SESSIONS

DAY ONE - 17/06/2019

Registration

07:50 - 09:00

Chairperson's opening remarks

09:00 - 09:10
EU Medical Device Regulation

Participants

Amanda Maxwell - Medtech Regulatory Affairs Editor, MedTech Insight, Pharma Intelligence, Informa, UK

Chairperson's opening remarks

09:00 - 09:10
EU Medical Device Law

Participants

Amanda Maxwell - Medtech Regulatory Affairs Editor, MedTech Insight, Pharma Intelligence, Informa, UK

Implementation of the MDR: Feedback from the MHRA

09:10 - 09:40
EU Medical Device Regulation

Participants

Speaker Invited:: (Invited Speaker) Graeme Tunbridge - Group Manager – Devices Regulatory Affairs, MHRA

Implementation of the MDR: Feedback from the MHRA

09:10 - 09:40
EU Medical Device Law

Participants

Speaker Invited:: (Invited Speaker) Graeme Tunbridge - Group Manager – Devices Regulatory Affairs, MHRA

Competent Authority feedback: The EU Medical Device Regulation – the road to implementation

09:40 - 10:10
EU Medical Device Regulation

- An update on the scope of the MDR and clarifying remaining areas of uncertainty
- How are Competent Authorities interpreting the MDR and how can we ensure a harmonised approach to compliance?
- Clarifying new business processes for Competent Authorities under the MDR
- Addressing key industry challenges associated with implementation and advice to overcome these challenges

Participants

Matthias Neumann - Senior Executive, Medical Device Safety Unit, German Federal Ministry of Health

Competent Authority feedback: The EU Medical Device Regulation – the road to implementation

09:40 - 10:10
EU Medical Device Law

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Participants

Matthias Neumann - Senior Executive, Medical Device Safety Unit, German Federal Ministry of Health

Notified Body feedback: The EU Medical Device Regulation and preparing for implementation

10:10 - 10:35
EU Medical Device Regulation

- Key learnings from the joint assessments
- Assessing different Notified Body interpretations of MDR: How can we ensure a harmonised approach?
- Understanding Notified body priorities for MDR implementation: when will industry be able to start submissions for certification according to the new rules? And with which product to start first?
- Period between now and Date of Application: How long will Notified Bodies be accepting submissions according to the old MDD/AIMDD Rules?

Participants

Bassil Akra - Vice President – Global Focus Teams (Cardiovascular, Orthopaedic and Clinical), TÜV SÜD Product Service GmbH, Germany

Notified Body feedback: The EU Medical Device Regulation and preparing for implementation

10:10 - 10:35
EU Medical Device Law

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Participants

Bassil Akra - Vice President – Global Focus Teams (Cardiovascular, Orthopaedic and Clinical), TÜV SÜD Product Service GmbH, Germany

Practically implementing the MDR: Large medical device manufacturer

10:35 - 11:00
EU Medical Device Regulation

- Undertaking a gap analysis to assess where additional resource and time and cost should be invested
- Structure, timing and governance are essential
- Strategies for continually monitoring the latest requirements and ensure progress despite uncertainty
- Scoping resources internally to ensure compliance from a QMS and technical file perspective
- Training and explaining: Communicating the key differences between the MDD and the MDR to staff in a meaningful way and explaining the new associated processes

Participants

Søren Holck - Senior Vice President, Coloplast AS

SESSIONS

DAY ONE - 17/06/2019

Practically implementing the MDR: Large medical device manufacturer

10:35 - 11:00
EU Medical Device Law

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Participants

Søren Holck - Senior Vice President, Coloplast AS

Morning coffee and networking break

11:00 - 11:40

Presentation to be delivered by BSI

11:40 - 12:10
EU Medical Device Regulation

Managing New Requirements for the Economic Operators Regime: Drafting and Negotiating Agreements

11:40 - 12:10
EU Medical Device Law

- Assessing legal obligations of manufacturers, authorised representative's importers and distributors
- Managing risk: documenting duties for your supply chain and managing ongoing obligations
- Legal tools to manage and demonstrate compliance
- Implementing and updating standard operating procedures

Participants

Erik Vollebregt - Partner, Axon Lawyers LLP, The Netherlands

Nicole Dura - Senior Regional Counsel EEMEA, Stryker GmbH & Co.KG, Germany

Panel discussion: Beyond March 2019: Brexit and the MDR – what does it mean for implementation?

12:10 - 12:55
EU Medical Device Regulation

- Understanding how Competent Authorities will approach Brexit
- Understanding how Brexit will impact industry's relationship with Competent Authorities
- Clarifying Notified Body procedures and representatives based in the UK
- Providing clarification on the position Authorised Representatives based in the UK
- Examining the extent has Brexit is changing the way industry are preparing for implementation

Participants

Thomas Wejs Møller - Section Manager - Medical Devices, Danish Medicines Agency

Gert Bos - Executive Director & Partner, Qserve

DUAL DIALOGUE Understanding and Managing Product Liability and Risks in the Supply Chain

12:10 - 12:55
EU Medical Device Law

- Overview of the European product liability regime and case law, and how these relate to wider regulation of medical devices
- Guidance on identifying your potential liability and mitigating risks
- Future developments: the Commission's proposals to reform the Product Liability Directive and the draft Directive on consumer collective redress

Participants

Andrew Austin - Partner, Freshfields Bruckhaus Deringer LLP, UK and Member, EU Commission Expert Group on Liability and New Technologies

Amelie Chollet - Legal Regulatory Counsel, EMEA, Abbott Laboratories UK Ltd, UK

Networking Lunch

12:55 - 14:15

NOTIFIED BODY PANEL DISCUSSION: An update on Notified Body designation: Scope, resource and timelines

14:15 - 15:00
EU Medical Device Regulation

- Clarifying the timelines for Notified Body designation
- Assessing Notified Body capacity and resource: how big is the window and will MDD certificates be extended?
- Will your Notified Body have the scope? Understanding if and when your Notified Body will be able to re-certify your products
- How will Notified Body delays impact certificates up for renewal and clarifying what will happen if certificates don't get issued in time
- What happens if your Notified Body goes out of business? When and how to switch your notified body

Participants

Gert Bos - Executive Director & Partner, Qserve

Bart Mersseman - Medical Devices Product Manager, SGS

DUAL DIALOGUE New Regulatory Requirements for Advertising and Promotion

14:15 - 15:00
EU Medical Device Law

- Update on regulations, promotion and advertising for medical devices across Europe
- Provision of public information: guidance on listing adverse events, side effects and risk
- Practical approach and scenarios: the do's and don'ts of advertising

Participants

Alison Dennis - Medical Device and Pharmaceuticals Lawyer, Head of Life Sciences Sector Group, Fieldfisher LLP, UK

Wojciech Olszewski - Senior Legal Counsel EMEA, Align Technology, B.V., The Netherlands

SESSIONS

DAY ONE - 17/06/2019

Countdown to the European Medical Device Regulation (MDR)

15:00 - 15:30
EU Medical Device Regulation

- Access to Notified Body services is like a modern art of gambling (50:50 chance)
- Implementing & Delegating acts make the MDR a moving target (with a deadline)
- Overhaul of Labelling (UDI) & Technical Documentation cost can "kill" a Medical Device Company
- The macro-economic consequences of MDR for European Consumer & Economic Operator
- Law Suites as last resort to restore fair competition for Medical Device(s) in Europe

Participants

Oliver P. Christ, Dipl.-Ing. - Executive Vice President, PROSYSTEM GmbH

DUAL DIALOGUE Legal Obligations and Relationship with your Notified Body

15:00 - 15:30
EU Medical Device Law

- Update on the legal status of notified bodies: regulators or private bodies
- New regulations and the implications on your relationship with notified bodies
- Understanding new liabilities under the MDR and IVDR for Notified Bodies

Participants

Peter Bogaert - Partner, Covington & Burling LLP, Belgium

Bassil Akra - Vice President – Global Focus Teams (Cardiovascular, Orthopaedic and Clinical), TÜV SÜD Product Service GmbH, Germany

Afternoon tea and networking break

15:30 - 16:10

Software classification: Examining the new rule for medical device software

16:10 - 16:55
EU Medical Device Regulation

- Clarifying and interpreting MDR Annex VIII: Section 6.3. Rule 11 and the requirements surrounding diagnostic decisions
- Understanding the different requirements for standalone and integrated software
- Software apps and wearables: clarifying when a clinical investigation should be carried out to gain a CE mark
- Industry case study

Participants

Koen Cobbaert - Senior Manager - Quality, Standards & Regulations, COCIR

Managing your Relationship with your Notified Body: Legal Remedies and Recourse

16:10 - 17:30
EU Medical Device Law

- Understanding your legal recourse against notified bodies
- How do you go about changing notified bodies: models and approaches?
- Tools and avenues are available if you are let down

Participants

Maurits J.F. Lugard - Partner, Sidley Austin LLP, Belgium

Josefine Sommer - Associate, Sidley Austin LLP, Belgium

ISO13485:2016 – Quality Management Systems (QMS) and the MDR: what's new and how can industry prepare?

16:55 - 17:30
EU Medical Device Regulation

- Assessing the role of the Quality Management Systems in ensuring compliance with the MDR
- Organising Quality Management Systems internally and understanding how and why it is key to supporting MDR compliance
- Understanding how quality and regulatory teams can collaborate to ensure safety and performance throughout the device lifecycle

Participants

Vanessa Windscheid - Quality & Clinical Affairs Manager, Nipro Europe NV

Chair's closing remarks and end of conference day one

17:30 - 17:35

SCHEDULE

DAY ONE - 17/06/2019

TIME	EU MEDICAL DEVICE LAW	EU MEDICAL DEVICE REGULATION
07:00	**07:50** - Registration	**07:50** - Registration
08:00		
09:00	**09:00** - Chairperson's opening remarks **09:10** - Implementation of the MDR: Feedback from the MHRA **09:40** - Competent Authority feedback: The EU Medical Device Regulation – the road to implementation	**09:00** - Chairperson's opening remarks **09:10** - Implementation of the MDR: Feedback from the MHRA **09:40** - Competent Authority feedback: The EU Medical Device Regulation – the road to implementation
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11:00	**11:00** - Morning coffee and networking break **11:40** - Managing New Requirements for the Economic Operators Regime: Drafting and Negotiating Agreements	**11:00** - Morning coffee and networking break **11:40** - Presentation to be delivered by BSI
12:00	**12:10** - DUAL DIALOGUE Understanding and Managing Product Liability and Risks in the Supply Chain **12:55** - Networking Lunch	**12:10** - Panel discussion: Beyond March 2019: Brexit and the MDR – what does it mean for implementation? **12:55** - Networking Lunch
13:00		
14:00	**14:15** - DUAL DIALOGUE New Regulatory Requirements for Advertising and Promotion	**14:15** - NOTIFIED BODY PANEL DISCUSSION: An update on Notified Body designation: Scope, resource and timelines
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16:00	**16:10** - Managing your Relationship with your Notified Body: Legal Remedies and Recourse	**16:10** - Software classification: Examining the new rule for medical device software **16:55** - ISO13485:2016 – Quality Management Systems (QMS) and the MDR: what's new and how can industry prepare?
17:00	**17:30** - Chair's closing remarks and end of conference day one	**17:30** - Chair's closing remarks and end of conference day one

SESSIONS

DAY TWO - 18/06/2019

Opening remarks from the Chairperson

09:00 - 09:10
EU Medical Device Regulation

Opening remarks from the Chairperson

09:00 - 09:10
EU Medical Device Law

Opening remarks from the Chairperson

09:00 - 09:10
Clinical Evaluations and Investigations for Medical Devices

Opening remarks from the Chairperson

09:00 - 09:10
Post Market Surveillance and Vigilance

Economic Operator obligations: Creating a structure for all Economic Operators to avoid duplication and ensure compliance

09:10 - 09:40
EU Medical Device Regulation

- Creating quality agreements to centralise activities of the authorised representative
- Accessing guidance at a local level and implementing internal procedures for distributors to ensure access to documentation
- Strategies to ensure the authorised reps and distributors comply with the requirements
- Guaranteeing good and systematic communications

Participants

Carol Mahon - Senior Director, EMEA Regulatory Compliance & Technical Services, Medtronic

KEYNOTE PANEL DISCUSSION Future Scoping New Market Developments and the Impact on the Medical Device Market

09:10 - 09:40
EU Medical Device Law

- Outlook: examining the most significant changes occurring across the industry
- Brexit: impact on existing and new licencing agreements
- Digital health and AI: legal implications for the medical device industry
- Responding to trends: legal risk management to equip your organization to respond to challenges

Participants

Suzanne Durdevic - Former Senior Director, General Counsel EMEA, Boston Scientific, France

Giorgio Rizzello - Legal Director EMEA, Johnson & Johnson, Belgium

Robert Abbott - VP, Chief Legal Counsel EMEA, Stryker, The Netherlands

David Morkan - Director and Senior Counsel EMEA, Cook Medical, Ireland

Competent Authority expectations for clinical evaluations and investigations under the MDR

09:10 - 09:40
Clinical Evaluations and Investigations for Medical Devices

- Highlighting the key differences between MDD and the MDR requirements for clinical evaluations and investigations
- Understanding what Competent Authorities are now looking for from industry
- Assessing the key challenges for Competent Authorities implementing the MDR
- Clarifying the pre-market processes for class 3 devices: what is the timeline from Competent Authorities for registering Class 3 devices?
- Class 1 devices and declaration of conformity

Participants

Steve Eglem - Head of Clinical Investigation Unit, FAMHP

Examining new post market surveillance (PMS) and vigilance requirements under the MDR

09:10 - 09:40
Post Market Surveillance and Vigilance

- Clarifying key differences between MDD and MDR requirements
- Strategies for effective and efficient implementation of PMS and vigilance under the MDR
- Ensuring the QMS effectively supports PMS and vigilance
- Examining the specific requirements for IVDs
- Assessing the current timelines and impact of Brexit on implementation

Participants

Patrick Caines - Quality & Compliance Senior Director, Baxter

Structuring and mapping out Economic Operators in light of the MDR

09:40 - 10:10
EU Medical Device Regulation

- Mapping Economic Operator responsibilities out against quality systems
- Making the visibility work when there are global sites and processes need to be harmonised centrally
- Centralising processes through system checks and availability of documentation
- Understanding the process when sites don't control their processes, but they still have ultimate responsibility for their location
- Classifying and rationalising Economic Operators to assess compliance and reduce the number that are used

Participants

Michel Marboeuf - Senior Director RA Corporate, Stryker

Strategic Legal Advice: Responding to the Changing Regulatory Landscape

09:40 - 10:10
EU Medical Device Law

- Leveraging opportunities from regulatory challenges: combining legal and regulatory insight for best practice approach
- Taking a holistic approach to your portfolio: selling or acquiring new product lines in response to market challenges and changes

Participants

Alex Denoon - Partner, Bristows LLP, UK

Devika Sahdev - Corporate Counsel, International, KCI An Acelity Company, UK

SESSIONS

DAY TWO - 18/06/2019

Notified Body expectations for clinical evaluations and investigations under the MDR

09:40 - 10:10
Clinical Evaluations and Investigations for Medical Devices

- Clarifying Notified Body interpretation of MDR clinical evidence requirements
- Understanding expectations of Notified Bodies for the various product classes and types
- Key challenges and opportunities with the new clinical requirements

Participants

Bassil Akra - Vice President – Global Focus Teams (Cardiovascular, Orthopaedic and Clinical), TÜV SÜD Product Service GmbH, Germany

INDUSTRY CASE STUDY: PMS requirements under the MDR – Preparing your medical devices for PMS

09:40 - 10:10
Post Market Surveillance and Vigilance

- Expectations of PMS activities under the EU MDR. Anything new?
- When to start the PMS process, plans and activities. After launch?
- How to define teams and train teams.
- How about Product Life Cycle Management and updating Risk Management (trending) and Clinical Evaluation?
- Questions from Notified Bodies and Competent Authorities. Is there a focus on product quality?
- Is there any relationship of PMS with the pre-market product development?
- Do we need design for system safety, design for reliability, and design for human factors?
- Going from corrective to preventive actions

Participants

Ruben Roijers - Post Market Surveillance, Philips, The Netherlands

Presentation to be delivered by Deloitte

10:10 - 10:40
EU Medical Device Regulation

Drafting Commercial Agreements in an M&A context

10:10 - 10:40
EU Medical Device Law

- Practical commercial agreement drafting considerations – dos and don'ts
- Red flags and deal breakers based on due diligence
- Practical guidance and pitfalls to avoid in order to get the deal through

Participants

Phillip Schmidt - Legal Counsel EMEA, Zimmer Biomet, Switzerland

Moritz Maurer - Corporate/M&A, Niederer Kraft Frey Ltd, Switzerland

Class 3 implantables: Understanding the new process for class 3 implantables

10:10 - 10:40
Clinical Evaluations and Investigations for Medical Devices

- Clarifying the new requirements for class 3 implantable devices
- When are Notified Bodies able to issue a certificate?
- Submitting a clinical consultation to an expert panel – how long will the process last and how will it impact getting your device on the market?

Participants

Peter Schroeer - Senior Director Regulatory Affairs, Policy and Innovation, Johnson & Johnson

A step by step guide to putting your PMS plan together

10:10 - 10:40
Post Market Surveillance and Vigilance

- Clarifying the difference between PMS and vigilance
- Understanding the key elements of a PMS system
- Assessing the different requirements for class 1, 2 and 3 devices
- Best practice for data collection and review procedures: putting a system in place to access and assess clinical data

Participants

Martin Oswald - QE Manager PMS, DepuySynthes

Morning coffee and networking break

10:40 - 11:20

An update on the latest labelling and symbol requirements under the Medical Device Regulation

11:20 - 11:50
EU Medical Device Regulation

- Symbol Harmonisation
- Implant Card Implementation

Participants

Joachim Wilke - Director Regulatory Affairs & Policy Europe, Medtronic GmbH, Germany

IP Protection for Medical Devices

11:20 - 11:50
EU Medical Device Law

- Practical tools to protect your products: understanding patents, trade mark protection and design rights
- Determining True Value of your IP: assessing patent strength and commercial viability
- Freedom-to-operate: examining the impact of pending and granted patent and design rights

Participants

Judith Krens - Partner, Taylor Wessing, The Netherlands

Practically implementing the new requirements for clinical evaluations and investigations

11:20 - 11:50
Clinical Evaluations and Investigations for Medical Devices

- The bar has been raised in terms quality of clinical data. E.g. Class III and implantable devices are expected to have clinical data derived from clinical investigations that were conducted under the supervision of a sponsor, recognized ethical principles, and in the end must align with Clinical Evaluation Plan.
- Will peer-reviewed publications suffice? NBs raise the problem of "publication-bias", questioning the quality of scientific papers. These will be seen as sub-par compared to manufacturer-owned/ sponsored clinical investigations.
- Exactly what is "sufficient" clinical data? How can manufacturers profit from this without neglecting the aim to provide the best data possible to prove that benefits outweigh the risks of their devices?

Participants

Ivo Machatschke - Team Leader, Clinical Evaluations/ Research & Development, MED-EL, Austria

SESSIONS

DAY TWO - 18/06/2019

Proactive PMS: Strategies for a PMS system implementation

11:20 - 11:50
Post Market Surveillance and Vigilance

- Defining proactive post market surveillance and understanding what the authorities are looking for
- Data sources:
  - Level 0: Complaints
  - Level 1: Registries, databases, scientific literature, surveys and PMCF studies to source data
  - Level 2: Social Media
  - Level 3: IoT and Big Data in connected devices
- A QMS gap analysis to map processes interaction: Understanding to what extent the QMS could be impacted by a proactive PMS system
- Methods and protocols to use identified data sources
- Data management: Establishing a resource plan and a prioritisation plan
- Connecting data sources to increase QMS and PMS efficiency and to improve products

Participants

Leonardo Ruggiero - Post Market Surveillance Coordinator, Agfa Radiology Solutions

Examining the impact of the MDR on product lifecycle and labeling changes

11:50 - 12:20
EU Medical Device Regulation

Participants

Luminita Tulea - Director RA & QA, Vyaire Medical

Focus on Classifications: Combination, Complementary, Companion and Borderline Products

11:50 - 12:20
EU Medical Device Law

- Assessing classifications under the MDR and IVDR
- Demystifying what is covered under the MDR: practical scenarios around challenging areas
- Changing obligations and legal responsibilities

Participants

Annabelle Bruyndonckx - Counsel, Simmons & Simmons LLP, Belgium

Vanessa Carpano-Chauvin - EMA Regional General Counsel, Align Technology B.V., The Netherlands

Examining the implications of the MDR on data management: collection, triage, management and reuse of data for regulatory purposes

11:50 - 12:50
Clinical Evaluations and Investigations for Medical Devices

- Best practices for organising and managing data in a regulatory setting
- Provisioning and curation of regulatory data for use across the organisation
- Methods for efficient training and assessment of data in the preparation of regulatory submissions.

Participants

Peter O'Blenis - President, Evidence Partners, Canada

Bassil Akra - Vice President – Global Focus Teams (Cardiovascular, Orthopaedic and Clinical), TÜV SÜD Product Service GmbH, Germany

Caroline Byrd - Director Regulatory Affairs, EU MDR: Project Quantum, Abbott

Laurie Mitchell - CEO, Criterion Edge

PANEL DISCUSSION: Sharing experiences of post market surveillance and vigilance best practice under the MDR

11:50 - 12:50
Post Market Surveillance and Vigilance

- How to manage the additional workload
- Assessing the best methods for data collection
- Using third party providers
- What challenges have been encountered in different companies?
- Success stories and lessons for industry

Participants

Leonardo Ruggiero - Post Market Surveillance Coordinator, Agfa Radiology Solutions

Fayez Abou Hamad - Fayez Abou Hamad, MD PMS & Vigilance Expert – Owner and Founder of MDV-Solve Medical Device Consulting Firm Clinical evaluation, Risk management, PMS & MDR implementation expertise MD Vigilance Expert Consultant – MDR PMS leader, Terumo Europe

Practically implementing UDI requirements

12:20 - 12:50
EU Medical Device Regulation

- Understanding the guidance surrounding classification changes and UDI
- Clarifying the interchangeability rules – when do you need a new UDI?
- Using UDI to successfully track and trend data over the lifecycle of a device

Focus on Classifications: EHealth, mHealth and Connected Devices

12:20 - 12:50
EU Medical Device Law

- Assessing the standards for approval under the MDR and IVDR
- Obligations and legal responsibilities for software classifications and digital health
- Overcoming the challenge when a product is marketed as a non-medical device but turned into a medical device by users
- Examining data privacy considerations for digital health products

Participants

Laure Le Calvé - Managing Partner, LCH Avocats LLP, France

Networking lunch

12:50 - 14:10

Strategies for engaging stakeholders and gaining senior management buy-in to ensure MDR readiness

14:10 - 14:40
EU Medical Device Regulation

- Working internally to organise teams and ensuring leadership understand the financial, legal and regulatory implications of non-compliance
- Building a business case for leadership to invest in regulatory activities
- Engaging non-regulatory groups: engineering, IT, Supply Chain, Quality, R&D, etc
- Strategies to ensure ALL stakeholders are aware of the dates in 2020 (MDR) and 2022 (IVDR)
- Engaging non-EU staff and making sure the MDR is deemed as important outside the EU (US and ROW)

Participants

Sanziana Negreanu Arboreanu - Regulatory Affairs Manager, MDR Implementation, Johnson & Johnson

Legal Perspective on Changes under the MDR for Medical Device Clinical Investigations

14:10 - 14:40
EU Medical Device Law

- Ethics compliance and practical advice on interacting with ethics committees
- Best practice on SOPs, contracting agreements and governance for clinical investigations
- Insight into contracting challenges under new MDR and IVDR

Please contact linda.cole@knect365.com, Tel +44 (0) 20 7017 6631 if you are interested in participating as a speaker, panellist, moderator or hosting webinar.

SESSIONS

DAY TWO - 18/06/2019

Medical Device Software (MDSW): Examining the new clinical evidence requirements

14:10 - 14:40
Clinical Evaluations and Investigations for Medical Devices

- Understanding what the clinical evidence requirements are
- What are Notified Bodies looking for from manufacturers to obtain a CE Mark?
- Roadmap for clinical evaluation of MDSW

Participants

Zuzanna Kwade - Clinical Evaluation Team Lead, EU Task Force on Clinical Evaluation of Software, Agfa HealthCare

Field Safety Corrective Action: Understanding new requirements under the MDR

14:10 - 14:40
Post Market Surveillance and Vigilance

- Outlining the new requirements for FSCA reporting and implications for industry
- What are Competent Authorities looking for from industry when initiating a recall?

Evaluating product portfolio and driving strategic decisions about divesting and removing products

14:40 - 15:10
EU Medical Device Regulation

- Rationalising the product portfolio and assessing which products to keep and which to remove
- Assessing cost for technical documentation Remediation vs. cost for divestment
- Best practice from the industry

Participants

Susanne Wesch - Senior Global Product Manager, Institut Straumann

The Interaction between GDPR, MDR and IVDR

14:40 - 15:10
EU Medical Device Law

- Reviewing the overlaps and gaps between MDR; IVDR and GDPR
- Clinical trial data: GDPR data requirements and obligations under MDR for clinical trial data to be disclosed
- Examining the challenges surrounding the legal basis for processing and collating data for medical device vigilance

Participants

An Vijverman - Partner, Dewallens & Partners LLP, Belgium

Industry panel: Sharing experiences of gaining regulatory approval for software devices

14:40 - 15:25
Clinical Evaluations and Investigations for Medical Devices

- Identifying the changes to the international regulatory landscape for medical device software
- Exploring go-to-market strategies across the world
- Assessing time and resources required to ensure sufficient clinical evidence is gathered
- Timelines for approval
- Feedback from Competent Authorities and Notified Bodies

Participants

Merja Hiltunen - Senior Officer, Medical, Valvira

Zuzanna Kwade - Clinical Evaluation Team Lead, EU Task Force on Clinical Evaluation of Software, Agfa HealthCare

Koen Cobbaert - Senior Manager - Quality, Standards & Regulations, COCIR

Implementing a robust Complaints handling system

14:40 - 15:10
Post Market Surveillance and Vigilance

- Overview of regulations/ISO standards with regards to complaint handling
- Establishing a Complaint Handling Process: suggested approach
- Complaint handling & Distributors: strategies for capturing accurate data from Distributors

Participants

Marta Carnielli - Senior Manager, Safety Risk Management & Surveillance, Ortho Clinical Diagnostics

Afternoon tea and networking break

15:25 - 15:55

A manufacturer's view: regulatory strategy for migrating product portfolio of high risk devices to Medical Devices Regulation requirements

15:55 - 16:25
EU Medical Device Regulation

- What are the main points?
- What are the new requirements?
- What timelines need to be taken into consideration?

Participants

Sophie Tabutin - EMEA Regulatory Affairs Leader, WL GORE

Responding to the Changing Market Access and Reimbursement Landscape

15:55 - 16:30
EU Medical Device Law

- Understanding the scope and stages of new legislation for centralised HTA assessments
- Evaluating the credibility of HTA co-operation and how this will sit with existing routes to market
- Overview of pricing and reimbursement for devices
- Legal recourse and practical strategies available for unfavourable HTA decisions

Participants

Francine Brogyanyi - Partner, Dorda Brugger Jordis Rechtsanwälte GmbH, Austria

Post market clinical follow up – what do we need to do and how can we do it?

15:55 - 16:25
Clinical Evaluations and Investigations for Medical Devices

- Understanding the new requirements for PMCF: what additional information is required?
- Clarifying which devices require PMCF
- Putting a system in place to enable visibility of clinical data
- Using surveys, customer feedback, field change orders to successfully implement PMCF

Participants

Deborah Klestadt - Clinical Study Manager, NAMSA Clinical Consulting

Post market clinical follow up – what do we need to do and how can we do it?

15:55 - 16:25
Post Market Surveillance and Vigilance

- Understanding the new requirements for PMCF: what additional information is required?
- Clarifying which devices require PMCF
- Putting a system in place to enable visibility of clinical data
- Using surveys, customer feedback, field change orders to successfully implement PMCF

Participants

Deborah Klestadt - Clinical Study Manager, NAMSA Clinical Consulting

SESSIONS

DAY TWO - 18/06/2019

PANEL DISCUSSION: Global convergence of regulatory requirements: challenges opportunities and looking to the future

16:25 - 17:25
EU Medical Device Regulation

- Safeguarding the health of patients and users while avoiding unnecessary burdens on manufacturers
- Clarifying the key differences between EU and US medical device legislation and assessing opportunities for harmonisation
- International acceptance and planning: Understanding how the ROW accept the MDR
- Feedback from IMDRF

Participants

Erik Raadsheer - Senior Director, Regulatory & Government Affairs and Quality Assurance, EMEA, Align Technology

Shokoufeh Khodabandeh - MDR Implementation Lead, Institut Straumann AG

Gert Bos - Executive Director & Partner, Qserve

Elizabeth Gfoeller - Corporate Director, Regulatory Affairs, MED-EL, Austria

Case study: Implementing a successful post market clinical follow up (PMCF) strategy

16:25 - 16:55
Clinical Evaluations and Investigations for Medical Devices

- Understanding which devices require a post market clinical investigation
- Best practice for preparing and performing a robust clinical investigation following ISO 14155
- Strategies for managing adverse events in PMCF studies
- Encouraging buy-in from senior management: creating a business case for post-market clinical data collection activity
- Examining the increased importance on PMCF data: what should the balance between pre and post-market data be?

Participants

Gudrun Denke - Head of Clinical Science Support, Geistlich Pharma AG

Case study: Implementing a successful post market clinical follow up (PMCF) strategy

16:25 - 16:55
Post Market Surveillance and Vigilance

- Understanding which devices require a post market clinical investigation
- Best practice for preparing and performing a robust clinical investigation following ISO 14155
- Strategies for managing adverse events in PMCF studies
- Encouraging buy-in from senior management: creating a business case for post-market clinical data collection activity
- Examining the increased importance on PMCF data: what should the balance between pre and post-market data be?

Participants

Gudrun Denke - Head of Clinical Science Support, Geistlich Pharma AG

End of conference day two

17:25 - 17:30

Drinks reception in the Hotel Bar

17:30 - 19:30

SCHEDULE

DAY TWO - 18/06/2019

TIME	CLINICAL EVALUATIONS AND INVESTIGATIONS FOR MEDICAL DEVICES	EU MEDICAL DEVICE LAW	EU MEDICAL DEVICE REGULATION	POST MARKET SURVEILLANCE AND VIGILANCE
09:00	**09:00** - Opening remarks from the Chairperson **09:10** - Competent Authority expectations for clinical evaluations and investigations under the MDR **09:40** - Notified Body expectations for clinical evaluations and investigations under the MDR	**09:00** - Opening remarks from the Chairperson **09:10** - KEYNOTE PANEL DISCUSSION Future Scoping New Market Developments and the Impact on the Medical Device Market **09:40** - Strategic Legal Advice: Responding to the Changing Regulatory Landscape	**09:00** - Opening remarks from the Chairperson **09:10** - Economic Operator obligations: Creating a structure for all Economic Operators to avoid duplication and ensure compliance **09:40** - Structuring and mapping out Economic Operators in light of the MDR	**09:00** - Opening remarks from the Chairperson **09:10** - Examining new post market surveillance (PMS) and vigilance requirements under the MDR **09:40** - INDUSTRY CASE STUDY: PMS requirements under the MDR – Preparing your medical devices for PMS
10:00	**10:10** - Class 3 implantables: Understanding the new process for class 3 implantables **10:40** - Morning coffee and networking break	**10:10** - Drafting Commercial Agreements in an M&A context **10:40** - Morning coffee and networking break	**10:10** - Presentation to be delivered by Deloitte **10:40** - Morning coffee and networking break	**10:10** - A step by step guide to putting your PMS plan together **10:40** - Morning coffee and networking break
11:00	**11:20** - Practically implementing the new requirements for clinical evaluations and investigations **11:50** - Examining the implications of the MDR on data management: collection, triage, management and reuse of data for regulatory purposes	**11:20** - IP Protection for Medical Devices **11:50** - Focus on Classifications: Combination, Complementary, Companion and Borderline Products	**11:20** - An update on the latest labelling and symbol requirements under the Medical Device Regulation **11:50** - Examining the impact of the MDR on product lifecycle and labeling changes	**11:20** - Proactive PMS: Strategies for a PMS system implementation **11:50** - PANEL DISCUSSION: Sharing experiences of post market surveillance and vigilance best practice under the MDR
12:00	**12:50** - Networking lunch	**12:20** - Focus on Classifications: EHealth, mHealth and Connected Devices **12:50** - Networking lunch	**12:20** - Practically implementing UDI requirements **12:50** - Networking lunch	**12:50** - Networking lunch
13:00				

SCHEDULE

DAY TWO - 18/06/2019

TIME	CLINICAL EVALUATIONS AND INVESTIGATIONS FOR MEDICAL DEVICES	EU MEDICAL DEVICE LAW	EU MEDICAL DEVICE REGULATION	POST MARKET SURVEILLANCE AND VIGILANCE
14:00	**14:10** - Medical Device Software (MDSW): Examining the new clinical evidence requirements **14:40** - Industry panel: Sharing experiences of gaining regulatory approval for software devices	**14:10** - Legal Perspective on Changes under the MDR for Medical Device Clinical Investigations **14:40** - The Interaction between GDPR, MDR and IVDR	**14:10** - Strategies for engaging stakeholders and gaining senior management buy-in to ensure MDR readiness **14:40** - Evaluating product portfolio and driving strategic decisions about divesting and removing products	**14:10** - Field Safety Corrective Action: Understanding new requirements under the MDR **14:40** - Implementing a robust Complaints handling system
15:00	**15:25** - Afternoon tea and networking break **15:55** - Post market clinical follow up – what do we need to do and how can we do it?	**15:25** - Afternoon tea and networking break **15:55** - Responding to the Changing Market Access and Reimbursement Landscape	**15:25** - Afternoon tea and networking break **15:55** - A manufacturer's view: regulatory strategy for migrating product portfolio of high risk devices to Medical Devices Regulation requirements	**15:25** - Afternoon tea and networking break **15:55** - Post market clinical follow up – what do we need to do and how can we do it?
16:00	**16:25** - Case study: Implementing a successful post market clinical follow up (PMCF) strategy		**16:25** - PANEL DISCUSSION: Global convergence of regulatory requirements: challenges opportunities and looking to the future	**16:25** - Case study: Implementing a successful post market clinical follow up (PMCF) strategy
17:00	**17:25** - End of conference day two **17:30** - Drinks reception in the Hotel Bar	**17:25** - End of conference day two **17:30** - Drinks reception in the Hotel Bar	**17:25** - End of conference day two **17:30** - Drinks reception in the Hotel Bar	**17:25** - End of conference day two **17:30** - Drinks reception in the Hotel Bar

SESSIONS

DAY THREE - 19/06/2019

Registration

08:00 - 09:00

Opening remarks from the Chairperson

09:00 - 09:10
Clinical Evaluations and Investigations for Medical Devices

Opening remarks from the Chairperson

09:00 - 09:10
Post Market Surveillance and Vigilance

Chairman's Opening Remarks

09:00 - 09:10
Medical Device Regulatory Affairs in Emerging Markets

Introduction to Project Management

09:00 - 10:40
TRAINING COURSE: Medical Device Regulatory Project Management

- Early development stages in a project:
  - Capturing the value proposition
  - Clinical and benefit-risk considerations
  - Early validation through feasibility studies
  - Regulatory strategy

- Planning and initiating the project
  - Timelines, responsibilities and team communication
  - Document and records management

Participants

Heikki Pitkänen - CEO & Founder, Digital Regulatory Runways, Lean Entries

Assessing the increased requirements for Clinical Evaluation Reports (CERs) under the MDR

09:10 - 09:40
Clinical Evaluations and Investigations for Medical Devices

- Clarifying what information needs to be included in the CER
- Understanding the quality of content needed to submit a sufficient CER to the authorities
- Defining equivalency and clarifying what needs to be demonstrated
- Examining how GCP guidelines have been incorporated into the MDR and how this impacts CERs
- Comparing CER requirements for legacy and new products: what's changed and what's stayed the same?

Participants

Basira Salehi - Senior Manager Clinical Science & Medical Affairs, Biotronik

Post market surveillance and the risk management process

09:10 - 09:40
Post Market Surveillance and Vigilance

- Sources for PMS
- Understanding how PMS data contributes to a more efficient risk management process
- How to efficiently incorporate the complaint and vigilance data into risk management?
- How to link PMS to RM
- The most typical deficiencies of the manufacturers

Participants

Radim Smitka - Manager Regulatory Affairs, Complaints & Vigilance, Straub Medical

Regulatory Overhaul: Updates on the Medical Device Regulation in China

09:10 - 09:40
Medical Device Regulatory Affairs in Emerging Markets

- Discussing the rationale behind the recent CFDA/ NMPA restructuring
- A review of the newly published amendments to the Chinese Medical Device Regulations and its impact on industry
- Assessing the associated challenges and opportunities for market entry into China

Participants

Jack Wong - Head of Regulatory Affairs APAC, Baxter & Founder, Asia Regulatory Professional Association

Case study: Performing clinical evaluations in context of the new MDR

09:40 - 10:10
Clinical Evaluations and Investigations for Medical Devices

- Practical advice on how clinical evaluations should be completed
- Assessing the key issues and understanding how to address them

Participants

Alexandros Charitou - Life Sciences Consultant / Clinical, Regulatory, Quality & Safety, Navigant

Successfully bringing together Risk Management, Clinical Evaluation and Post Market Surveillance Plans to streamline ways of working

09:40 - 10:10
Post Market Surveillance and Vigilance

- Risk Management, Clinical Evaluation and PMS under the MDR
- Understanding how RM, CE and PMS Plans are aligned and correlated in different companies
- Assessing how the data are collected and analysed - managing stakeholders, sites and countries - examining the best way to consolidate available information
- Assessing some of the common pitfalls and advice for overcoming them

Participants

Berlind Kalve - Corporate Expert Postmarket Compliance, Otto Bock Healthcare Products GmbH, Austria

Case Study: Best Practice for Successful Product Registrations in China

09:40 - 10:10
Medical Device Regulatory Affairs in Emerging Markets

- Tackling the expectations of the NMPA during registration
- Developing a comprehensive strategy for product approval in China
- Practical advice for overcoming regulatory hurdles and nonconformities

Participants

Ed Woo - AP Regulatory Affairs Director, Varian Medical, Hong Kong

SESSIONS

DAY THREE - 19/06/2019

Clinical evaluations: comparing IMDRF vs MDR items and assessing what this means in practice for manufacturers

10:10 - 10:40
Clinical Evaluations and Investigations for Medical Devices

- Comparable (IMDRF) versus the two types of EU Equivalence (MDR)
- Clinical Evaluation: IMDRF vs MDR
- Clinical Evidence / Data, including "overseas" clinical investigation: IMDRF vs MDR

Participants

Leo Hovestadt - International Regulatory Affairs and Quality Assurance Director, Elekta, The Netherlands

High-Quality Real-World Clinical Big Data to Support Post-Market Clinical Follow- ups/ Studies of Medical Devices

10:10 - 10:40
Post Market Surveillance and Vigilance

- High-Quality Real-World Clinical Big Data on clinical performance and safety of medical devices
- Thorough in-hospital data with years of clinical-follow ups available
- Competitor data on clinical performance and safety
- Projects experiences for EU MDR PMCF reports and FDA PMS with top MNC players
- Post Market Clinical Follow up Reports have been accepted by EU Notified Bodies

Participants

Vivian Tian - Overseas Business Development Manager, 1MData (Beijing Yiming Technology Co.,Ltd), China

Jing Du - Manager, Biostatistics, Abbott, US

Guidance on Chinese Clinical Conformity Evaluations for Device Approval

10:10 - 10:40
Medical Device Regulatory Affairs in Emerging Markets

- Review of the NMPA requirements for device testing and clinical evaluation
- Determining the appropriate route to clinical conformity (including CERs, clinical trial data, GCP)
- Best practice for conducting clinical trials for medical device registration in China

Participants

Heinrich Martens - Director Regulatory Affairs & QA, Fresenius Kabi

Morning coffee and networking break

10:40 - 11:30

Practical Experience in conducting Clinical Evaluation Reports for Medical Devices

11:30 - 12:00
Clinical Evaluations and Investigations for Medical Devices

- Structuring a template for the plan and report
- Explaining the most important success factors for conducting clinical evaluations
- Sharing lessons learned and "what to avoid"
- Assessing difficulties when clinical evaluations get started

Participants

Sandra Bugler - Managing Consultant for Clinical Affairs, PROSYSTEM

Post market surveillance and standards: Strategies for maintaining State of the Art

11:30 - 12:00
Post Market Surveillance and Vigilance

- Understanding the extent to which standards are harmonised to the MDR
- Examining what Notified Bodies are looking for from industry to demonstrate compliance
- Defining State of the Art
- Strategies to ensure and demonstrate compliance with the latest version of the standard
- Defining post market testing plans prior to product launch
- Putting in place testing plans to make sure the data is collected

Participants

Hendrik Heinze - Quality & Regulatory Affairs Director, Berlin Heart GmbH

Understanding the Medical Device Regulatory Landscape in Pakistan and India

11:30 - 12:00
Medical Device Regulatory Affairs in Emerging Markets

- An overview of the Pakistani and Indian regulatory framework and requirements for product registration
- Explore the differences between regulatory approval systems and assessing the impact of the new regulations on industry
- Discuss nuances in the in vitro diagnostic regulatory pathway
- Cover any specific QMS requirements

Participants

Maham Ansari - Director of Regulatory Affairs, Synaptive Medical, Canada

Applying Regulatory Requirements to Project Management

11:30 - 12:30
TRAINING COURSE: Medical Device Regulatory Project Management

- The role of global regulations and standards in medical device project management
- Key regulatory considerations throughout the medical device lifecycle:
  - General Safety and Performance Requirements
  - Clinical Evaluation
  - Risk Management
- Other regulatory considerations for project management:
  - Quality system requirements (ISO 13485, FDA QSR)
  - Design Control
  - Vendor control

Participants

Heikki Pitkänen - CEO & Founder, Digital Regulatory Runways, Lean Entries

Industry case study: Practically gathering and using clinical evidence for legacy products

12:00 - 12:30
Clinical Evaluations and Investigations for Medical Devices

- The pivotal role of Scientific Societies and clinical investigators under the MDR era
- The value of real world clinical evidence for post-market surveillance and regulatory decision-making
- Common pitfalls and opportunities

Participants

Benjamin Rochette - Regulatory Affairs Director, Medtronic

Spotlight Session: Examining available content management tools for PMS data

12:00 - 12:30
Post Market Surveillance and Vigilance

If you are interested in speaking in this session, please contact Linda Cole Tel +44 (0) 20 7017 6631; email linda.cole@knect365.com

SESSIONS

DAY THREE - 19/06/2019

Developing a Labelling Strategy for APAC Device Registrations

12:00 - 12:30
Medical Device Regulatory Affairs in Emerging Markets

- Sharing practical experience of label preparation in the APAC region
- Discussing the regulatory challenges of multi-country labelling strategies
- Best practice for designing a successful regulatory strategy to speed time to market

Participants

Kelvin Koh - Director APAC Regulatory Affairs, Terumo BCT

Networking lunch

12:30 - 13:50

MDR requirements on clinical investigations compared to the current legislation (MDD/ AIMDD) and ISO 14155

13:50 - 14:20
Clinical Evaluations and Investigations for Medical Devices

- Definitions
- Planning and design of a clinical investigation
- Application or notification to the competent authority
- Conduct of the clinical investigation
- Documentation and Reporting

Participants

Klaus Schichl - Director Clinical Affairs CRM/EP, BIOTRONIK

An update on the templates that are being developed for Periodic Summary Update Reports (PSURs)

13:50 - 14:20
Post Market Surveillance and Vigilance

- Understanding why PSURs have been updated and examining the extent to which they are becoming more like medicinal product reports
- What will the new PSUR templates look like?
- Establishing who the owner of the document should be and what needs to be included on the form

Participants

Paola Borgnolo - Regulatory and Compliance Specialist, Biomerieux

Regulatory Requirements for Accessing the South Korean Market

13:50 - 14:20
Medical Device Regulatory Affairs in Emerging Markets

- Main regulatory changes in South Korea regulation
- Changes in the KGMP within South Korea regulation
- Understanding MFDS on-site inspections of foreign facilities
- Practical APAC RA/QA insights on Northern Asia regulatory changes for China and Taiwan

Participants

Mei Ru Li - Global Regulatory Affairs Consultant, Knoell Germany GmbH, Germany

Applying Clinical Evaluation in a Project

13:50 - 14:50
TRAINING COURSE: Medical Device Regulatory Project Management

- The importance of conducting a literature review
- Clinical investigations and post-market activities

Participants

Heikki Pitkänen - CEO & Founder, Digital Regulatory Runways, Lean Entries

Legacy products under the MDR - using equivalence?

14:20 - 14:50
Clinical Evaluations and Investigations for Medical Devices

- Examining the definition of “sufficient clinical data”
- Performing gap analysis and setting up a roadmap
- Understanding and using equivalence
- Assessing money and time required to successfully collect data on legacy products
- Advice for industry working with legacy products

Participants

Alexandra Rieben - Global Lead Clinical Research & University Account Management, NOBEL BIOCARE SERVICES AG

Serious incident reporting: clarifying the new requirements under the MDR and the practical implications for manufacturers

14:20 - 14:50
Post Market Surveillance and Vigilance

- MDD vs MDR - Impact on vigilance reporting requirements
- Ensure systems and processes are up to scratch to ensure compliance

Participants

Angeles Sanfrancisco - Manager, Quality Compliance, Transcatheter Heart Valves, Edwards Lifesciences SL

ASEAN Medical Device Directive (AMDD) Implementation Status Update

14:20 - 14:50
Medical Device Regulatory Affairs in Emerging Markets

- Discussing the harmonisation efforts in the region and upcoming timelines
- Updates on the current adoption and implementation progress of ASEAN MDD
- Guidance on how best to prepare for the for the 2020 deadline
- Q&A

Participants

Sasikala Devi Thangavelu - Director of Policy, Code & Standard Division, Medical Device Authority Malaysia, Malaysia

Afternoon tea and networking break

14:50 - 15:20

Running a clinical investigation: Examining the pitfalls and opportunities

15:20 - 15:50
Clinical Evaluations and Investigations for Medical Devices

- Defining the goals of the investigation
- Best practice for complying with ISO 13485
- Evaluating and deciding in which country to conduct the clinical investigation
- Examining which factors should be considered when recruiting clinicians and investigators
- Understanding how best to document your clinical study

Participants

E. Lynne Kelley, MD, FACS - Chief Medical Officer, Histogenics

SESSIONS

DAY THREE - 19/06/2019

Economic Operator responsibilities and PMS and vigilance

15:20 - 15:50
Post Market Surveillance and Vigilance

- How have the new responsibilities placed upon economic operators impacted PMS and vigilance activities and processes?
- Mapping out economic operator responsibilities to ensure PMS and vigilance requirements are adhered to
- How are companies implementing the changes?
- Examining key challenges faced by industry

Participants

Markus Pöttker - MDR Post Market Surveillance Lead, Safety & Surveillance, Smith & Nephew

Interactive Discussion: Sharing Experiences of Successfully Registering Devices in ASEAN Countries

15:20 - 15:50
Medical Device Regulatory Affairs in Emerging Markets

- Feedback and advice for designing a successful regulatory strategy for ASEAN medical device registration
- Sharing experiences of registration hurdles and how to overcome them
- Filling in the blanks: discussing regional requirements for classification, licensing, labelling and post-market surveillance issues

Participants

Chairing:: May Ng - Global Regulatory & Quality Consultant, Director, ARQon, Singapore

Maham Ansari - Director of Regulatory Affairs, Synaptive Medical, Canada

Johanna Wright - Regulatory Affairs Director, ResMed

Applying Risk Management in a Project

15:20 - 16:05
TRAINING COURSE: Medical Device Regulatory Project Management

- Risk management practicalities
  - ISO 14971 and Design FMEA (Failure Modes & Effects Analysis)
  - Relation to Biocompatibility, Electrical safety, Software life cycle and Usability
- Benefit-risk analysis as the final outcome

Participants

Heikki Pitkänen - CEO & Founder, Digital Regulatory Runways, Lean Entries

Assessing the impact of the General Data Protection Regulation on clinical investigations

15:50 - 16:20
Clinical Evaluations and Investigations for Medical Devices

- Evaluating the balance between data privacy and transparency
- Distinguishing pseudonymisation and anonymisation terms in trial protocols
- Advice for industry to ensure compliance with MDR and GDPR

Participants

An Vijverman - Partner, Dewallens & Partners LLP, Belgium

Risk management and trend reporting

15:50 - 16:20
Post Market Surveillance and Vigilance

• Providing an update on the new trend reporting requirements

• How your risk management improve surveillance and trend reporting

• Be efficient when processing information for trending; surveillance setup for high volume end-user products

• Strategies for incorporating risk management in single incidents

Participants

Rikke Lewinsky - Principal Specialist, Complaint Surveillance, Novo Nordisk

Feedback on the Malaysian Medical Device Registration Process

15:50 - 16:20
Medical Device Regulatory Affairs in Emerging Markets

- An update on the latest Malaysian regulatory requirements for medical devices
- Feedback on best practices, challenges and how to overcome them
- Discussing the policies and implementation timelines for fast track registrations in Malaysia

Participants

Sasikala Devi Thangavelu - Director of Policy, Code & Standard Division, Medical Device Authority Malaysia, Malaysia

Managing Medical Device Project Cycles

16:05 - 16:50
TRAINING COURSE: Medical Device Regulatory Project Management

- Product life cycle thinking: Does the project have an end?
- Design Control as the middle cycle: The typical project cycle
  - Design Inputs, Outputs, Verification, Validation, Process Validation, Transfer, Changes and Reviews
- The micro cycles of project management: The daily work
  - Plan-Do-Check-Act / Build-Validate-Learn / Agile methodologies
- Maintaining alignment and adapting to change
  - Corrective and preventive actions and methods
  - Project metrics

Participants

Heikki Pitkänen - CEO & Founder, Digital Regulatory Runways, Lean Entries

Reviewing the Australian Registration and Approval Processes for Medical Device

16:20 - 16:50
Medical Device Regulatory Affairs in Emerging Markets

- Understanding the Australian regulatory landscape and TGA expectations for submissions
- Discussing challenges and strategies for overcoming them
- Experiences and practical guidance for the use of expedited pathways

Participants

Johanna Wright - Regulatory Affairs Director, ResMed

End of conference day three

16:50 - 16:55

SCHEDULE

DAY THREE - 19/06/2019

TIME	CLINICAL EVALUATIONS AND INVESTIGATIONS FOR MEDICAL DEVICES	MEDICAL DEVICE REGULATORY AFFAIRS IN EMERGING MARKETS	POST MARKET SURVEILLANCE AND VIGILANCE	TRAINING COURSE: MEDICAL DEVICE REGULATORY PROJECT MANAGEMENT
08:00	**08:00** - Registration	**08:00** - Registration	**08:00** - Registration	**08:00** - Registration
09:00	**09:00** - Opening remarks from the Chairperson **09:10** - Assessing the increased requirements for Clinical Evaluation Reports (CERs) under the MDR **09:40** - Case study: Performing clinical evaluations in context of the new MDR	**09:00** - Chairman's Opening Remarks **09:10** - Regulatory Overhaul: Updates on the Medical Device Regulation in China **09:40** - Case Study: Best Practice for Successful Product Registrations in China	**09:00** - Opening remarks from the Chairperson **09:10** - Post market surveillance and the risk management process **09:40** - Successfully bringing together Risk Management, Clinical Evaluation and Post Market Surveillance Plans to streamline ways of working	**09:00** - Introduction to Project Management
10:00	**10:10** - Clinical evaluations: comparing IMDRF vs MDR items and assessing what this means in practice for manufacturers **10:40** - Morning coffee and networking break	**10:10** - Guidance on Chinese Clinical Conformity Evaluations for Device Approval **10:40** - Morning coffee and networking break	**10:10** - High-Quality Real-World Clinical Big Data to Support Post-Market Clinical Follow- ups/ Studies of Medical Devices **10:40** - Morning coffee and networking break	**10:40** - Morning coffee and networking break
11:00	**11:30** - Practical Experience in conducting Clinical Evaluation Reports for Medical Devices	**11:30** - Understanding the Medical Device Regulatory Landscape in Pakistan and India	**11:30** - Post market surveillance and standards: Strategies for maintaining State of the Art	**11:30** - Applying Regulatory Requirements to Project Management
12:00	**12:00** - Industry case study: Practically gathering and using clinical evidence for legacy products **12:30** - Networking lunch	**12:00** - Developing a Labelling Strategy for APAC Device Registrations **12:30** - Networking lunch	**12:00** - Spotlight Session: Examining available content management tools for PMS data **12:30** - Networking lunch	**12:30** - Networking lunch
13:00	**13:50** - MDR requirements on clinical investigations compared to the current legislation (MDD/ AIMDD) and ISO 14155	**13:50** - Regulatory Requirements for Accessing the South Korean Market	**13:50** - An update on the templates that are being developed for Periodic Summary Update Reports (PSURs)	**13:50** - Applying Clinical Evaluation in a Project
14:00	**14:20** - Legacy products under the MDR - using equivalence? **14:50** - Afternoon tea and networking break	**14:20** - ASEAN Medical Device Directive (AMDD) Implementation Status Update **14:50** - Afternoon tea and networking break	**14:20** - Serious incident reporting: clarifying the new requirements under the MDR and the practical implications for manufacturers **14:50** - Afternoon tea and networking break	**14:50** - Afternoon tea and networking break

SCHEDULE

DAY THREE - 19/06/2019

TIME	CLINICAL EVALUATIONS AND INVESTIGATIONS FOR MEDICAL DEVICES	MEDICAL DEVICE REGULATORY AFFAIRS IN EMERGING MARKETS	POST MARKET SURVEILLANCE AND VIGILANCE	TRAINING COURSE: MEDICAL DEVICE REGULATORY PROJECT MANAGEMENT
15:00	**15:20** - Running a clinical investigation: Examining the pitfalls and opportunities **15:50** - Assessing the impact of the General Data Protection Regulation on clinical investigations	**15:20** - Interactive Discussion: Sharing Experiences of Successfully Registering Devices in ASEAN Countries **15:50** - Feedback on the Malaysian Medical Device Registration Process	**15:20** - Economic Operator responsibilities and PMS and vigilance **15:50** - Risk management and trend reporting	**15:20** - Applying Risk Management in a Project
16:00	**16:50** - End of conference day three	**16:20** - Reviewing the Australian Registration and Approval Processes for Medical Device **16:50** - End of conference day three	**16:50** - End of conference day three	**16:05** - Managing Medical Device Project Cycles **16:50** - End of conference day three

SESSIONS

DAY FOUR - 20/06/2019

Registration

08:30 - 09:00

Opening Remarks from Chairperson

09:00 - 09:10
IVD Regulation and Strategy

Opening Remarks from Chairperson

09:00 - 09:10
Clinical Outsourcing for Medical Device Trials

Opening Remarks from Chairperson

09:00 - 09:10
Medical Device Regulatory Affairs in Emerging Markets

Opening remarks from the Chairperson

09:00 - 09:10
Drug Device Combination Products

Overview of FDA regulation

09:00 - 10:55
TRAINING COURSE: US Regulatory Affairs for Medical Devices

- Comparison with EU Regulation
- Medical devices, drugs, and combination products
- FDA Structure: Divisions and offices
- FDA Center for Devices and Radiological Health (CDRH)
- Code of Federal Regulations (CFR)
- Regulatory requirements
  - Establishment registration
  - Medical device listing
  - Clearance, approval, exemptions
  - Investigational device exemptions for clinical investigations
  - Quality system regulation
  - Labelling
  - Medical device reporting

Sources of Information

- FDA website / guidance / Standards / databases

Managing the transition to IVDR – the road to 2022

09:10 - 09:45
IVD Regulation and Strategy

- How are Competent Authorities interpreting the IVDR?
- Exploring strategies Competent Authorities are employing to prepare for the IVDR
- Understanding whether the transition period will be extended
- Highlighting the changes in Competent Authority procedures following the IVDR

Participants

Speaker Invited:: (invited speaker) Stephen Lee - Biosciences Team Manager, MHRA

Notified Body perspective: Practical advice for industry on meeting new requirements for clinical operations and outsourcing under the MDR

09:10 - 09:45
Clinical Outsourcing for Medical Device Trials

- Clarifying Notified Body interpretation of MDR clinical trial requirements
- Understanding what Notified Bodies are looking for from manufacturers to obtain a CE Mark
- Defining "sufficient clinical data": what are the requirements and clinical expectations for new devices?
- Examining the extent to which the MDR is aligned with ISO 14155
- Key challenges and opportunities

ANVISA Feedback – Updates on the Regulatory Landscape and Requirements in Brazil

09:10 - 09:45
Medical Device Regulatory Affairs in Emerging Markets

- Discussing the current regulatory requirements for medical device registration and ANVISA plans for future
- Examining the impact of the clinical trials regulation on industry
- Practical guidance on registrations, common nonconformities and answering your questions

Participants

Augusto Geyer - Deputy General Manager, Medical Devices Office, ANVISA, Brazil

An Overview of the Current Regulatory Landscape for Drug Device Combination Products

09:10 - 09:45
Drug Device Combination Products

- Competent Authority perspective on drug device combination products
- Proposed actions to align regulation of both drug and device industry
- Practical advice to manufacturers on preparing for MDR
- Discussing the recent challenges and Competent Authority expectations

Participants

Ann Jans - Medical Devices Quality Assessor, FAMHP, Belgium

Practically preparing for the transition to the IVDR: large company perspective

09:45 - 10:20
IVD Regulation and Strategy

- Highlighting key differences between the previous and new regulations
- Interpreting the guidance around common specifications and product groups
- Undertaking a gap analysis to assess where resource should be dedicated
- Understanding and planning for the new classification requirements
- Implementation success: strategies for gaining senior management buy in and keeping the momentum going

Participants

Mirna DiPano - Regulatory Affairs Director, Abbott Diagnostics, US

Successfully selecting vendors with the most relevant experience for your clinical trials

09:45 - 10:20
Clinical Outsourcing for Medical Device Trials

- Strategies for reviewing potential outsourcing partners
- Examining the level of medical device expertise
- Assessing vendor competency and knowledge of the regulatory requirements (MDR and ISO 14155) surrounding medical device trials
- Selecting the right CRO to suit the specific trial needs and expectations

Participants

E. Lynne Kelley, MD, FACS - Chief Medical Officer, Histogenics

SESSIONS

DAY FOUR - 20/06/2019

Case Study: Implementing Brazilian Regulatory Requirements for High-Risk Devices

09:45 - 10:20
Medical Device Regulatory Affairs in Emerging Markets

- Industry perspective of the current regulatory framework for devices classified as high-risk
- Guidance on implementing requirements such as UDI, clinical data and mechanical testing
- A comparison of the Brazilian requirements to US and EU regulations: to what extent can harmonisation be achieved

Notified Body Perspective on EU MDR and its Impact on Combination Products

09:45 - 10:20
Drug Device Combination Products

- Notified Body interpretations of Article 117 and expectations for manufacturers
- Understanding the impact of additional Notified Body scrutiny during the conformity assessment
- Outlining common pitfalls and how they can be avoided

Participants

Julia Frese - Department Manager Centre of Combination Products, , TÜV SÜD Product Service GmbH, Germany

Practically preparing for the transition to the IVDR: small company perspective

10:20 - 10:55
IVD Regulation and Strategy

- Know your enemy
- Banging the drum
- Eating the elephant
- Culling the herd
- Boiling the frog

Participants

Paul Kenny - Regulatory Affairs Head, Oxford Gene Technology

Strategies for successful sponsor/vendor relationship management: SME perspective

10:20 - 10:55
Clinical Outsourcing for Medical Device Trials

- Different options for outsourcing a clinical investigation, or the execution activities to a CRO
- Strategies for ensuring an early alignment of expectations between both sponsor and vendor
- Assessing the CRO's understanding of what's involved: the study protocol, monitoring requirements, etc.
- Ensuring effective communication and vendor oversight throughout the clinical investigation life cycle
- Ensuring non-clinical goals of the clinical investigation are met: budgets, timelines and protocols

Participants

Colin Irwin - Clinical Operations Manager, Cochlear AG

Ensuring Compliance for INMETRO Medical Device Certification

10:20 - 10:55
Medical Device Regulatory Affairs in Emerging Markets

- Evaluating the current registration procedures required by INMETRO
- Developing a successful QMS strategy to ensure GMP compliance during audits
- Feedback for industry on submissions under the newest requirements and guidance on what INMETRO is looking for

Participants

Georg Bauer - Department Manager Regulatory Affairs, TÜV SÜD, Germany (subject to final confirmation)

Presentation to be delivered by 3D Communications

10:20 - 10:55
Drug Device Combination Products

Participants

Susan Resnick - Scientific Lead, 3D Communications

Morning coffee and networking break

10:55 - 11:25

Notified Body feedback: Implementing the IVDR

11:25 - 12:00
IVD Regulation and Strategy

- Understanding how Notified Bodies and planning and preparing for the 2022 deadline
- Understanding how best manufacturers can utilise transition time to the IVDR
- Defining the standards, clarifying the requirements and understanding what Notified Bodies are looking for from industry

Participants

Andreas Stange - Vice President MHS global IVD, TÜV SÜD

PANEL: Examining different trial models and assessing the benefit of outsourcing v's in-house

11:25 - 12:00
Clinical Outsourcing for Medical Device Trials

- Early stage considerations: Determining the nature of the trial
- Examining outsourcing options, full service v's specific activities
- Strategies for minimising costs when deciding on your outsourcing model
- Exploring the options for site selection and patient recruitment: outsourcing v's in-house

Dual Presentation: Updates and Practical Advice for Registrations Using the MDSAP

11:25 - 12:00
Medical Device Regulatory Affairs in Emerging Markets

- An update on the status of Brazil's MDSAP program and future outlook for the medical device industry
- Understanding the GMP audit system and determining the right course of action (MDSAP, ANVISA, INMETRO)
- Sharing experiences and advice for successfully registering products through MDSAP

Participants

Bill Kurani - MSRA, MSEE, Head of RA/QA, Genomics, Agilent Technologies, USA

Mercedes Bayani - Global Director Clinical and Regulatory Affairs, Bioness

SESSIONS

DAY FOUR - 20/06/2019

Industry Case Study: Building a Successful Regulatory Strategy for Drug Device Combination Products

11:25 - 12:00
Drug Device Combination Products

- Discussing strategies for practical implementation of the EU MDR and Article 117 for drug device combination products
- Addressing key conclusions and lessons learned since the release of the EU MDR
- Guidance on working with Notified Bodies to achieve regulatory success

Routes to Market

11:25 - 12:05
TRAINING COURSE: US Regulatory Affairs for Medical Devices

- Device classification

using Section 513(g)

- Premarket notification – 510(k)
  - Traditional
  - Abbreviated
  - Special
  - de novo
  - exemptions

- Predicates and Substantial equivalence
- Premarket Approval – PMA

Spotlight Session: Examining labelling and UDI requirements for IVDs

12:00 - 12:35
IVD Regulation and Strategy

If you are interested in speaking in this session, please contact Linda Cole Tel +44 (0) 20 7017 6631; email *linda.cole@knect365.com*

CASE STUDY: Managing the situation when disputes occur between sponsor and vendor

12:00 - 12:35
Clinical Outsourcing for Medical Device Trials

- Understanding where things might go wrong
- Best practice communication and relationship management between sponsor and vendor
- Overcoming difficulties and differences throughout the trial process
- Examining lessons learned and how to improve future ways of working

Participants

Dr. Victoria J. Cavendish - Director, Orca Solutions Ltd.

Designing an Effective Labelling Strategy for Product Registrations in LATAM

12:00 - 12:35
Medical Device Regulatory Affairs in Emerging Markets

- Examining the unique labelling requirements for the major markets in Latin America
- Clarification on expectations of LATAM regulators and discussing the challenges
- Success stories: how to comply with labelling regulations across the region

Participants

Gloria Schneider-Ferrer - Manager, Global Strategy - Brazil, DePuy Synthes, Switzerland

Panel Session: Regulatory feedback, Plans and Practical Advice for Drug Device Combination Products

12:00 - 12:35
Drug Device Combination Products

- Exploring current regulatory timelines
- Discussing common pitfalls during the registration process and how they can be avoided
- Outlining regulatory expectations, potential challenges and views on where the industry is heading

Participants

Panellist: Kirsten Paulson - Senior Director, Global CMC-Medical Device Lead, Pfizer, US

Julia Frese - Department Manager Centre of Combination Products, , TÜV SÜD Product Service GmbH, Germany

Verification and Validation

12:05 - 12:35
TRAINING COURSE: US Regulatory Affairs for Medical Devices

- Preclinical safety testing
- Clinical evaluation
  - Clinical data
  - Clinical evaluation reports
  - Post-market clinical follow-up

Networking lunch

12:35 - 14:00

Product classification: Understanding the new classification rules for IVDs on the market

14:00 - 14:35
IVD Regulation and Strategy

- Assessing the difference between previous and new classification requirements
- Examining the transition to 4 classes of IVD devices – understanding all products that are in the scope of the regulation
- Undertaking a gap analysis and understanding how to manage the reclassification process and ensure the different stages are managed effectively
- Managing the transition and working with the Notified Body
- Borderline products: common technical specifications – transitioning across to the new common specifications
- Risk benefit/GSPR/new products which don't have a current CTS

Participants

Dieter Schoenwald , TÜV SÜD PRODUCT SERVICE GMBH

Understanding and applying Risk Based Monitoring: Large company perspective

14:00 - 14:35
Clinical Outsourcing for Medical Device Trials

- Strategies for practically implementing risk based monitoring
- Exploring methods of risk identification
- Examining centralized monitoring as a component to take mitigation and other actions

Participants

Nurcan Coskun, Ph.D - Global Risk Based Monitoring & Technology Solutions Program Manager, Medtronic, Switzerland

Industry Experiences of Bringing Products to Market in Mexico

14:00 - 14:35
Medical Device Regulatory Affairs in Emerging Markets

- Industry perspective of the expectations and regulatory requirements during registration with COFEPRIS
- Discussing challenges and strategies for overcoming them
- Experiences and practical guidance for the use of expedited pathways

SESSIONS

DAY FOUR - 20/06/2019

Real life case study: Insulin drug device combination products – practical considerations for compliance and compatibility

14:00 - 14:35
Drug Device Combination Products

- Highlighting the common challenges of insulin combination products
- Best practice for complying with both device and drug regulations when evaluating insulin combination products
- Assessing drug/device compatibility and the impact on biocompatibility, stability, extractables & leachables, reactive leachables and proteins

Quality Management and Manufacturing

14:00 - 15:10
TRAINING COURSE: US Regulatory Affairs for Medical Devices

- Quality standards and guidance
- Manufacturing standards and guidance
- Quality assurance and quality control

Labelling

- Overview and guidance
- Unique Device Identification (UDI)
- UDI final rule and how it has been phased in
- Labels and instructions for use

Classification: Discussing the specific requirements for borderline products

14:35 - 15:10
IVD Regulation and Strategy

- Making the transition to the new common specifications and new requirements
- Risk benefit and GSPR
- Understanding which products will need a new common specification

Examining the key opportunities of Investigator Initiated Trials

14:35 - 15:10
Clinical Outsourcing for Medical Device Trials

- Understanding the current landscape of Investigator Initiated Trials
- Examining the recent increase in conducting IIT's for medical devices
- Exploring the win-win opportunities for site and sponsor including cost savings

Participants

Ruud Nonnekens - Project Manager Investigator Initiated Research, Philips- Image Guided Therapy Device International

LATAM Pain Points Panel Session

14:35 - 15:10
Medical Device Regulatory Affairs in Emerging Markets

- Sharing best practices and success stories of registrations across the region
- Discussing common registration challenges and nonconformities
- Practical advice for building a LATAM regulatory strategy
- Q&A

Participants

Gloria Schneider-Ferrer - Manager, Global Strategy - Brazil, DePuy Synthes, Switzerland

Panel Session: Global Requirements for Combination Products

14:35 - 15:10
Drug Device Combination Products

- Examining combination product classifications and regulations in key global markets
- Sharing experiences with DDCP registration for products around the world
- Common challenges associated with innovative combination product registration in emerging markets

Afternoon networking refreshments

15:10 - 15:40

Notified Body interactive discussion: Designation, resource and capacity

15:40 - 16:40
IVD Regulation and Strategy

- Understanding the timeline for Notified Body designation
- Capacity and resource: Understanding which Notified Bodies support IVDs
- How can industry prepare for Notified Body audits?
- Advice for industry

Participants

Sue Spencer - Head of Global Medical Device Services, UL, UK

Dieter Schoenwald , TÜV SÜD PRODUCT SERVICE GMBH

Nick Baker - Head of IVD Notified Body, LRQA, UK

Andreas Stange - Vice President MHS global IVD, TÜV SÜD

Revision of the ISO 14155: Clinical investigation of medical devices for human subjects-Good clinical practice

15:40 - 16:15
Clinical Outsourcing for Medical Device Trials

- Understanding and aligning with the current revisions of the upcoming third (2020) edition of the ISO 14155
- Examining the differences between the 2011 and 2020 editions
- Evaluating the ISO 14155 alongside MDR Gap Analysis
- Implementing and complying with the changes in the ISO 14155

Participants

Klaas van't Klooster - Clinical Manager, JnJ Medical

Shedding Light on the Progress of Medical Device Regulation in South Africa

15:40 - 16:15
Medical Device Regulatory Affairs in Emerging Markets

- Updates on the draft regulations for medical devices and its impact on industry
- Examining the guidelines for licensing, safety and performance and classification of medical devices and IVDs
- Building a model for successful device registration in South Africa

Participants

Deepa Maharaj - African Regulatory Director, GSK,

Avanthi Bester - Regulatory Affairs Manager Africa, Becton Dickinson

Regulatory Updates from the FDA on Drug Device Combination Products (presentation to be delivered by teleconference)

15:40 - 16:15
Drug Device Combination Products

- Updates on combination products policy
- Recent developments in premarket review (e.g., procedures, pathways, regulatory expectations)
- Recent developments in postmarket regulation (e.g., manufacturing, postmarket safety reporting)

Participants

John Barlow Weiner - Associate Director for Policy, Office of Combination Products, Food and Drug Administration, US

Audits and Inspections

15:40 - 16:20
TRAINING COURSE: US Regulatory Affairs for Medical Devices

SESSIONS

DAY FOUR - 20/06/2019

Panel Session: The Challenges and Opportunities for SaMD and Electronic Devices in the Emerging Markets

16:15 - 16:50
Medical Device Regulatory Affairs in Emerging Markets

- Reviewing the current regulatory landscape for electronic devices, Software as Medical Devices (SaMD) and Cyber Security
- Comparing regulations in the established and emerging markets
- Country Highlights: Australia, China and Russia
- Discussing the current challenges faced when registering these devices
- Assessing the future of medical technology & software regulation in the emerging markets

Participants

Kelvin Koh - Director APAC Regulatory Affairs, Terumo BCT

Challenges faced by global organizations to comply with PMSR Requirements

16:15 - 16:50
Drug Device Combination Products

- Essential Global Regulatory Alignment needed
- Highlight the challenges and solutions faced by industry in a global environment
- Best practices to streamline compliance for successful implementation
- Risk-based approach to PMSR decision-making – Roles / Responsibilities

Participants

Khaudeja Bano - Head of Medical Affairs, Abbott Molecular, US

Post approval considerations in the US

16:20 - 16:50
TRAINING COURSE: US Regulatory Affairs for Medical Devices

- Post-Market Surveillance
- Vigilance
- PMCF

End of conference day four

16:50 - 17:00

SCHEDULE

DAY FOUR - 20/06/2019

TIME	CLINICAL OUTSOURCING FOR MEDICAL DEVICE TRIALS	DRUG DEVICE COMBINATION PRODUCTS	IVD REGULATION AND STRATEGY	MEDICAL DEVICE REGULATORY AFFAIRS IN EMERGING MARKETS	TRAINING COURSE: US REGULATORY AFFAIRS FOR MEDICAL DEVICES
08:00	**08:30** - Registration	**08:30** - Registration	**08:30** - Registration	**08:30** - Registration	**08:30** - Registration
09:00	**09:00** - Opening Remarks from Chairperson **09:10** - Notified Body perspective: Practical advice for industry on meeting new requirements for clinical operations and outsourcing under the MDR **09:45** - Successfully selecting vendors with the most relevant experience for your clinical trials	**09:00** - Opening remarks from the Chairperson **09:10** - An Overview of the Current Regulatory Landscape for Drug Device Combination Products **09:45** - Notified Body Perspective on EU MDR and its Impact on Combination Products	**09:00** - Opening Remarks from Chairperson **09:10** - Managing the transition to IVDR – the road to 2022 **09:45** - Practically preparing for the transition to the IVDR: large company perspective	**09:00** - Opening Remarks from Chairperson **09:10** - ANVISA Feedback – Updates on the Regulatory Landscape and Requirements in Brazil **09:45** - Case Study: Implementing Brazilian Regulatory Requirements for High-Risk Devices	**09:00** - Overview of FDA regulation
10:00	**10:20** - Strategies for successful sponsor/vendor relationship management: SME perspective **10:55** - Morning coffee and networking break	**10:20** - Presentation to be delivered by 3D Communications **10:55** - Morning coffee and networking break	**10:20** - Practically preparing for the transition to the IVDR: small company perspective **10:55** - Morning coffee and networking break	**10:20** - Ensuring Compliance for INMETRO Medical Device Certification **10:55** - Morning coffee and networking break	**10:55** - Morning coffee and networking break
11:00	**11:25** - PANEL: Examining different trial models and assessing the benefit of outsourcing v's in-house	**11:25** - Industry Case Study: Building a Successful Regulatory Strategy for Drug Device Combination Products	**11:25** - Notified Body feedback: Implementing the IVDR	**11:25** - Dual Presentation: Updates and Practical Advice for Registrations Using the MDSAP	**11:25** - Routes to Market
12:00	**12:00** - CASE STUDY: Managing the situation when disputes occur between sponsor and vendor **12:35** - Networking lunch	**12:00** - Panel Session: Regulatory feedback, Plans and Practical Advice for Drug Device Combination Products **12:35** - Networking lunch	**12:00** - Spotlight Session: Examining labelling and UDI requirements for IVDs **12:35** - Networking lunch	**12:00** - Designing an Effective Labelling Strategy for Product Registrations in LATAM **12:35** - Networking lunch	**12:05** - Verification and Validation **12:35** - Networking lunch
13:00					

SCHEDULE

DAY FOUR - 20/06/2019

TIME	CLINICAL OUTSOURCING FOR MEDICAL DEVICE TRIALS	DRUG DEVICE COMBINATION PRODUCTS	IVD REGULATION AND STRATEGY	MEDICAL DEVICE REGULATORY AFFAIRS IN EMERGING MARKETS	TRAINING COURSE: US REGULATORY AFFAIRS FOR MEDICAL DEVICES
14:00	**14:00** - Understanding and applying Risk Based Monitoring: Large company perspective **14:35** - Examining the key opportunities of Investigator Initiated Trials	**14:00** - Real life case study: Insulin drug device combination products – practical considerations for compliance and compatibility **14:35** - Panel Session: Global Requirements for Combination Products	**14:00** - Product classification: Understanding the new classification rules for IVDs on the market **14:35** - Classification: Discussing the specific requirements for borderline products	**14:00** - Industry Experiences of Bringing Products to Market in Mexico **14:35** - LATAM Pain Points Panel Session	**14:00** - Quality Management and Manufacturing
15:00	**15:10** - Afternoon networking refreshments **15:40** - Revision of the ISO 14155: Clinical investigation of medical devices for human subjects-Good clinical practice	**15:10** - Afternoon networking refreshments **15:40** - Regulatory Updates from the FDA on Drug Device Combination Products (presentation to be delivered by teleconference)	**15:10** - Afternoon networking refreshments **15:40** - Notified Body interactive discussion: Designation, resource and capacity	**15:10** - Afternoon networking refreshments **15:40** - Shedding Light on the Progress of Medical Device Regulation in South Africa	**15:10** - Afternoon networking refreshments **15:40** - Audits and Inspections
16:00	**16:50** - End of conference day four	**16:15** - Challenges faced by global organizations to comply with PMSR Requirements **16:50** - End of conference day four	**16:50** - End of conference day four	**16:15** - Panel Session: The Challenges and Opportunities for SaMD and Electronic Devices in the Emerging Markets **16:50** - End of conference day four	**16:20** - Post approval considerations in the US **16:50** - End of conference day four

SESSIONS

DAY FIVE - 21/06/2019

Registration

08:30 - 09:00

Opening remarks from the Chairperson

09:00 - 09:10
IVD Regulation and Strategy

Opening remarks from the Chairperson

09:00 - 09:10
Medical Device Regulatory Affairs in Emerging Markets

Opening remarks from the Chairperson

09:00 - 09:10
Drug Device Combination Products

Chair's Opening Remarks

09:00 - 09:10
Sterilisation and Reprocessing of Medical Devices

Clinical guidance for IVDs: Feedback from the European Commission IVD Technical Group

09:10 - 09:45
IVD Regulation and Strategy

Participants

Sue Spencer - Head of Global Medical Device Services, UL, UK

Navigating the Russian Regulatory Requirements for Medical Devices

09:10 - 09:45
Medical Device Regulatory Affairs in Emerging Markets

- Exploring the latest regulatory requirements from Roszdravnadzor
- Guidance on the necessary preparation for GMP inspections
- Practical advice for successfully registering products in Russia

Participants

Alexey Stepanov - Quality Assurance and Regulatory Affairs Manager, Medical Devices in Russia, Russia

Dual dialogue: Creating an Effective End-to-End Quality Management System for DDCPs

09:10 - 09:45
Drug Device Combination Products

- Clarifying the guidelines on quality management requirements for combination products across the life-cycle
- Tips for managing changes and risk for controlling quality in the supply chain
- Discussing quality challenges and how to overcome them

Participants

Judith Svarczkopf - Principal Technical Advisor, Genentech, US

Kerstin Cleek - Global Pharma Quality Systems Implementation Lead, F. Hoffmann-La Roche Ltd, Basel, Switzerland

STERILISATION AND REPROCESSING REGULATORY UPDATE: MDR, ISO Standards and New Legislation on Reprocessing Single Use Devices

09:10 - 09:45
Sterilisation and Reprocessing of Medical Devices

- MDR impact: changes to sterilisation, packaging and labelling requirements
- Reprocessing Class I reusable medical devices
- Examining new Dutch legislation on sterilisation and reprocessing of single use devices

Participants

Arjan van Drongelen - Scientific Officer, Project Leader, The Dutch National Institute for Public Health and the Environment (RIVM), The Netherlands

Understanding and practically preparing for the new clinical evidence requirements for IVDs under the IVDR

09:45 - 10:20
IVD Regulation and Strategy

- How is clinical evidence defined in the IVDR
- Analytical vs. clinical performance studies
- New aspects, e.g. scientific validity vs clinical utility, clinical benefit, risk/benefit
- Clinical evidence levels
- Clinical performance data
- Practically implementing the new requirements

Participants

Anne Timonen - Clinical Study Manager & Global Study Manager, PerkinElmer

Anna Sahlberg - Clinical Study Manager, PerkinElmer

Case Study: Best Practice for Successful IVD Product Registrations in Russia

09:45 - 10:20
Medical Device Regulatory Affairs in Emerging Markets

- Tackling the expectations of Roszdravnadzor during registrations
- Developing a comprehensive strategy for product approval in Russia
- Practical advice for overcoming regulatory hurdles and nonconformities

Participants

Zaman Khan - Associate Director, Regulatory Affairs, South East Europe, Middle East, Africa, CIS, and Pakistan, Abbott GmbH & Co. KG, Germany

Medic's input in Defining Harm, Severity of Harm and P2 for Drug Device/Device Drug Combination Products

09:45 - 10:20
Drug Device Combination Products

- Appropriately defining Harms that occur due to a Hazardous situation
- Understanding the severity (of harm) scale
- Understanding what P2 is
- Examining methodologies and complexities involved in estimating P2
- Assessing Medic's input in defining harms, severity and P2

Participants

Asif Mahmood - Disease Area Cluster Lead (Drug Delivery Devices & Combination products)/Senior Director, Worldwide Safety, Pfizer, US

PRACTICAL SESSION Requirements for Certification of Reusable Class I Medical Devices

09:45 - 10:20
Sterilisation and Reprocessing of Medical Devices

- Reprocessing steps and what to validate
- Additional challenges when outsourcing reprocessing
- Step by step examination of the certification process
- Practical guidance on what to submit for validations

Participants

Jan Havel - Global Director – General Essential Modules (GEM) Biocompatibility, Sterilization, Packaging, TÜV SÜD Product Service GmbH, Germany

SESSIONS

DAY FIVE - 21/06/2019

Assessing post market surveillance requirements under the IVDR and ensuring compliance

10:20 - 10:55
IVD Regulation and Strategy

- Clarifying the difference between the previous and new post market surveillance requirements
- Understanding how to generate post market data for IVDs
- Best practice for data collection and review procedures: putting a system in place to access and assess clinical data
- Why your marketing colleagues should listen and understand that their work is now a regulatory requirement

Participants

Maurizio Suppo - Vice President Regulatory Affairs, QARAD, Italy

Challenges in Developing Appropriate Strategy to Clinical Conformity Assurance Across the CIS Region

10:20 - 10:55
Medical Device Regulatory Affairs in Emerging Markets

- An overview of regulatory requirements to clinical evidence across the region: highlighting the similarities and differences between countries
- Assessing potential challenges during clinical conformity evaluations for device approval
- Sharing experiences with determining the appropriate route to clinical evidence generating

Participants

Iryna Berchak - Head of Regulatory Compliance Department, Yuria-pharm, Ukraine

Biocompatibility Requirements for a Drug Device Combination Product

10:20 - 10:55
Drug Device Combination Products

- Exploring the recent changes to the ISO 10993 standards
- Analysing the current revision of ISO 10993-1 and its effect on combination products
- What is expected? Outlining dossier and testing requirements for successful product applications

Participants

Laurence Lister - Director of Biocompatibility, Toxikon

INDUSTRY CASE STUDY Lifecycle Management of Reusable Medical Devices: Reprocessing Validation

10:20 - 10:55
Sterilisation and Reprocessing of Medical Devices

- Validating reprocessing lifecycles: case studies
- Challenges that need to be addressed during validation studies
- Validating reprocessing lifecycles: gaps in current regulatory guidelines

Participants

Stefanie Roberfroid - Study Director Microbiology, Nelson Laboratories LLC, Belgium

Morning networking refreshments

10:55 - 11:25

Key vigilance reporting updates under the IVDR

11:25 - 12:00
IVD Regulation and Strategy

- Understanding new vigilance reporting requirements under the IVDR
- Providing an update on the Periodic Safety Update Reports (PSURS) and the Manufacturer Incident Form (MIR)
- An update on the trend reporting form

Current Status of the EEU Regulations for Medical Devices

11:25 - 12:00
Medical Device Regulatory Affairs in Emerging Markets

- Where does the EEU stand on the implementation of their medical device framework?
- How best to prepare for the implementation of EEU regulation?
- Assessing potential challenges and developing strategies to manage them

Participants

Margaret Bessenbach - Manager Regulatory Affairs and Quality, 3M

Examining the impact of the MDR on the borderline between medicinal products, substance-based devices and combination products

11:25 - 12:00
Drug Device Combination Products

- Understanding how to come up with the correct product category for your products
- New guidelines – what is needed and planned from the regulators?

Participants

Jörg Plessl - Director EU Affiliates, Regulatory Affairs, Norgine

INDUSTRY CASE STUDY Optimisation of the Ethylene Oxide (EO) Sterilisation Process

11:25 - 12:00
Sterilisation and Reprocessing of Medical Devices

- Optimisation of sterilisation processes to reduce product cycle time and increase efficiencies
- Dynamic processing: ensuring efficient turnaround time for sterilisation activities and driving down residual levels
- Optimisation through validation approach

Participants

Jan Douglas - Engineering Manager, Cook Medical, Denmark

Understanding the new responsibilities for economic operators and the changes to Authorised Representatives under the IVDR

12:00 - 12:35
IVD Regulation and Strategy

- Determining the new economic operator structure
- Understanding the scope
- Structuring and classifying economic operators
- Strategies to ensure authorised representatives and distributers comply with the regulation
- Examining the role of the person responsible for regulatory compliance
- Understanding the role of EU reference labs and expert panels

Participants

Sinem Yaman - Vice President, Regulatory Affairs EMEA, Sysmex Europe

SESSIONS

DAY FIVE - 21/06/2019

Exploring the Latest Regulatory Requirements in Kazakhstan

12:00 - 12:35
Medical Device Regulatory Affairs in Emerging Markets

- An overview of the Kazakhstani regulatory framework and requirements for product registration
- An update on the expectations and procedures for clinical trials
- Building a comprehensive QMS strategy in preparation for Ministry of Health GMP audits

Participants

Stephanie Haselwanter - Regulatory Affairs Specialist, MED-EL

Substance Based Devices: an analysis of the EU MDR requirements

12:00 - 12:35
Drug Device Combination Products

- Discussing the regulation and understanding the definitions of substance-based devices
- Exploring the impact of the higher classification of substance-based devices
- Unpacking the consultation process
- Conformity assessment routes and tips for successful submissions

Participants

Elizma Parry - Director, Global Clinical Practice, MAETRICS

INDUSTRY CASE STUDY Reducing Ethylene Oxide (EO) Residue Levels and Compliance to ISO 10993-7

12:00 - 12:35
Sterilisation and Reprocessing of Medical Devices

- Reviewing requirements for compliance with ISO 10993-7
- Practical insight into adjusting EO parameters: temperature, humidity and concentration
- Examining how industry should demonstrate their products are at acceptable sterility levels to comply with the standards through labelling

Participants

Tim Carlson - Sterilization Program Manager, Global Sterilization Assurance, BD, USA

Networking lunch

12:35 - 14:00

Understanding how Companion Diagnostics are developed

14:00 - 14:35
IVD Regulation and Strategy

- Examining the process of working with Notified Bodies and the EMA
- Gathering clinical evidence for the development of Companion Diagnostics
- Examining the challenges and opportunities associated with co-development of Companion Diagnostics (developing the drug and the assay together)
- Strategies for ensuring drug and patient safety

Panel Session: Sharing Experiences with Registrations in the CIS Region

14:00 - 14:35
Medical Device Regulatory Affairs in Emerging Markets

- Highlighting the similarities and differences of regulatory requirements across the region
- Sharing experiences with strategies for bringing products to market in the CIS countries
- Determining the challenges, opportunities and best practice during the registration process

Participants

Iryna Berchak - Head of Regulatory Compliance Department, Yuria-pharm, Ukraine

Anna Koptina - Regulatory Affairs Manager, Nestlé Skin Health, Sweden

Case study: SEIZE IT – solving the unmet need

14:00 - 14:35
Drug Device Combination Products

- How to make Public private initiative a success
- Co-creating with the patients to solve an unmet need
- A mid-size pharma, university and startups working together
- EIT health grant – 2,75 million Euro to further develop and clinically validate the device
- Oxford, King`s college, Freiburg, Karolinska, Aachen, Leuven, Coimbra
- Class II A certification and the MDD effect today

Participants

Gergely Vertes - Solution Acceleration Lead, UCB, Belgium

INDUSTRY CASE STUDY: Evaluating the Interaction between Sterilisation, Packaging and Biocompatibility

14:00 - 14:35
Sterilisation and Reprocessing of Medical Devices

- Examining key process parameters and key product considerations
- Understanding the interplay between sterilisation, packaging and biocompatibility
- Reviewing challenging validations that have arisen

Participants

Daniel Herber - Senior Project Microbiologist, Zimmer Biomet, Switzerland

Examining the regulatory requirements for companion diagnostics

14:35 - 15:10
IVD Regulation and Strategy

- How are companion diagnostics regulated under the IVDR?
- Understanding steps companion diagnostics manufacturers need to prepare for implementation
- Assessing the difference between US and EU Companion Diagnostic regulations and understanding the challenges this may present
- Advice for industry

Participants

Camilla Recke - Regional CDx Regulatory Affairs Program Manager, Europe, Agilent Technologies Denmark

Ministry of Health Feedback: Medical Devices and Regulatory Affairs in Turkey

14:35 - 15:10
Medical Device Regulatory Affairs in Emerging Markets

- Updates on the implementation and use of the UTS system and its impact on industry
- Exploring the latest requirements for labelling (UDI)
- Discussing industry challenges and how to overcome them
- Strategies for accelerating device approvals for faster time-to-market

Participants

Olgun Sener - Public Administration Expert, Turkish Ministry of Health

SESSIONS

DAY FIVE - 21/06/2019

Digital Health: Exploring the Interaction of Drug Device Combination Products and Software

14:35 - 15:10
Drug Device Combination Products

- Outlining EU and US regulatory requirements for software and app incorporation with combination products
- Discussing the classification regulations and evaluation challenges for these products
- Effective human factors testing, labelling and PMS options for digital combination products

Microbiological Monitoring of Product and Production Clean Rooms

14:35 - 15:10
Sterilisation and Reprocessing of Medical Devices

- Update on standards for Bioburden testing, environmental monitoring and Bacterial Endotoxin
- Bioburden and ISO 11737-1:2018 changes
- What to look for when using an external bioburden test laboratory
- Best practice for monitoring frequency and alert / action levels

Participants

Henry Sibun - Director of Henry Sibun Associates Ltd, External Notified Body Reviewer/Lead Auditor, TÜV SÜD Product Service, UK

Afternoon networking refreshments

15:10 - 15:40

Panel discussion: Portfolio rationalisation for IVDs – feedback from industry, Notified Bodies and Competent Authorities

15:40 - 16:40
IVD Regulation and Strategy

- Sharing experiences of how manufacturers are deciding which products to keep on the market
- Examining key challenges facing the industry regarding portfolio rationalisation
- Strategies for evaluating products in the most time-efficient way
- Understanding how Competent Authorities manage the process

Speakers from the Day

Exploring the Latest Regulatory Framework for Medical Devices in the Middle East

15:40 - 16:15
Medical Device Regulatory Affairs in Emerging Markets

- Discussing recent regulatory developments in the region
- Spotlight countries: Saudi Arabia, Jordan and the UAE discussing highlights and timelines
- Best practice for creating a harmonised dossier for product registration in the Middle East

Participants

Mercedes Bayani - Global Director Clinical and Regulatory Affairs, Bioness

Case Study on Advanced Therapy Medicinal Products (ATMPs): Regulatory Requirements and Best Approval Pathway

15:40 - 16:15
Drug Device Combination Products

- Industry perspective on borderline product approvals in the EU and US
- Evaluating risk classification, testing strategies and clinical trial requirements for advanced therapy combination products
- Sharing experiences of the challenges and opportunities associated with ATMPs in combination products

Participants

Alexander Natz - Director General, EUCOPE, Belgium

INDUSTRY CASE STUDY Gamma Sterilisation Validation and Monitoring

15:40 - 16:15
Sterilisation and Reprocessing of Medical Devices

- Process overview: key process parameters and key product considerations
- Different validation methods: benefits and drawbacks
- Process development and process improvement: sharing best practice advice

Participants

Arthur Dumba - Director General Manager, Society for Sterility Assurance Professionals (SfSAP), Switzerland

An Issue of Global Proportions: Addressing the Impact of the EU MDR on Emerging Markets

16:15 - 16:50
Medical Device Regulatory Affairs in Emerging Markets

- Discussing the impact of the updated EU MDR on the CIS region including Ukraine and Turkey
- Assessing the potential challenges around imported devices and countries that currently use the EU MDD framework

Participants

Zaman Khan - Associate Director, Regulatory Affairs, South East Europe, Middle East, Africa, CIS, and Pakistan, Abbott GmbH & Co. KG, Germany

Anna Koptina - Regulatory Affairs Manager, Nestlé Skin Health, Sweden

Case Study: Practical Implementation of Sterilisation Processes for Drug Device Combination Products

16:15 - 16:50
Drug Device Combination Products

- Discussing the required documentation that Competent Authorities will request for sterilisation
- Best practice for sterilisation testing and packaging for combination products
- Determining how the medical device and drug components create sterilisation challenges and how to overcome them

Participants

Tim Carlson - Sterilization Program Manager, Global Sterilization Assurance, BD, USA

Standards and Approaches for Packaging Validation

16:15 - 16:50
Sterilisation and Reprocessing of Medical Devices

- Experiences of new Standards of EN ISO 11607 and regulatory gaps
- Examining strategies to ensure robust packaging processes for transport, temperature and altitude
- Assessing the steps to take to ensure processes are in place to ensure packaging is supporting best practice for usability evaluations: challenges to retain sterility
- Common pitfalls for packaging sterility

Participants

Jan Havel - Global Director – General Essential Modules (GEM) Biocompatibility, Sterilization, Packaging, TÜV SÜD Product Service GmbH, Germany

Chair's Closing Remarks

16:50 - 17:00

SESSIONS

DAY FIVE - 21/06/2019

End of Conference

17:00 - 17:10

SCHEDULE

DAY FIVE - 21/06/2019

TIME	DRUG DEVICE COMBINATION PRODUCTS	IVD REGULATION AND STRATEGY	MEDICAL DEVICE REGULATORY AFFAIRS IN EMERGING MARKETS	STERILISATION AND REPROCESSING OF MEDICAL DEVICES
08:00	**08:30** - Registration	**08:30** - Registration	**08:30** - Registration	**08:30** - Registration
09:00	**09:00** - Opening remarks from the Chairperson **09:10** - Dual dialogue: Creating an Effective End-to-End Quality Management System for DDCPs **09:45** - Medic's input in Defining Harm, Severity of Harm and P2 for Drug Device/Device Drug Combination Products	**09:00** - Opening remarks from the Chairperson **09:10** - Clinical guidance for IVDs: Feedback from the European Commission IVD Technical Group **09:45** - Understanding and practically preparing for the new clinical evidence requirements for IVDs under the IVDR	**09:00** - Opening remarks from the Chairperson **09:10** - Navigating the Russian Regulatory Requirements for Medical Devices **09:45** - Case Study: Best Practice for Successful IVD Product Registrations in Russia	**09:00** - Chair's Opening Remarks **09:10** - STERILISATION AND REPROCESSING REGULATORY UPDATE: MDR, ISO Standards and New Legislation on Reprocessing Single Use Devices **09:45** - PRACTICAL SESSION Requirements for Certification of Reusable Class I Medical Devices
10:00	**10:20** - Biocompatibility Requirements for a Drug Device Combination Product **10:55** - Morning networking refreshments	**10:20** - Assessing post market surveillance requirements under the IVDR and ensuring compliance **10:55** - Morning networking refreshments	**10:20** - Challenges in Developing Appropriate Strategy to Clinical Conformity Assurance Across the CIS Region **10:55** - Morning networking refreshments	**10:20** - INDUSTRY CASE STUDY Lifecycle Management of Reusable Medical Devices: Reprocessing Validation **10:55** - Morning networking refreshments
11:00	**11:25** - Examining the impact of the MDR on the borderline between medicinal products, substance-based devices and combination products	**11:25** - Key vigilance reporting updates under the IVDR	**11:25** - Current Status of the EEU Regulations for Medical Devices	**11:25** - INDUSTRY CASE STUDY Optimisation of the Ethylene Oxide (EO) Sterilisation Process
12:00	**12:00** - Substance Based Devices: an analysis of the EU MDR requirements **12:35** - Networking lunch	**12:00** - Understanding the new responsibilities for economic operators and the changes to Authorised Representatives under the IVDR **12:35** - Networking lunch	**12:00** - Exploring the Latest Regulatory Requirements in Kazakhstan **12:35** - Networking lunch	**12:00** - INDUSTRY CASE STUDY Reducing Ethylene Oxide (EO) Residue Levels and Compliance to ISO 10993-7 **12:35** - Networking lunch
13:00				

SCHEDULE

DAY FIVE - 21/06/2019

TIME	DRUG DEVICE COMBINATION PRODUCTS	IVD REGULATION AND STRATEGY	MEDICAL DEVICE REGULATORY AFFAIRS IN EMERGING MARKETS	STERILISATION AND REPROCESSING OF MEDICAL DEVICES
14:00	**14:00** - Case study: SEIZE IT – solving the unmet need **14:35** - Digital Health: Exploring the Interaction of Drug Device Combination Products and Software	**14:00** - Understanding how Companion Diagnostics are developed **14:35** - Examining the regulatory requirements for companion diagnostics	**14:00** - Panel Session: Sharing Experiences with Registrations in the CIS Region **14:35** - Ministry of Health Feedback: Medical Devices and Regulatory Affairs in Turkey	**14:00** - INDUSTRY CASE STUDY: Evaluating the Interaction between Sterilisation, Packaging and Biocompatibility **14:35** - Microbiological Monitoring of Product and Production Clean Rooms
15:00	**15:10** - Afternoon networking refreshments **15:40** - Case Study on Advanced Therapy Medicinal Products (ATMPs): Regulatory Requirements and Best Approval Pathway	**15:10** - Afternoon networking refreshments **15:40** - Panel discussion: Portfolio rationalisation for IVDs – feedback from industry, Notified Bodies and Competent Authorities	**15:10** - Afternoon networking refreshments **15:40** - Exploring the Latest Regulatory Framework for Medical Devices in the Middle East	**15:10** - Afternoon networking refreshments **15:40** - INDUSTRY CASE STUDY Gamma Sterilisation Validation and Monitoring
16:00	**16:15** - Case Study: Practical Implementation of Sterilisation Processes for Drug Device Combination Products **16:50** - Chair's Closing Remarks	**16:50** - Chair's Closing Remarks	**16:15** - An Issue of Global Proportions: Addressing the Impact of the EU MDR on Emerging Markets **16:50** - Chair's Closing Remarks	**16:15** - Standards and Approaches for Packaging Validation **16:50** - Chair's Closing Remarks
17:00	**17:00** - End of Conference	**17:00** - End of Conference	**17:00** - End of Conference	**17:00** - End of Conference