MedTech Summit

11-15 June 2018
Hotel NH Brussels Bloom
Brussels

EU MDR & IVDR: THE RACE IS ON...

Including Clinical Strategies,
PMS & Vigilance, Legal,
Combination Products,
Sterilisation, and
Emerging Markets Requirements

#MEDTECH

MedTech Summit

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TRACKS

DAY ONE MONDAY 11 JUNE	DAY TWO TUESDAY 12 JUNE	DAY THREE WENESDAY 13 JUNE	DAY FOUR THURSDAY 14 JUNE	DAY FIVE FRIDAY 15 JUNE
EU Medical Device Regulation	EU Medical Device Regulation	Medical Device Regulatory Affairs in Emerging Markets Asia	Medical Device Regulatory Affairs in Emerging Markets RUSSIA & CEE	Medical Device Regulatory Affairs in Emerging Markets LATAM, Middle East & Africa
	Clinical Evaluations & Investigations	Clinical Evaluations & Investigations	Drug Device Combination Products	Drug Device Combination Products
	Post Market Surveillance & Vigilance	Post Market Surveillance & Vigilance	IVD Regulatory & Strategic Forum	IVD Regulatory & Strategic Forum & CDx
EU Medical Device Law	EU Medical Device Law		Sterilisation and Reprocessing of Medical Devices	Sterilisation and Reprocessing of Medical Devices

MAIN CONFERENCE DAY ONE • MONDAY 11 JUNE 2018

07:50	*Registration*
08:50	**Chairperson's opening remarks** **Amanda Maxwell,** Medtech Regulatory Affairs Editor, MedTech Insight, Pharma Intelligence, **Informa,** *UK*
09:00	**Scientific and technical challenges of the novel EU medical devices legislative framework** **Arnd Hoeveler,** Head of Unit of JRC (Joint Research Centre), **European Commission,** *Italy*
09:20	**SME perspective: Where are we with EU MDR implementation?** **Susana de Azevedo Wäsch,** Head of Global Regulatory Affairs, **Geistlich Pharma AG,** *Switzerland*
09:40	**Competent Authority perspective: Practical advice and expectations for industry in preparing for EU MDR implementation** **Graeme Tunbridge,** Group Manager – Devices Regulatory Affairs, **MHRA,** *UK*
10:00	**Perspective on Notified Bodies: Preparing for EU MDR implementation and expectations for industry** **Gert Bos,** Executive Director & Partner, **Qserve Group,** *The Netherlands*
10:20	**IMPLEMENTATION PANEL DISCUSSION:** **Sharing experiences with interpreting and implementing the EU MDR in practice** **Gert Bos, Qserve Group** **Elizabeth Gfoeller, MED-EL** **Hans-Heiner Junker, TÜV SÜD Product Service** **Juliette Cook, Cochlear AG** **Alexander Natz, EUCOPE** **Rainer Voelksen, Occlutech** **Lincoln Tsang, Arnold & Porter**
11:00	*Morning coffee break*

Speaking, panellist, moderator and webinar opportunities

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	EU Medical Device Regulation	EU Medical Device Law
	Chairperson: **Amanda Maxwell, Medtech Regulatory Affairs Editor, MedTech Insight, Pharma Intelligence, Informa,** *UK*	*Chairperson:* **Sean Fahey,** Partner, **Pepper Hamilton LLP,** *USA*
11:40	**Notified Body perspective: Preparing for re-designation and latest status of the application process** **Julien Sénac,** Certification Project Manager, **LNE/G-MED,** *USA*	**Practical implications of the new regulations and case law on commercial relationships** **Jackie Mulryne,** Counsel, **Arnold & Porter,** *UK* **Ewan Townsend,** Counsel, **Arnold & Porter,** *UK*
12:15	**PANEL DISCUSSION: Sharing latest experiences and concerns on the Notified Body re-designation process** **Guy Buijzen, DEKRA** **Bassil Akra, TÜV SÜD Product Service GmbH** **Julien Sénac, LNE/G-MED**	**Understanding new liability rules under the MDR** **Sean Fahey,** Partner, **Pepper Hamilton LLP,** *USA*
12.50	*Networking Lunch*	
14:00	**Outlining significant changes in the responsibilities and obligations of economic operators under the EU MDR** **Juliette Cook,** Regional Regulatory Director EMEA, **Cochlear AG,** *Switzerland*	**Person Responsible for Regulatory Compliance** **Bjorn Delbeecke,** Regulatory Affairs Specialist EMEA, **Agfa HealthCare,** *Belgium*
14:35	**Latest updates on the MDSAP program including Canada's 1 January 2019 deadline and impacts on industry** **Maham Ansari,** Director of Regulatory Affairs, **Synaptive Medical,** *Canada*	**Recent antitrust developments in the pharma field** **Axel Schulz,** Partner, **White & Case LLP,** *Belgium*
15:10	*Afternoon tea break*	
15:50	**Understanding the role of CEN and CENELEC (and their European standards) in the context of the new EU MDR and their priorities for ensuring a smooth transition** **Catherine Vigneron**, Customer Service Specialist, Standardization and Digital Solutions, **CEN-CENELEC Management Centre,** *Belgium*	**Exploring key legal and contractual considerations for economic operators under the EU MDR** **Erik Vollebregt,** Partner, **Axon Lawyers,** *The Netherlands*
16:25	*End of conference day one*	**Notified Body liability and legal status under the EU MDR** **Heike Wachenhausen,** Partner**, Wachenhausen Rechtsanwälte Partnerschaft mbB,** *Germany*
		17:00 *End of conference day one*

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MAIN CONFERENCE DAY TWO • TUESDAY 12 JUNE 2018

	EU Medical Device Regulation	EU Medical Device Law	Clinical Evaluations & Investigations	Post Market Surveillance and Vigilance
09:00	**Chairperson's Opening Remarks** **Robert van Boxtel,** Principal Consultant, **Medical Device Project B.V.,** *The Netherlands*	**Chairperson's Opening Remarks** **Emmanuel Garnier,** Managing Associate, **Simmons & Simmons,** *France*	**Chairperson's Opening Remarks** **Carine Cochereau,** QRA and Clinical Director EMEA, **Cardinal Health,** *Belgium*	**Chairperson's Opening Remarks** **Fabio Cirillo,** Managing Director, **Avanti Europe AG,** *Switzerland*
09:10	**EUDAMED: Latest timelines and updates** **Céline Bourguignon,** Director, Government Affairs EMEA Medical Device & IVDs Department, **Johnson & Johnson,** *Belgium*	**Exploring recent EU case law related to the EU MDR** **Emmanuel Garnier,** Managing Associate, **Simmons & Simmons,** *France*	**CASE STUDY: Exploring the key impacts of the EU MDR and EUDAMED developments on clinical evaluations and investigations** **Carine Cochereau,** QRA and Clinical Director EMEA, **Cardinal Health,** *Belgium*	**Exploring the changes in the new MDR relating to post market surveillance (PMS) and vigilance** **Hans-Heiner Junker,** Senior International Affairs Manager, **TÜV SÜD Product Service,** *Germany*
09:45	**CASE STUDY: Practically getting into compliance with UDI Unique Device Identification (UDI): Latest status, requirements and practically preparing in Europe** **Bianca M. Gravenhorst Greve,** Senior RA Manager, **Coloplast A/S,** *Denmark* **Inge Ørnhøj,** Senior Master Data Manager, **Coloplast A/S,** *Denmark*	**Exploring the legal implications of the General Data Protection Regulation (GDPR) and impact on manufacturers** **Wolfgang Werner,** VP Regulatory and Quality, **Biovotion AG,** *Switzerland*	**Competent Authority perspective: Expectations from industry on new requirements for clinical evaluations and investigations under the MDR** **Tom Melvin, Health Products Regulatory Authority,** *Ireland*	**CASE STUDY: Developing an ISO guidance document for PMS** **Arjan van Drongelen,** Scientific Officer, **National Institute for Public Health and the Environment (RIVM),** *The Netherlands*
10:20	**The Big Picture: UDI and the Product Visibility and Control Imperative** **Jay Crowley,** VP of UDI Services and Solutions, **USDM Life Sciences,** *USA*	**Interactive Q&A Session** A chance for questions from the morning session	**Interactive Q&A Session** A chance for questions from the morning session	**Interactive Q&A Session** A chance for questions from the morning session
10:45	*Morning coffee break*			
11:15	**Clarifying the relationship between ISO 13485:2016 – Quality Management Systems (QMS) and the EU MDR** **Robert van Boxtel**, Principal Consultant, **Medical Device Project B.V.,** *The Netherlands*	**PANEL DISCUSSION: Sharing experiences with preparing for requirements of the GDPR** **Wolfgang Werner, Biovotion AG** **Olivier Mignolet, Simmons & Simmons**	**Competent Authority perspective: Expectations for clinical investigations and GCP under the MDR** **Tim De Schutter,** Inspector Medical Devices, **FAMHP,** *Belgium*	**PANEL DISCUSSION: How are different companies practically implementing new PMS and vigilance requirements under the new MDR?** **Fayez Abou Hamad, Terumo Europe N.V.** **Nathalie Gerard, Terumo Europe N.V.** **Andrea Sparti, Cendres+Métaux SA**
11:50	**Outlining significant changes for manufacturers falling under the self-certification process (Class I and custom made devices)** **Katrien Martens,** Inspector, **FAMHP,** *Belgium*	**PANEL DISCUSSION: The global courtroom: Strategies for managing cross-border products liability litigation** **Lori G. Cohen,** Shareholder; Chair, Pharmaceutical, Medical Device & Health Care Litigation Group; Chair, Trial Practice Group, **Greenberg Traurig LLP,** *USA* **Maria H. Bragaglia,** Partner, **Demarest Advogados,** *Brazil* **Ashley L. Paterson,** Associate, **Bennett Jones LLP,** *Canada* **Aimee H. Wagstaff,** Partner, **Andrus Wagstaff,** *USA*	**PANEL DISCUSSION: Clinical evaluation of software as a medical device: Challenges and Indegene's perspective** **Priya Kumar,** Senior Manager, Medical Services, **Indegene Inc.,** *India* **Sudy Vengarai,** Sr. Account Director, **Indegene Inc.,** *USA*	**Presentation to be delivered by Elsevier**
12:25	*Networking Lunch*			

	EU Medical Device Regulation	EU Medical Device Law	Clinical Evaluations & Investigations	Post Market Surveillance and Vigilance
13:45	**Exploring the regulatory qualification, classification and future of medical device software** **Koen Cobbaert, AGFA Healthcare** **Mette Kraag Luxhøj, Radiometer**	**Understanding the classification of borderline products and associated legal issues** **John P. Lavelle, Jr.,** Partner, **Morgan, Lewis & Bockius LLP,** *USA*	**Notified Body perspective: Practical advice for industry on meeting new requirements for clinical evaluations and investigations under the MDR** **Bassil Akra,** Vice President – Global Focus Teams (Cardiovascular, Orthopaedic and Clinical), **TÜV SÜD Product Service GmbH,** *Germany*	**Exploring the impact the obligations of economic operators will have on manufacturers' implementation of the PMS process** **Andrea Sparti,** Regulatory Affairs Manager, **Cendres+Métaux SA,** *Switzerland*
14.20		**Reviewing the current status of advertising and claims for medical devices** **Bill Kurani, MSRA, MSEE,** Head of RA/QA, Genomics, **Agilent Technologies,** *USA*	**Clinical Evaluations: Moving from MDD to MDR** **Vincent Legay,** Senior Project Manager, **NAMSA,** *France*	**CASE STUDY: Compiling post market surveillance (PMS) plans and meeting requirements of the new MDR** **Andrea Castañeda,** Associate Manager - International Quality Compliance, **Edwards Lifesciences,** *Spain*
14.55	*Afternoon tea break*			
	Chairperson: **Robert van Boxtel,** Principal Consultant, **Medical Device Project B.V.,** *The Netherlands*			
15.25	**Post Market Clinical Follow-Up (PMCF): Exploring Competent Authority and Notified Body expectations** **Bassil Akra,** Vice President – Global Focus Teams (Cardiovascular, Orthopaedic and Clinical), **TÜV SÜD Product Service GmbH,** *Germany*			
16:00	**OPEN FLOOR Q&A INTERACTIVE SESSION** **Gert Bos, Qserve Group** **Hans-Heiner Junker, TÜV SÜD Product Service** **Elizabeth Gfoeller, MED-EL** **Robert van Boxtel,** Principal Consultant, **Medical Device Project B.V.**			
17:00	*End of conference day two*			

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MAIN CONFERENCE DAY THREE • WEDNESDAY 13 JUNE 2018

09:00	**Chairperson's Opening Remarks** **Ilona Anderson,** Director of Clinical Research, **MED-EL GmbH,** *Austria*	**Chairperson's Opening Remarks** **Philippe Auclair,** Senior Director, Regulatory Strategy & Advocacy, Abbott Quality & Regulatory, **Abbott,** *Belgium*	**Chairperson's Opening Remarks**
	Clinical Evaluations & Investigations	**Post Market Surveillance and Vigilance**	**Regulatory Affairs in Emerging Markets**
09:10	**Notified Body perspective: MEDDEV 2.7.1 Revision 4 expectations and observations from industry on clinical evaluations** **Itoro Udofia,** Head of Notified Body, **UL International (UK) Ltd.,** *UK*	**CASE STUDY: Ensuring best practice for Field Safety Corrective Action (FSCA) reporting** **Maite Llácer,** Director Quality Compliance INT'L, **Edwards Lifesciences,** *Spain*	**Clarification and exploration of the expectations of the CFDA for medical device registration** **Jack Wong,** Director, **Asia Regulatory Professional Association,** *Singapore*
09:45	**CASE STUDY: Practically applying the new MEDDEV 2.7.1 rev 4 guidance for clinical evaluations** **Avanti Kulkarni,** Global Regulatory Affairs – Principal Clinical Evaluation Manager, **Abbott Vascular,** *USA* **David Rutledge,** Director Global Regulatory Affairs, **Abbott Vascular,** *USA*	**CASE STUDY: Successfully implementing a robust complaint handling and surveillance system** **Anne Mørkeberg Larsen,** Senior Product Surveillance Advisor, **Novo Nordisk A/S,** *Denmark* **Lavinia Marinescu Pedersen,** Senior Product Defect and Recall Advisor, **Novo Nordisk A/S,** *Denmark*	**Understanding China's CFDA clinical evaluation requirements** **Ed Woo,** Asia Pacific Regulatory Affairs Director, **Varian Medical,** *Hong Kong*
10:20	**INTERACTIVE PANEL DISCUSSION: Sharing experiences with writing a CER following MEDDEV 2.7.1 rev 4** **Ilona Anderson,** Director of Clinical Research, **MED-EL GmbH,** *Austria* **Representative speaker from Cactus Communications**	**How to integrate Complaint Trending with Risk Management** **Ruben Roijers,** Post Market Surveillance, **Philips,** *The Netherlands*	**CASE STUDY: Navigating China's regulatory processes for successful product registration** **Wen Peng,** Director, Regulatory Affairs, Asia Pacific, **Edwards Lifesciences,** *China*
10:55	*Morning coffee break*		
11:30	**CASE STUDY: Practically preparing for stricter clinical evidence requirements for legacy products under the new MDR** **Leo Hovestadt,** International Regulatory Affairs and Quality Assurance Director, **Elekta,** *The Netherlands*	**Outlining new timelines for post market reporting and practically meeting requirements** **Tabitha Reed,** Senior Manager, Regulatory Post Market Surveillance, **Intuitive Surgical, Inc.,** *USA*	**INTERACTIVE ROUNDTABLE DISCUSSION: Sharing experiences with successfully registering products in China** **Jack Wong,** Director, **Asia Regulatory Professional Association,** *Singapore* **Bernd Schell,** Senior Manager RA EMEA CCEM, **Baxter,** *Germany* **Maduagwu Oji,** Senior Manager RA EMEA CCEM, **Baxter,** *UK*
12:05	**State of the art best practices and literature review using distiller** **Laurie Mitchell,** President, **Criterion Edge Inc.,** *USA* **Peter O'Blenis,** President, **Evidence Partners,** *Canada*	**CASE STUDY: Best strategies for leveraging post market surveillance (PMS) data to become better informed about your products** **Patrick Caines,** Senior Director, Quality & Compliance, **Baxter,** *USA*	**Software as a Medical Device (SaMD) and Cybersecurity in China** **Tobias Schreiegg,** Quality & Regulatory Affairs Manager, **Siemens Healthcare,** *Germany*
12:40		*Networking Lunch*	
12:50	*Networking Lunch*		

	Clinical Evaluations & Investigations	Post Market Surveillance and Vigilance	Regulatory Affairs in Emerging Markets
14:00	**CASE STUDY: Practically applying risk based monitoring for medical device clinical investigations** **Nurcan Coskun,** Global Risk Based Monitoring & Technology Solutions Program Manager, **Medtronic,** *Switzerland*	**INTERACTIVE SESSION: How can I be compliant with the MDR Post Market activities and reports?** **Philippe Auclair, Abbott** **Laure-Anne Thieren, Johnson & Johnson Medical Devices**	**The implementation progress of the ASEAN Medical Device Directive (AMDD)** **Jack Wong,** Director, **Asia Regulatory Professional Association,** *Singapore*
14:35	**CASE STUDY: Implementing a successful clinical investigation / post market clinical follow up (PMCF) strategy** **Dorota Johansson,** Clinical and Research Director, **Bactiguard,** *Sweden*		**Practical guidance on ASEAN labelling requirements** **Dr. Jennifer Neff,** Director Regulatory & Medical Affairs, **bess AG,** *Germany*
15:10	*Afternoon tea break*		
15.50	**CASE STUDY:Successfully outsourcing clinical investigations** **Frank Van Leeuwen, Focus Clinical Consultancy,** *Belgium*	**Generating the necessary evidence through Life Cycle Communication strategy** **Patrice Becker,** Global Director Scientific Communications, Medical Affairs, **Medtronic,** *France*	**INTERACTIVE ROUNDTABLE SESSION: Sharing experiences with medical device registration in ASEAN countries** **Dr. Jennifer Neff,** Director Regulatory & Medical Affairs, **bess AG,** *Germany*
16.25	**Reviewing requirements of the new MDR for demonstrating equivalence for clinical evaluations** **Regina Moeckel,** Medical Devices, **TÜV Rheinland LGA Products GmbH,** *Germany*	**End of the Day Q&A: A chance for any remaining questions**	**Exploring an overview of the regulatory environment in Hong Kong** **Ed Woo,** Asia Pacific Regulatory Affairs Director, **Varian Medical,** *Hong Kong*
17:00	**Outlining requirements for clinical evidence for class III devices in the MDR** **Eddie Van Eeckhoven,** Medical Device Regulatory and Clinical Advisor, **Eeckhoven bvba,** *Belgium*	*End of conference day three*	**The impact of the EU Medical Device Regulation (MDR) on emerging markets** **Elena Mateo-Buesa,** Regulatory Affairs Manager – Global Strategy, **Ethicon (part of J&J family of companies),** *Germany*
17:35	*End of conference day three*		*End of conference day three*

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MAIN CONFERENCE DAY FOUR • THURSDAY 14 JUNE 2018

09:00	**Chairperson's Opening Remarks** **Hagen Thielecke,** Director R&D, **Vanguard AG,** *Germany*	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**
	Sterilisation and Reprocessing of Medical Devices	**Drug Device Combination Products**	**IVD Regulatory & Strategic Forum**	**Regulatory Affairs in Emerging Markets**
09:10	**Understanding the impact of the EU Medical Device Regulation (MDR) on sterilisation processes** **Jeff Vest,** Principal Specialist – MHS (Technical Reviewer), **TÜV SÜD Product Service,** *UK*	**Notified Body Perspective: Practically implementing new requirements of the EU MDR for drug device combination products (DDCPs)** **Daniel Shoukier,** Lead Auditor, **SQS,** *Switzerland*	**Practically implementing the IVDR: Competent Authority perspective** **Stephen Lee,** Senior Regulatory Policy Advisor – IVDR, **MHRA,** *UK*	**Shedding light on Russian requirements for manufacturing site inspections** **Maria Bogorad,** Regulatory, Quality & Continuous Improvement, **Johnson & Johnson,** *Russia*
09:45	**Latest updates on national implementation of reprocessing single-use devices and implications of Common Specifications for industry** **Dan Vukelich,** President, **Association of Medical Device Reprocessors (AMDR),** *USA*	**Industry Perspective: Practically implementing new requirements of the EU MDR for drug device combination products** **Hilde Viroux,** Global Head EU MDR Compliance, **Alcon,** *USA*	**Practically implementing the IVDR: Notified Body perspective** **Nick Baker,** IVD Technical Manager, **LRQA,** *UK*	**Understanding the Russian Federation government procurement system and the implications for industry** **Yana Pruss-Galynsky,** CEO, **Zephyr Biomedical,** *Israel*
10:20	**Exploring new and existing requirements for reprocessing of devices for sterile use** **Hagen Thielecke,** Director R&D, **Vanguard AG,** *Germany*	**INTERACTIVE PANEL DISCUSSION: The impact of the EU MDR on drug device combination products** **Hilde Viroux,** Global Head EU MDR Compliance, **Alcon,** *USA* **Alice Maden,** Associate Director, Regulatory Affairs, **BD,** *France* **Janine Jamieson,** IPQ Publications, **JCombinations,** *Sweden*	**INTERACTIVE PANEL DISCUSSION: Working with Notified Bodies and Competent Authorities to meet IVDR requirements** **Stephen Lee,** Senior Regulatory Policy Advisor – IVDR, **MHRA,** *UK* **Nick Baker,** IVD Technical Manager, **LRQA,** *UK* **Sue Spencer,** Head of Global Medical Device Services, **UL,** *UK* **Catherine Holzmann,** Certification Division Manager In Vitro Diagnostics, **LNE/G-MED,** *France* **Simon Richards,** VP, Regulatory Affairs, **EMER, Alere,** *UK*	**Safety monitoring: Best practises for successfully conducting post-market surveillance in Russia**
10:55	*Morning coffee break*			
11:25	**Exploring new EU MDR requirements for classification of class I reusable medical devices** **Jeff Vest,** Principal Specialist – MHS (Technical Reviewer), **TÜV SÜD Product Service,** *UK*	**Understanding the requirements for biocompatibility as outlined in ISO 10993 for drug device combination products** **Clemens Günther,** Director Nonclinical Safety, **Bayer,** *Germany*	**Practically implementing the IVDR: Industry perspective** **Simon Richards,** VP, Regulatory Affairs, **EMER, Alere,** *UK*	**EXTENDED INTERACTIVE SESSION: Practical guidance on successfully registering medical devices in Russia A case study from industry followed by a collaborative discussion** **Chris Dark,** Head of Regulatory Affairs, **Arkray Factory Ltd,** *United Kingdom* **Marina Semenova,** QA Manager, **Arkray ooo,** *Russia*
12:00	**The MDR requires evidence regarding the qualification and competency of personnel in sterilization – how is the Medical Device industry going to achieve this?** **Arthur Dumba,** Medical Device Sterilization Consultant, **International Irradiation Association (iia),** *Switzerland*	**Drug-device compatibility: Where is the guideline?** **Lise Vanderkelen,** Department Head Pharma Services, **Nelson Lab Europe (formerly Toxikon Europe),** *Belgium*	**Understanding the new classification system for IVDs under the IVDR** **Catherine Holzmann,** Certification Division Manager In Vitro Diagnostics, **LNE/G-MED,** *France*	
12:35	*Networking Lunch*			

MAIN CONFERENCE DAY FOUR • THURSDAY 14 JUNE 2018 *(continued)*

	Sterilisation and Reprocessing of Medical Devices	Drug Device Combination Products	IVD Regulatory & Strategic Forum	Regulatory Affairs in Emerging Markets
14:00	**CASE STUDY: Best practice for successfully carrying out Ethylene Oxide (EO) sterilisation** **Jan Douglas,** Engineering Manager, **Cook Medical,** *Denmark*	**CHMP Meetings: How to prep for, manage and excel at these EU regulatory meetings** **Bert Regeer, MD,** Senior Scientific Lead, **3D Communications,** *USA*	**New requirements of clinical evidence under the IVDR** **Sue Spencer,** Head of Global Medical Device Services, **UL,** *UK*	**Updates on the progress of the Eurasian Economic Union (EAEU) regulations and the impact on industry** **Alexey Stepanov**
14.35	**Exploring Ethylene Oxide (EO) residual testing per ISO 10993-7** **Pamela Barrows,** Director, Controlled Environments and Sterilization Control, **Getinge Group,** *USA*	**EU MDR Rule 21: Evaluating the impact on substance-based devices** **Jörg Plessl,** Director EU Affiliates, Regulatory Affairs, **Norgine,** *Germany*	**Implications of the IVDR clinical evidence requirements on legacy products** **Maurizio Suppo,** Vice President Regulatory Affairs, **QARAD,** *Italy*	**Understanding labelling requirements for medical devices in Russia** **Bulat Magdiev,** Regulatory Associate, **RB,** *Russia*
15.10	*Afternoon tea break*			
15.40	**CASE STUDY: Exploring sterilization validation approaches for Gamma and ETO sterilization** **Bjoern Wiese,** Director, Sterilization Technology and Analytical Testing EMEA, **Zimmer Biomet,** *Switzerland*	**Updates from the FDA on new regulations regarding drug device combination products** **Barr Wiener,** Associate Director Combination Products Office, **FDA,** *USA*	**INTERACTIVE ROUNDTABLE SESSION: Sharing experience with increased clinical evidence requirements under the IVDR** **Chris Weatherall,** Senior Director Quality Assurance & Regulatory Affairs, **Meridian Bioscience Inc.,** *UK*	**Practically exploring updates to medical device regulations in Kazakhstan** **Yana Pruss-Galynsky,** CEO, **Zephyr Biomedical,** *Israel*
16.15	*End of conference day four*	**Comparing EU MDR and US FDA drug device combination product regulations to identify effective regulatory strategies** **Winifred Wu,** President and Principal Advisor, **Strategic Regulatory Partners,** *USA*	**Overview and updates to EUDAMED and implications to IVDs** **Céline Bourguignon,** Director, Global regulatory policy, Government Affairs & Policy, **Johnson & Johnson,** Chair of the MedTech Eudamed Taskforce, **MedTech Europe,** *Belgium*	**The adoption of an EU Medical Device Directive (MDD)-based regulation system in Ukraine** **Alexander Schapovalov,** Foreign Affairs Manager, **TÜV SÜD,** *Germany*
16.50		*End of conference day four*	**Unique Device Identifiers (UDI) requirements for IVDs** **Melissa Finocchio,** Project Portfolio Leader, Global Quality, **bioMérieux,** *France*	**The Product Tracking System (UTS): Turkey's new registration database and other upcoming changes** **Ilker Yilmaz,** Regulatory Affairs & Market Access Manager, **Meril,** *Turkey*
17.25			*End of conference day four*	

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MAIN CONFERENCE DAY FIVE • FRIDAY 15 JUNE 2018

09:00	**Chairperson's Opening Remarks** **Byron Lambert,** Sr Assoc Fellow, Sterilization, **Abbott Vascular,** *USA*	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**	**Chairperson's Opening Remarks**
	Sterilisation and Reprocessing of Medical Devices	**Drug Device Combination Products**	**IVD Regulatory & Strategic Forum**	**Regulatory Affairs in Emerging Markets**
09:10	**Moving from the MDD to the MDR – what will be the impact on sterile packaging, including latest status updates to ISO 11607 – Packaging for terminally sterilized medical devices** **Thierry Wagner,** Regulatory Affairs Director - Europe, Middle-East & Africa, **DuPont Medical and Pharmaceutical Protection,** *Luxembourg*	**Practically overcoming regulatory and practical challenges with the design, manufacture, and distribution of pre-filled syringes** **Ann Jans,** Quality Assessor, **FAMHP,** *Belgium*	**Clarification of the role of the Person Responsible for Regulatory Compliance (PRRC) under the IVDR from a practical standpoint** **Petra Kaars-Wiele,** Senior Director International Regulatory Affairs & Global Labeling, **Abbott,** *Germany*	**ANVISA perspective: Understanding the latest regulatory framework in Brazil and the implications for industry** **Augusto Greyer,** Deputy General Manager, Medical Devices Office, **ANVISA,** *Brazil*
09:45	**CASE STUDY: Handling sterile packaging waste** **Karina Engels,** Product Manager, Sterilisation & InteguSeal EMEA, **Halyard Health,** *Belgium*	**Practically approaching the co-development of drug and device components of drug device combination products** **Sanjay Jain,** Drug Delivery Systems Principal Engineer, **Janssen,** *USA*	**The effects the IVDR will have on economic operators** **Chris Dark,** Head of Regulatory Affairs, **Arkray Factory Ltd,** *UK*	**CASE STUDY: How to pass the ANVISA GMP audit** **Gloria Schneider-Ferrer,** Manager, Global Strategy - Brazil, **DePuy Synthes,** *Switzerland*
10:20	**Global sterility assurance challenges and opportunities** **Byron Lambert,** Sr Assoc Fellow, Sterilization, **Abbott Vascular,** *USA*	**Considerations for how increased clinical data requirements as proposed in the EU MDR impacts combination products** **Florian Tolkmitt,** Clinical Evaluation & Regulatory Affairs Expert, *Germany*	**New requirements of post-market surveillance under the IVDR** **Gary Carpenter,** Director of Clinical and Regulatory Affairs, **BioSure,** *UK*	**MDSAP pilot update: The impact of the MDSAP on the Brazilian regulatory environment** **Georg Bauer,** Department Manager Foreign Affairs, **TÜV SÜD,** *Germany*
10:55	*Morning coffee break*			
11:25	**Exploring latest updates to the Radiation Sterilization standard ISO 11137 and implications for industry** **Arne Miller,** Professor, **Risø High Dose Reference Laboratory,** *Denmark*	**An overview of recent changes and updates in human factors engineering guidance and the implications for drug device combination products** **Molly Story,** Senior Director, Global Usability Engineering and Risk Management, **Sanofi,** *USA*	**Incident reporting for IVDs under the IVDR** **Caroline Alexander,** Head of Quality and Regulatory Affairs, **QuantuMDx Group Ltd.,** *UK*	**Review of updates to INMETRO certification requirements: How to ensure compliance** **Luciano Oliveira Ferreira,** Head of Quality & Regulatory Affairs, **QA/RA Works,** *Brazil*
12:00	**Understanding the liquid sterilisation of medical devices with derivatives of animal origin** **Wilhelm Erdbrügger,** Sen. Manager Process Development, **BIOTRONIK,** *Switzerland*	**INTERACTIVE SESSION: A hands-on exploration of human factors testing for combination products** **Yvonne Limpens,** Managing Human Factors Specialist, **UL,** *Netherlands* **Frauke Schuurkamp,** Managing Human Factors Specialist, **UL,** *Netherlands*	**Comparing US and EU regulatory requirements for IVDs** **Carol Lindsay,** Senior Regulatory Scientist, **Promega,** *USA*	**Updates to COFEPRIS regulations in Mexico and guidance for implementation** **Ana Luisa Fritschy,** Manager Regulatory Affairs, **Aptar Stelmi,** *France*
12:35	*Networking Lunch*			

MAIN CONFERENCE DAY FIVE • FRIDAY 15 JUNE 2018 *(continued)*

	Sterilisation and Reprocessing of Medical Devices	Drug Device Combination Products	IVD Regulatory & Strategic Forum	Regulatory Affairs in Emerging Markets
14:00	**Microbiological aspects** **Ciming Li,** Product Safety Expert, *Switzerland*	**Understanding the challenges associated with packaging and labelling for drug device combination products** **Judit Jávor,** Regulatory Affairs Expert & Compliance Director, **PharmaPatent,** *Hungary*	**The impacts of the IVDR for companion diagnostics manufacturers** **Alex Laan,** Principal Certification Manager, **Dekra Certification,** *Netherlands*	**New requirements for post-market surveillance and vigilance in Latin America**
14.35	**Exploring sterilisation techniques for 3D printed products** **James McCoy,** Staff Quality Scientist, Global Sterilization Research and Innovation, **BD,** *USA*	**Identifying latest regulatory requirements and practical approaches to designing generic or biosimilar/device combination products** **Alice Maden, Associate Director, Regulatory Affairs, BD,** *France*	**How the IVDR impacts both pharmaceutical and diagnostics manufacturers** **Claudia Dollins,** Head of Global Regulatory Affairs, Biomarkers & Diagnostics, **Merck,** *Germany*	**PANEL DISCUSSION: Exploring the latest regulatory requirements across Latin America** **Ana Luisa Fritschy,** Manager, Regulatory Affairs, **Aptar Stelmi,** *France* **Patricia Pascale,** Regulatory Affairs Director, LATAM, **ConvaTec,** *Brazil*
15.10	*Afternoon tea break*			
15.40	**CASE STUDY: Best practice sterilisation processes for drug device combination products** **Jeff Vest,** Principal Specialist – MHS (Technical Reviewer), **TÜV SÜD Product Service,** *UK*		**INTERACTIVE ROUNDTABLE SESSION: How is the companion diagnostics industry preparing for changes with the IVDR?**	**A practical overview of Saudi Arabia's pre-market process** **Naif Alhussinan,** Acting Section Head for Licensing Importers and Distributors, **SFDA,** *Saudi Arabia*
16.15	**INTERACTIVE Q&A SESSION: Sterilisation of drug device combination products** **Tim Carlson,** Sterilization Program Manager, Global Sterilization Assurance, **BD,** *USA*		**Discussion of the implications of Brexit on the IVD industry** **Fabien Roy,** Counsel, **Hogan Lovells International LLP,** *Belgium*	**PANEL DISCUSSION: Navigating requirements and strategies for registering medical devices in the Middle East and North Africa (MENA)** **Naif Alhussinan,** Acting Section Head for Licensing Importers and Distributors, **SFDA,** *Saudi Arabia* **Mamoona Firdous,** Regulatory Affairs Manager, **Julphar,** *UAE*
16.50	*End of conference day five*			

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