## RAPS Regulatory Conference Europe 2019

Where Global Experts Meet  

13-14 May 2019  
Radisson Blu Royal Hotel, Brussels

### SCHEDULE*

<table>
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<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>8:30–15:00</td>
<td>Conference Registration</td>
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<tr>
<td>9:00–09:15</td>
<td>Opening Remarks</td>
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<tr>
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<td><strong>Panelists:</strong> Gert Bos, Qserve; Bassil Akra, TÜV SÜD Product Service GmbH; Oliver Bisazza, MedTech Europe; Sabina L. Hoekstra-van den Bosch, Central Committee for Research Involving Human Subject (CCMO); Graeme Tunbridge, Medicines &amp; Healthcare Products Regulatory Agency; Valerie Nys, Federal Agency of Medicines and Health Products (FAMHP); Maren von Fritschen, Ph.D., European Confederation of Pharmaceutical Entrepreneurs (EUCOPE); Erik Hansson, European Commission; Armin Ritzhaupt, European Medicines Agency and Waldo Weijers, Medicines Evaluation Board (NL)</td>
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<td>New medical devices regulations (MDR, IVDR) and other regulatory developments in Europe significantly impact EU market access for device, IVD, combination products and pharmaceutical products. Hear the latest critical insights from prominent thought leaders and influencers; authorities, regulators and industry representatives will highlight what’s high on their radar and action lists. Concise summary presentations from experts followed by interactive panel with audience participation to guide understanding of the requirements and discuss implementation challenges.</td>
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<tr>
<td>10:30–11:00</td>
<td>Break - Royal Foyer &amp; Capitals Room</td>
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<tr>
<td>11:00–12:00</td>
<td>Concurrent Schedule of Sessions</td>
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<td></td>
<td><strong>In Vitro Diagnostics Focused Session:</strong></td>
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<tr>
<td></td>
<td>- Clinical Evidence and Clinical Performance Study Requirements Under the New European IVD Regulation</td>
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<td><strong>Session Leader:</strong> Maria E. Donawa, Donawa Lifescience Consulting</td>
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<td><strong>Session Speakers:</strong> Daniela Karrer, Donawa Lifescience Consulting and Sandra Bulger, PROSYSTEM</td>
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<tr>
<td>11:00–17:30</td>
<td>Exhibit Hall Open</td>
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<td>12:00–13:30</td>
<td>Lunch - Royal Foyer &amp; Capitals Room</td>
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<td><strong>Medical Devices – MDR Focused Session:</strong></td>
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<tr>
<td></td>
<td>- Post-Brexit Medical Devices Regulation</td>
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<td><strong>Session Leaders and Speakers:</strong> Paul Brooks, RAPS; Graeme Tunbridge, Medicines &amp; Healthcare Products Regulatory Agency; Philippe Auclair, Abbott</td>
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<td><strong>Pharmaceutical Focused Session:</strong></td>
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<td>- A New Look at EU Pediatric Investigation Plans (PIPs) and FDA Pediatric Study Plans (PSPs)</td>
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<td><strong>Session Leaders and Speakers:</strong> Klaus Rose, klausrose Consulting, Pediatric Drug Development &amp; More and Dimitrios Anthanasiou, EURORDIS</td>
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<tr>
<td>14:30–15:00</td>
<td>Break - Royal Foyer &amp; Capitals Room</td>
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<td><strong>Medical Devices – MDR Focused Sessions:</strong></td>
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<tr>
<td></td>
<td>- A Manufacturer’s View: Regulatory Strategy for Migrating Product Portfolio of High-Risk Devices to Medical Devices Regulation Requirements</td>
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<td><strong>Session Leaders and Speakers:</strong> Sophie Tabutin, W.L. Gore &amp; Associates, Inc. and Patrick Biggerstaff, W.L. Gore &amp; Associates, Inc.</td>
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<td>- Clinical Evaluations: Practical Advice on Gold-Standard Literature Reviews and Overcoming Major Logistical Challenges</td>
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<td><strong>Session Leaders and Speakers:</strong> Leo Hovestadt, Elekta and Isabella Steffensen, Thera-Business Consulting</td>
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<td>16:00–17:00</td>
<td>Break - Royal Foyer &amp; Capitals Room</td>
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<td>17:00–18:00</td>
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<td><strong>Pharmaceutical Focused Session:</strong></td>
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<tr>
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<td>- How to Deal with Global Ambiguity in Regulation of Non-Biological Complex Drug Follow-on Products, Are They Generic, Similar, Or...?</td>
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<td><strong>Session Leader:</strong> Pieter Stolk, Lygature - NBCD Working Group</td>
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<td><strong>Speakers:</strong> H. (Bert) G.M. Leufkens, Lygature – NBCD Working Group and Henrike Potthast, Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)</td>
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14:30–15:30  Concurrent Schedule of Sessions

Medical Devices – MDR Focused Sessions

- Can EU Regulations Requirements on NBS Organization and Certification Services Modify the Relationship with the Manufacturers and Product Conformity Demonstration?
  
  **Session Leaders and Speakers:** Corinne Delorme, GMED Group LNE and Olivier Lantres, Fieldfisher

- GCP inspections of Clinical Investigations Under the MDR
  
  **Session Leader:** Sabina L. Hoekstra-van den Bosch, Central Committee for Research Involving Human Subject (CCMO)

  **Session Speakers:** Tim De Schutter, Federal Agency of Medicines and Health Products; Steve Eglem, AFMPH (Competent Authority of Belgium); and Manon Gielkens, Medtronic

Pharmaceutical Focused Session

- CHMP Oral Explanations and FDA Advisory Committee Meetings - Understanding Similarities and Differences to Optimize Your Preparation
  
  **Session Leaders and Speakers:** Cindy DiBiasi, 3D Communications, LLC and Bert Regeer, MD – 3D Communications LLC

15:30–16:00  Break - Royal Foyer & Capitals Room

16:00–17:00  Concurrent Schedule of Sessions

In Vitro Diagnostics Focused Session

- SME Concerns About their IVD Transition Under the New IVDR by 2022
  
  **Session Leaders and Speakers:** Luc Van Hove, MARACA International bvba and Carole Harris, Biocartis

Medical Devices – MDR Focused Session

- Practical Implementation of the Person Responsible for Regulatory Compliance Role
  
  **Session Leader and Speaker:** Leo Hovestadt, Elekta

Pharmaceutical Focused Session

- Regulators’ Expectations: Quality Risk Management in Pharmaceuticals
  
  **Session Leaders and Speakers:** Muhammad Naeem, Indus Pharma Private Limited and Muhammad Zubair, Indus Pharma Private Limited

17:00–18:00  Concurrent Schedule of Sessions

In Vitro Diagnostics Focused Session

- Medical Device Single Audit Program and In Vitro Diagnostics: Is it for My Company?
  
  **Session Leader and Speaker:** Hilary A. Baldwin, Caris Life Sciences

Medical Devices – MDR Focused Session

- Impact of MDR on Self-Certification: NCA Point of View
  
  **Session Leader and Speaker:** Katrien A. Martens, Federal Agency of Medicines and Health Products (FAMHP) - DG Inspection

  **Session Speaker:** Valerie Nys, Federal Agency of Medicines and Health Products (FAMHP)

Medical Devices & General RA Focused Session

- Cultural Intelligence for the Global Regulatory Affairs Professional
  
  **Session Leader and Speaker:** Susan Hibbeln, Network Partners; Lilianna Hibbeln, Medline

18:00–20:00  Reception

Tuesday, 14 May 2019

8:30–15:00  Conference Registration
8:30–16:00  Exhibit Hall Open
8:30–9:30  Concurrent Schedule of Sessions

In Vitro Diagnostics Focused Session

- In Vitro Medical Diagnostics Regulation—What Do ‘They’ Expect for Clinical Performance? Focus on Manufacturers IVDs and In-House Developed Devices
  
  **Session Leader:** Anja Wiersma, mi-CE consultancy

  **Speakers:** Andreas F. Stange, TÜV SÜD and Kees Maquelin, Afdeling Medische Technologie, Dutch Competent Authority

Medical Devices & General RA Focused Session

- Regulatory Requirements and Field Traceability for Stand-Alone Software Products
  
  **Session Leader and Speaker:** Amanda Brown, Beckman Coulter

Pharmaceutical Focused Session

- Brexit: The Latest Updates
  
  **Session Leader:** Adriaan N. Fruijtier, CATS Consultants GmbH

  **Session Speakers:** Parastoo Karoon, PAREXEL International and Marie-Helene Pinheiro, European Medicines Agency

9:30–10:30  Concurrent Schedule of Sessions

Medical Devices & General RA Focused Sessions

- How to Prepare for China Overseas Inspections
  
  **Session Leaders and Speakers:** Gert W. Bos, Qserve and Zeli Yu, Yuzeli Medteconsultant Inc.

- More Emphasis on Toxicological Risk Assessments in Medical Device Safety Evaluation
  
  **Session Leader and Speaker:** Albrecht Poth, knoell Germany GmbH

  **Session Speaker:** Anja Ramisch, knoell Germany, GmbH

Pharmaceutical Focused Session

- Trends in Market and Patient Access of Advanced Therapy Medicinal Products (ATMPs) in Ultra-Rare Conditions
  
  **Session Leader:** David Schwicker, ORPHA Strategy Consulting

10:30–11:00  Break - Royal Foyer & Capitals Room
11:00–12:00  Concurrent Schedule of Sessions
Medical Devices & General RA Focused Sessions

• The Gloom and Doom of Coming to America: The Reality of Regulatory Pathways, Timelines and Processes to Reach Approval
  
  **Session Leader & Speaker:** Tracy Eberly, Fang Consulting Ltd.

• Global Regulatory and Clinical Strategies: A New Paradigm for Integrated Product Design and Development?
  
  **Session Leader:** Robin Stephens, Psephos Biomedica
  
  **Session Speakers:** Semih Oktay, CardioMed Device Consultants LLC and Chao Xu, JMedTec

Pharmaceutical Focused Session

• Medical Device Regulation (MDR, Article 117): Impact on Pharma and Biotech Companies and State-of-Play
  
  **Session Leader and Speaker:** Urs Widmer, Confinis

  **Session Speakers:** Gert Bos, Qserve and Armin Ritzhaupt, European Medicines Agency

12:00–13:30  Lunch - Royal Foyer & Capitals Room

13:30–14:30  Concurrent Schedule of Sessions

Medical Devices & General RA Focused Session

• Organizing, Driving and Maintaining a Successful MDSAP Audit Process
  
  **Session Leaders and Speakers:** Lillie Crotts Thomas, AirStrip Technologies Inc., and Sam Rajkumar, Exact Imaging

Pharmaceutical Focused Session

• Global Regulatory Challenges during the Development of Investigational Products (IP) based on Genetically Modified Organism (GMO)
  
  **Session Leader and Speaker:** Kathryn Parsley, Boyd Consultants

Medical Devices – MDR Focused Session

• Substance-Based Medical Devices and the Regulatory Implications of the EU Medical Device Regulation (EU 2017/745)
  
  **Session Leaders and Speakers:** Anja Wiersma, mi-CE consultancy and Inette Nieveen, Qserve Group

14:30–15:30  Concurrent Schedule of Sessions

Pharmaceutical Focused Session

• EMA’s PRIority Medicines Scheme (PRIME): How to Make it More Successful
  
  **Session Leader and Speaker:** Adriaan N. Fruijtier, CATS Consultants GmbH

  **Session Speaker:** Marie-Helene Pinheiro, European Medicines Agency

Medical Devices – MDR Focused Session

• Implementation of the New Obligations of Economic Operators Under the European Medical Device Regulation
  
  **Session Leader:** Philippe Lartigue, GE Healthcare

  **Session Speakers:** Philippe Lartigue, GE Healthcare; Phillipe Soly, Philips Healthcare Systems, and Angele Taormina, GE Healthcare Systems

15:30–16:00  Farewell Coffee - Royal Foyer & Capitals Room
Wednesday, 15 May 2019

**MDR Workshop: Transitioning to the EU MDR and Managing Legacy Devices Implementation of the MDR**

8:00 Registration

8:30 – 9:00 Welcome
  Determining the Need of the Attendants
  Open Questions/ Experiences/ Open Cases
  Gert Bos, Qserve Group

9:00 – 9:30 Overview of the New Regulation:
  • Outline of the MDR
  • Strategic Timelines
  • Implementation of the New Regulation at CA and Notified Bodies
  Bassil Akra, TÜV SÜD

9:30 Coffee

9:30 - 11:00 Interactive Workshop on Legacy Products and Transition Strategy
  Philippe Auclair, Abbott (invited)

11:00 - 12:30 Interactive Workshop MDR General Safety and Performance Requirements
  Gert Bos, Qserve Group

12:30 - 13:15 Lunch

13:15 Interactive Workshop MDR and Economic Operators: Importer, Distributor EU REP
  Philippe Auclair, Abbott (invited)

14:45 – 15:00 Break

15:00 – 16:30 Interactive Workshop on Clinical Evidence, PMS and PMCF Requirements MDR
  Bassil Akra, TÜV SÜD

16:30 – 17:00 Closing panel Discussion and Q&A - All speakers

17:00 Closing meeting

* Subject to change
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           Anja Wiersma, mi-CE consultancy |
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          • Outline of the IVDR  
          • Strategic Timelines  
          • Implementation of the New Regulation at CA and Notified Bodies  
          Andreas Stange, TÜV SÜD |
| 9:30     | Coffee                                                                |
| 9:30 – 11:00 | Interactive Workshop on Legacy Products and Transition Strategy  
                Simon Richards, Abbott Diagnostics Business |
| 11:00 – 12:30 | Interactive Workshop IVDR General Safety and Performance Requirements  
                    Andreas Stange, TÜV SÜD |
| 12:30 – 13:15 | Lunch                                                              |
                        Dirk Stynen, Qarad BVBA |
| 14:45 – 15:00 | Break                                                               |
| 15:00 – 16:30 | Interactive Workshop on Clinical Evidence, PMS and Performance Evaluation Requirements IVDR  
                        Anja Wiersma, mi-CE Consultancy |
| 16:30 – 17:00 | Closing Panel Discussion and Q&A - All speakers                      |
| 17:00     | Closing meeting                                                       |