance improvements and innovation
 - Answers to your questions helping to unlock what few still believe to be a black box, incl. ideas on how to progress fast learning from mistakes and success of others.

Objectives:

- Show business impact of deploying advanced analytics and machine learning in MedTech industry and show what capabilities and organization needs to be put in place

Speaker:

- Simon WILLIAMS, Director & Co-Founder, QuantumBlack

FUTURE OF BUSINESS INTERACTION – HELPING HEALTHCARE PROVIDERS AND MEDTECH INDUSTRY TO INTERACT MORE EFFICIENTLY sponsored by Deloitte

Sponsored session

Through this session we will elaborate on the current state of business interactions between healthcare providers and the MedTech industry and explore ways to substantially improve them. Focusing on inefficiencies linked to transaction cost, cost to serve - reflecting complete go-to-market model -, and pricing arrangements, we will discuss the potential of mutually beneficial value creation processes through disruptive solutions.

We conducted a study set up on a pan-European level with the Vision to identify what the future of business interactions in this segment might look like. Our findings show that moving away from inefficient and unsegmented business interactions towards a more segmented approach could be the next catalyst for margins growth through, for instance, integrated information transaction, committed volumes, and innovative value based payment models tailored to respective requirements.

Objectives:

- To identify current perspective and appetite on disruptive efficiency improvements in business interactions
- To determine prerequisites for success and existing road-blocks of efficient business interactions
- To validate initial hypotheses on cost savings on the proposed solution going forward (including annual tracker)
- To fuel the ongoing discussion around common data and transaction standards and determine who is to further drive improvements.

Moderator:

- Michael DOHRMANN, Partner Life Science & Healthcare, Deloitte Germany

Speakers:

- Guido JONAS, Director Key Account Management Europe, Stryker
- Manuella WILTS, Senior Director Customer Services EMEA, Johnson & Johnson

12:45-14:30

NETWORKING LUNCH

14:30-15:15

POWERING A HEALTH SERVICE ON ARTIFICIAL INTELLIGENCE

Plenary

Powerful new apps are turning phones into mobile medical clinics with artificially intelligent medical advisers acting as superhuman doctors that diagnose and treat patients. Ali Parsa believes that artificial intelligence together with increasing advances in medicine will result in globally accessible and affordable healthcare earlier than most people realise. His digital healthcare company babylon recently received a US\$60m investment to build the world's most advanced artificial intelligence (AI) platform in healthcare, to support medical diagnosis and predict personalised health outcomes globally.

Babylon's technology, available from any mobile device or connected computer worldwide, has provided accurate, medical advice to over 250,000 people to date. In January 2017, babylon partnered with the NHS in the UK to use the same technology to power an NHS 111 app available to over a million north London residents, in what is the world's largest deployment of AI in healthcare.

Objectives:

- To give an overview of the current, practical implications of AI in medical diagnosis and treatment
- To paint a picture of the future of AI-based medical platforms that diagnose and treat patients
- To discuss how the MedTech industry can best cope with the upcoming changes (i.e. radical system-wide innovation).

Moderator:

- Ingmar DE GOOIJER

Speaker:

- Ali PARSA, Founder & CEO, Babylon Healthcare

15:15-16:00

WHAT'S HAPPENING WITH NOTIFIED BODIES?

Regulatory

Recent years have seen a consolidation in Notified Bodies, all of which will need to be re-accredited and re-designated under the new IVD and Medical Devices Regulations. The vast majority of IVDs and medical devices - both legacy and new products alike - can only be certified to these new Regulations once these Notified Bodies are fully up and running. Moreover, far more IVDs than ever before will need Notified Bodies in the future, and this has prompted concerns that Notified Bodies will face capacity challenges.

By when can industry realistically expect their Notified Bodies to be available?

How should the industry and authorities manage (and plan around) the timing and capacity uncertainties?

What can you do if your Notified Body disappears, or if you've never needed one before? Attend this panel between authorities, Notified Bodies and industry to find out!

Moderator:

- Philippe AUCLAIR, Senior Director Regulatory Strategy, Abbott

Speakers:

- Gert BOS, Executive Director & Partner, Qserve Group
- Suzanne HALLIDAY, Head of Medical Devices Notified Body, BSI Group
- Sue SPENCER, Global Service Line Director - Regulatory, Underwriters Laboratories

15:15-16:00

THE FUTURE OF CYBER WARFARE IN HEALTHCARE

Digital developments

Is your company or health service protected against cyber warfare? In an increasingly digital environment, strong cyber defences are essential to survival. Lieutenant Colonel, USMC (Retired) Bill Hagestad will elaborate on the future of cyber warfare in healthcare and the implications for the medtech industry from a corporate and product point of view. Mr. Hagestad is an internationally recognized and respected authority on cyber warfare having published three books on the topic and currently leads the cyber & information security engineering development for Smiths-Medical.

Objectives:

- To elaborate on the current and future state of play of cyber warfare in healthcare with a focus on the MedTech industry.
- To give a frank assessment of the current preparedness of the MedTech industry and how to cope with future trends.

Moderator:

- Ingmar DE GOOIJER

Speaker:

- Bill HAGESTAD, Senior Principal Cyber Security Engineer, Smiths Medical

MDR AND IVDR: CHALLENGES AND OPPORTUNITIES FOR START-UP AND SMEs

SMEs

sponsored by Hogan Lovells



The purpose of the sessions would be to take a horizontal approach of the MDR and IVDR and to determine the key challenges of the regulations for start-up and SMEs. The session will then also underline the opportunities for start-up and SMEs.

Objective:

- Identify key issues and opportunities for start-up and SMEs

Moderator:

- Fabien ROY, Counsel, Hogan Lovells

Speaker:

- Karin A. HUGHES, Vice President Clinical & Regulatory Strategy, Astute Medical, Inc.

15:15-17:15

MEAT VALUE-BASED PROCUREMENT: PROTEIN FOR MEDTECH

Market access

Building up on the drive towards value-based healthcare and smarter healthcare procurement, and taking advantage of the framework provided by the EU Public Procurement Directive, MedTech Europe, in partnership with The Boston Consulting Group and procurement experts, have developed the MEAT Value-Based Procurement framework. Its objective is to support healthcare institutions, hospitals, and health and procurement authorities to adopt value-based decision-making in healthcare procurement.

There is now a strong need for education and exposition to the concrete usage of this framework and related Excel tool throughout the different stages of a procurement process. This will be ensured during this session where via a role play, attendees will be asked to take an active part in a procurement process from the shaping of the tender to the award of the contract.

Format: Please note that this session is GENUINELY active. Each participant will be assigned a role (a buyer or a supplier) when they enter the meeting room. Tables of 12 participants will be set up and each person designated as supplier will have a product/solutions (fictional) to sell and each participant designated as buyer will express their needs. The group (per table) will go through the full procurement process.

Moderator:

- Götz GERECKE, Partner & Managing Director, The Boston Consulting Group

Speaker:

- Virginie DOR, Partner, CMS DeBacker

16:00-16:30

NETWORKING BREAK

16:30-17:15

CONNECTING WITH HEALTH CONSUMERS

Business strategy

That health consumers are becoming more assertive is no surprise to many. And addressing the health consumer as a partner in the healthcare delivery is increasingly viewed as the way forward. This approach is partially driven by popular rating websites such as iwantgreatcare.org in the UK and zorgkaartnederland.nl in the Netherlands, where 10.000 new reviews are uploaded monthly.

In this session two experts will elaborate on the implications of assertive health consumers and suggest various approaches of engagement.

Objectives:

- To explore the role of patients in the design and development of products
- To examine community- and science-based platforms for patient engagement
- To debate the ethical aspects of industry-patient interaction on these platforms

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Dirk PEKELHARING, Director, Pekelharing & Partners Ltd. Life science /healthcare consultancy
- Danny VAN DEN IJSSEL, Product manager, Zorgkaart initiative

16:30-17:15

IVD – EVOLVING BUSINESS ENVIRONMENT AND PRACTICES

Business strategy

Within the context of the evolving healthcare environment IVD businesses have been looking at adapting and working to continue to deliver value to the shifting priorities within healthcare systems. During the session we will explore the views of several business leaders from within the IVD field on how the IVD business itself is changing and of the different models and strategies which are being explored for future success within the IVD industry in Europe.

Moderator:

- Jesus RUEDA RODRIGUEZ, Director International Affairs, MedTech Europe

Speakers:

- Torsten HOOFF, Senior Vice President International, Genomic Health
- Filip MORIAU, Founder & CEO, Stragilon
- Jürgen SCHULZE, President & CEO EMEA, Sysmex Corp.

MDR AND IVDR: WHAT STRATEGIES TO QUICKLY ACCESS THE EU MARKET FOR START-UP AND SMEs?

SMEs Track

sponsored by Hogan Lovells



The purpose of the panel discussion would be to identify strategies and best practices that can be applied by start-up and SMEs to facilitate application of the MDR and IVDR and the commercialisation of their medical devices in the EU.

Objective:

- Identify strategies and best practices for start-up and SMEs

Moderator:

- Jörg SCHICKERT, Partner, Hogan Lovells

Speakers:

- Patricia FOREST-VILLEGAS, Scientific, Regulatory Affairs & Quality Manager, i-Sep
- Hein VAN DEN BOS, Partner, Hogan Lovells

WEDNESDAY 24 JANUARY

17:15-18:15

HEALTHCARE TECHNOLOGY FUNDING: THE ROLE AND DEMANDS OF PATIENTS

Plenary

Public anger over the cost of healthcare has burned hot for quite some time and it seems that patient advocacy groups have been largely absent from the public debate over funding. Some argue that patient groups should take a public position on affordability because, by avoiding the debate, they are failing in their patient-advocacy duties. In this session, various experts on the topic will elaborate on the role and purpose of patient organisations when it comes to healthcare technology funding and what they expect from industry.

Objectives:

- To discuss the role that funding plays on the agenda of patient advocacy groups
- To elaborate on the priority setting of patient advocacy groups regarding access and funding (and their interdependent relationship)
- To determine the current (and ideal) position of industry in working with patient advocacy groups

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Marc BOUTIN, CEO, National Health Council
- Rick CLAYPOOL, Research Director, Public Citizen
- Francesco FLORINDI, BBMRI-ERIC
- Yannis NATSIS, European Public Health Alliance (EPHA)

18:15-21:00

NETWORKING COCKTAIL

THURSDAY 25 JANUARY

09:00-09:30 **WELCOME COFFEE AND REGISTRATION**

09:30-16:00 **EXHIBITION AND NETWORKING**

09:30-10:30 **CEO #NOFILTER**

Plenary

Global leaders from the fields of medical devices, diagnostics and digital health come together for an open exchange about the latest trends, challenges and opportunities they face. How are they coping with the continuous pressure to innovate, the increased focus on ethics, the demand for new service and low-cost models and the role of Europe and Brexit? And what do they expect the next disruptive force to be? The audience will have the opportunity to ask direct questions that will be answered with #nofilter

Objectives:

- To understand the forces shaping the MedTech industry
- To give audience members an opportunity for an unfiltered Q&A with industry leaders

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Jean-Luc BELINGARD, Chairman of FEFIS, Fédération Française des Industries de Santé & Vice President International Relations, Institut Merieux
- Bernd MONTAG, CEO, Siemens Healthineers
- Nadim YARED, CEO & President, CVRx

10:30-11:15

OUTCOME-BASED FINANCING MODELS: WHO IN THE MEDTECH INDUSTRY CAN RISK IT?

Business strategy

Outcome-based healthcare financing is moving from theory to practice. But are health systems ready to collect outcomes data? And are health authorities and payers willing to pay for outcomes?

This session will explore how outcomes-based financing goes from concept to reality and the role of industry in driving this change. In addition, the roles of large and small companies in this transition will be examined.

Objectives:

- To provide a brief overview of the relevance of outcomes-based financing and current initiatives in outcomes data collection.
- To explore the impact of value-based healthcare on reimbursement models
- To look at how the MedTech business model will be transformed by the shift towards an outcome-based healthcare system

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Olivia CAVLAN, Partner, McKinsey
- Gottfried ENDEL, Lead HTA unit, Main Association of Austrian Social Insurance Institutions
- Luke SLAWOMIRSKI, Health Economist, OECD

10:30-11:15

ASK THE EXPERTS

Ask the experts

Roundtable discussions designed for smaller groups of 12 people together with 1 leader (expert) focusing on one topic.

- Antimicrobial Resistance & Healthcare Associated Infections: What role for MedTech?
Expert: Garance FANNIE UPHAM, Vice-president, World Alliance Against Antibiotic Resistance & Editor in Chief, AMR Control
- MedTech Europe Code of Ethical Business Practice & Conference Vetting System (CVS)
Experts: Christine SAINVIL, Compliance Officer, Director Market, Ethical MedTech
Pablo ROJAS ABAD, Officer Legal & Compliance, MedTech Europe
- MDR - Company implementation planning and execution
Expert: Hilde VIROUX, Global Head EU MDR compliance, Alcon
- Performance evaluation and clinical evidence for IVDs
Expert: Christian ZAUGG, Head Clinical Science, Roche Diagnostics International Ltd.
- MDR transitional provisions
Expert: Joachim WILKE, Director Regulatory Affairs & Policy EMEA, Medtronic GmbH
- Post Market Surveillance
Expert: Philippe AUCLAIR, Senior Director Regulatory Strategy, Abbott
- MDR Labelling
Expert: Christian PODOLAK, Project Manager MDR, Smiths Medical
- Eudamed under IVDR/MDR
Expert: Céline BOURGUIGNON, Director Global Regulatory Policy, Johnson & Johnson
- IVD Classification and Conformity Assessment
Expert: Volker FRANZEN, Director Regulatory Affairs EMEA, QIAGEN GmbH

DATA PROTECTION: THE DARK FORCE FOR HEALTHCARE INDUSTRY?

Business strategy

The General Data Protection Regulation (GDPR) and e-Privacy regulations are drastically changing how organisations can use personal data about their customers and employees. Retailers and marketers are catching up to something the medical technology sector has long been accustomed to: doing business in an environment in which the use of personal data is highly regulated and restricted. This gives the medtech sector potentially a head-start in the new world of data privacy legislation. This panel will debate if and how medtech can fully exploit the new business models and product opportunities flowing from this advantage.

Key questions include:

- What are the headline implications of the legislation(s)?
- Given the command and control risk, how should the medtech industry best embrace the legislation(s)?
- How are legislative issues being addressed at business leader level?

Moderator:

- Nichola HICKMAN, Founder & CEO, Inglis Jane Ltd

Speakers:

- Geff BROWN, Associate General Counsel, Microsoft
- Bill DOHERTY, Managing Director of Cook Medical's Irish operations & Executive Vice President EMEA, Cook Medical
- Rachel O'CONNELL, Co-Founder, Thetrustbridge & CEO, Trust Elevate

10:30-11:15

SOUTH AFRICA - LOCALIZATION AND REGULATION, IMPACT ON THE MARKET

International

South Africa's Department of Health has been working on a long awaited dedicated new regulatory framework for medical devices and in vitro diagnostics. The new legislative framework is in place with the publication of a Regulation on 9 December 2016 which is broadly based on guidance and principles of the International Medical Device Regulators Forum (IMDRF) and its predecessor the Global Harmonization Task Force (GHTF). A key new measure has been the formation of the South African Health Products Regulatory Authority which will oversee the medical device market in South Africa but there are still questions as to how this new regulatory body will operate and what the practical implementation of the new law will entail. At the same time the Government is also aiming at implementing localization measures favoring local manufacturers which raises new challenges and increases the complexity of doing business in South Africa.

Objectives:

- Understand what the key expected changes to the existing framework are
- Get insight into the impact the new framework will have on your business organization
- Next steps and potential industry contribution to future consultations

Moderator:

- Jesus RUEDA RODRIGUEZ, Director International Affairs , MedTech Europe

Speakers:

- Avanthi BESTER, Regulatory Affairs Manager, Becton Dickinson
- Vaughn HARRISON, Partner, Hogan Lovells Inc.
- Tanya May VOGT, Executive officer, South African Medical Technology Industry Association (SAMEDI)

11:15-11:45

NETWORKING BREAK

11:45-12:30

VALUE-BASED HEALTHCARE - WILL IT BECOME A REALITY AND HOW TO MAKE IT AN OPPORTUNITY FOR THE MEDTECH INDUSTRY?

Market access

While health systems are reforming and considering value-based healthcare (VBHC) as a way forward, MedTech Europe is taking a leading role in making this change a reality and moving to a value-based assess model for medical technologies.

The MedTech industry is committed to shifting from a technology-based model to a value-based system. Rather than payment based upon the technology with continued blunt cost cutting for our sector, a model is emerging that rewards value creation considering outcome relevant to patients, health professionals and health systems, as well as the positive impact medical technology can have on the total cost of care and avoiding the need to costly healthcare. Overall, we seek to increase the value of every euro invested in medical technologies and have EU citizens in good health supporting economy and actively contributing to the society. The questions we want to answer: "Is value-based healthcare a myth or a reality?" MedTech Europe is proposing move to value-based healthcare that awards true value creation.

Objectives:

- To provide latest update on the compelling case of VBHC, if empirical evidence becomes available and what is needed to see VBHC become a reality
- To present initiatives that MedTech Europe is promoting in the field of access to shift the industry from just a 'supplier' to a critical part of a value based landscape
- To debate the expectation from VBHC that drives health systems reforms, the value framework and initiatives for awarding value creation

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Rifat ATUN, Professor of Global Health Systems, Harvard University
- Yves VERBOVEN, Director Market Access and Economic Policies, MedTech Europe

11:45-12:30

ASK THE EXPERTS

Ask the experts

Roundtable discussions designed for smaller groups of 12 people together with 1 leader (expert) focusing on one topic.

- IVD Vigilance
Expert: Marta CARNIELLI, Senior Manager, Quality Regulatory & Compliance EMEA, Ortho Clinical Diagnostics
- Antimicrobial Resistance & Healthcare Associated Infections: What role for MedTech?
Expert: Garance Fannie UPHAM, Vice-president, World Alliance Against Antibiotic Resistance & Editor in Chief, AMR Control
- MedTech Europe Code of Ethical Business Practice & Conference Vetting System (CVS)
Experts: Christine SAINVIL, Compliance officer Director Market, Ethical MedTech
Pablo ROJAS ABAD, Officer Legal & Compliance, MedTech Europe
- MDR - Company implementation planning and execution
Expert: Hilde VIROUX, Global Head EU MDR compliance, Alcon
- Performance evaluation and clinical evidence for IVDs
Expert: Christian ZAUGG, Head Clinical Science, Roche Diagnostics International Ltd.
- MDR transitional provisions
Expert: Joachim WILKE, Director Regulatory Affairs & Policy EMEA, Medtronic GmbH
- Post Market Surveillance
Expert: Philippe AUCLAIR, Senior Director Regulatory Strategy, Abbott
- MDR Labelling
Expert: Christian PODOLAK, Project Manager MDR, Smiths Medical
- IVD Classification and Conformity Assessment
Expert: Volker FRANZEN, Director Regulatory Affairs EMEA, QIAGEN GmbH

HOW MEDICAL DEVICE COMPANIES CAN AVOID EU PARALLEL TRADE AND COMPETITION LAW PITFALLS: A PRIMER FOR EU REGULATORY LAWYERS

Business strategy

This session will tackle the EU Parallel Trade for Medical Device companies including changes brought by the 2017 Medical Devices Regulation, distribution strategies, the role of dominant players, the interaction with competitors and the rules around corporate events.

Moderator:

- Serge BERNASCONI, CEO, MedTech Europe

Speaker:

- Gianni DE STEFANO, Competition Law Counsel, Hogan Lovells

SPOTLIGHT ON USA

International

Medical technology companies are facing a wave of changes that could impact their businesses, including the potential repeal and replacement of the Affordable Care Act, changes in US trade policy, the potential passage of tax reform, continued pressure on pricing and user fee reforms. Many of these changes are interrelated and the impact to a company should be evaluated in total. This workshop will discuss the accomplishments and progress of the Trump Administration's first year in office and explore changing trade and tax policy with particular focus on the impacts to supply chains, capital investment, and other aspects of operations.

Objectives:

- Trump Administration Policies and Accomplishments - first year in Office
- Overview of potential reform and impact on tax and business operations
- Potential impact on the medical technology industry
- Next steps

Moderator:

- Jesus RUEDA RODRIGUEZ, Director International Affairs, MedTech Europe

Speakers:

- Trevor GUNN, Chair of International Affairs Committee, MedTech Europe & Vice-President International Relations, Medtronic
- Michael S. HEYL, Partner, Hogan Lovells
- Ralph IVES, Executive Vice President, AdvaMed
- Anne OSWALT BRUCE, Director Federal Affairs, Johnson & Johnson

12:30-13:15

WHY EVERY MEDTECH COMPANY NEEDS A VALUE-BASED STRATEGY sponsored by Boston Consulting Group



Sponsored session

Changing reimbursement models and pressure on traditional business models are forcing medtech companies to take a broader perspective on «value» and to develop their offerings accordingly. The innovators in the field who are ready to share accountability on outcomes will be able to extend their footprint in existing markets and to enter emerging markets with new business models. However, it is often unclear how innovative products should be enabled by Medtech services in order to become outcomes-based solutions. Where should Medtech companies be investing across their service portfolio? How should they move beyond small bets to really scale value-added services? And what capabilities should be developed internally, acquired or partnered for to become a value-based medtech company?

Objectives:

- Discuss how medtech companies should move from product-based business models in a fee-for-service world to outcomes-based solution models in a value-based health care system.
- Learn how product-related services and value-add services can be leveraged to enable outcomes based solutions.
- Share some best practice examples on outcomes-based solutions driven by medtech companies.

Speaker:

- Jens DEERBERG-WITTRAM, Director, The Boston Consulting Group

12:30-13:30

NETWORKING LUNCH

13:30-14:15

THE MEDTECH EUROPE CODE AS A BUSINESS ENABLER

Business strategy

1st January 2018 is a cornerstone date for the implementation of the MedTech Europe Code of Ethical Business Practice. As such, it is the right moment to take stake on:

- where we are, considering in particular the following players: MedTech Europe corporate Members, National Associations, SMEs, impacted stakeholders (e.g. medical societies, customers, PCOs, hospitals);
- what still needs to be done; and
- what were the unexpected challenges;
- what are the new business opportunities (e.g. new business models (e.g. value-based healthcare) emerging at the same time as the Code provides a new way to the relationship with customers, impacting how marketing was done until now)

Moderator:

- Roeland VAN AELST, VP MD EMEA Health Care Compliance & Privacy, Johnson & Johnson

Speakers:

- Michele PERRINO, Regional Vice President, Medtronic Italia
- Philippe JACON, Senior Vice President Global Access, Cepheid
- Nadim YARED, CEO & President, CVRx

13:30-14:15

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- Performance evaluation and clinical evidence for IVDs
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- Eudamed under IVDR/MDR
Expert: Céline BOURGUIGNON, Director Global Regulatory Policy, Johnson & Johnson
- IVD Classification and Conformity Assessment
Expert: Volker FRANZEN, Director Regulatory Affairs EMEA, QIAGEN GmbH
- Unique Device Identification
Expert: Andrew J. RUTTER, Regulatory Affairs Manager, Ortho-Clinical Diagnostics

MEAT: A NEW PHILOSOPHY FOR MEDTECH SALES

Business strategy

Procurement is the main access path for medical technology. Increasingly, price has become a main driver for making purchasing decisions, with administrators in the driving seat. The EU believes public procurement should apply the most economic advantageous Tendering (MEAT) concept. This is primarily to be achieved by obtaining the best price/quality ratio. The MedTech industry is ready to embrace value-based procurement with a broad value proposition for all levels and for different stakeholders. This requires companies to rethink the role of their sales organisation and to enhance cooperation between departments. Sales teams need to learn how to define and sell value to different stakeholders rather than focusing only on the product and its features.

Objectives:

- To present real procurement cases to indicate how this new value proposition can affect the awarding of tenders.
- To identify critical junctures in the procurement process when the criteria that will be used in decision-making are discussed and who is involved (i.e. in the pre-tendering space).
- To showcase MEAT Value-Based Procurement as a supportive framework and to raise awareness of how sales organizations can communicate the value proposition.

Moderator:

- Richard CHARTER, Head of Market Access & Pricing, Diabetes Care Europe and EMA BD Medical

Speakers:

- Götz GERECKE, Partner & Managing Director, The Boston Consulting Group
- Eszter KACSKOVICS, Public Affairs Director - Health and Medical solutions, Essity Hygiene And Health AB
- Ferran RODRIGUEZ OMEDES, Head of Clinical and Biomedical Engineering, Hospital Clinic de Barcelona

13:30-14:15

BECOMING HACKPROOF IN MEDTECH

Digital developments

In the past three years, the healthcare sector has been hacked more than the financial industry. As hackers increasingly take advantage of historically lax security on embedded devices, defending medical instruments has taken on new urgency. Two experts will elaborate on how to cope with cyber threats from a technical, regulatory and risk management point of view. Roman Lysecky, a recipient of the prestigious American National Science Foundation Early Career Award and an associate professor in the UA's Electrical and Computer Engineering Department, is building technology that enable medical devices to detect malware and security breaches while continuing to function properly.

Objectives:

- To discuss how to cope with cyber threats from a technical and process/regulatory/risk management point of view
- To give an overview of the current regulatory framework (EU & US), its effectiveness and implications for the industry
- To provide an overview of the current thinking of cyber security in designing the products and the implications for industry

Moderator:

- Ingmar DE GOOIJER

Speakers:

- Yves BENNAÏM, CIO, Geekko SA & Founder, 2B4CH
- Roman LYSECKY, Associate Professor of Electrical and Computer Engineering, University of Arizona

14:30-15:15

NAVIGATING THE BREXIT CLIFF

International

With Brexit inexorably approaching, business leaders within the MedTech industry will share insights on how they are preparing to face Brexit. Views from manufacturers active both on the continent and in the UK will be presented and though at this stage it is impossible to give all the answers, we will aim to deliver all the right questions to consider for a companies which need to start planning strategically for managing Brexit – or risk facing a very tough time getting across the Brexit cliff.

Moderator:

- Jesus RUEDA RODRIGUEZ, Director International Affairs, MedTech Europe

Speakers:

- Christian CLARUS, Senior Manager Government Affairs, B. Braun Melsungen AG
- Mark LLOYD DAVIES, Senior Director, Government Affairs & Policy, Johnson & Johnson

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A NOVEL AND FRESH VIEW ON TRANSFORMING HEALTH SYSTEMS WITH TECHNOLOGY AND INNOVATION

Digital developments

Dr Mahiben Maruthappu, educated at Oxford, Cambridge and Harvard Universities and the first person from British healthcare to be included in Forbes '30 under 30, will elaborate on how to successfully implement efficiency and innovation into health systems from a theoretical and practical point of view.

Dr Maruthappu is a renowned expert in the field and cofounded the NHS Innovation Accelerator and the NHS Diabetes Prevention Programme, as well as Cera, a technology company transforming social care. He currently also serves on the DigitalHealth.London and NHS Prevention boards.

Objectives:

- To elaborate on how health systems are successfully integrating efficiency and innovations (opportunities, challenges, hurdles and best practices)
- To give a frank assessment of the approach of the traditional MedTech players (e.g. Medtronic, J&J) versus the new players such as Cera, Babylon
- To showcase new innovative (service) models of care such as Cera

Moderator:

- Ingmar DE GOOIJER

Speaker:

- Ben MARUTHAPPU, Practicing doctor, Co-founder - NHS Innovation Accelerator, Co-founder & CEO, Cera Care

HOW TO MAKE EUROPE GREAT AGAIN FOR MEDTECH INNOVATION

Business strategy

What are the different initiatives in Europe expected to improve the access to innovation and awarding value by the medical technologies. New initiatives and financing schemes for innovation on EU level (e.g. Horizon 2020) and on country level are arising in Europe and they could be future viable solution for the industry and innovation in Europe.

Let's discuss «How to make the Europe great again for the medtech innovation».

Objectives:

- To foster a discussion from a business perspective on how different initiatives and trends in Europe could change the business in Europe in the next 5 years (e.g. increased demand for data, exchange knowledge, measure performance, more transparency across countries)
- To discuss from market access perspective what could be the solutions to identified barriers for innovation

Moderator:

- Patrick BOISSEAU, VP Healthcare, CEATech

Speakers:

- Markus SIEBERT, Chair of the Evidence & Payers Working Group, Senior Director Health Economics & Reimbursement, OUS, Abbott
- Vassilis TSANIDIS, Policy Officer, Directorate-General for Communications Networks, Content and Technology (CNECT) of the European Commission



THURSDAY 25 JANUARY

15:15-16:00

DISRUPTIVE HEALTHCARE

Plenary

Disruptive healthcare triggers changes for all healthtech stakeholders. It entails reviewing the old fashion way of doing things and adapting to new networks, new organisational structures, new players... Healthcare in general - and the MedTech industry in particular - can truly benefit from those new perspectives. Find out from Prof. Fitzgerald what disruptive healthcare has in store for you.

Moderator:

- Ingmar DE GOOIJER

Speaker:

- Peter J. FITZGERALD, Professor of Medicine and Engineering & Director of the Center for Cardiovascular Innovation, Stanford University Medical Center

16:00-16:15

CONCLUSIONS

Plenary

Moderators:

- Serge BERNASCONI, CEO, MedTech Europe
- Ingmar DE GOOIJER



A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

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