26–30 October 2020
FULL SCHEDULE
REGISTER NOW > raps.org/europe-2020/register
PRE-CONFERENCE WORKSHOPS

**09:00 – 16:00 CET**

*Developing a Global Unique Device Identification (UDI) Program*
- Lena Cordie-Bancroft, Qualitas Professional Services, LLC

*Usage of Standardised Test Methods to Comply with the General Safety and Performance Requirements*
- Bassil Akra, PhD, QUNIQUE GmbH

CONFERENCE DAY-1

**08:30 – 15:30 CET**

*Clinical Studies in PMCF*
- Sabina Hoekstra-van den Bosch, PharmD, FRAPS, TÜV SÜD Product Service GmbH

*In Vitro Diagnostics Regulation (IVDR)*
- Anja Wiersma, PhD, mi-CE consultancy

*Software as a Medical Device*
- Koen Cobbaert, MA, Philips

**CLINICAL STUDIES IN PMCF**
- Bassil Akra, MSc, PhD, TÜV SÜD Product Service GmbH

OPENING PLENARY SESSION

**15:30 – 17:30 CET**

*Opening Plenary*
- Sabina Hoekstra-van den Bosch, PharmD, FRAPS, TÜV SÜD Product Service GmbH
- Gert Bos, PhD, FRAPS, Qserve Group
- Simon Richards, PhD, Abbott Rapid Diagnostics
- Natascha Cuper, PhD, DARE Medical Certifications
- Erica Conway, PhD, BSI
- Waldo Weijers, PharmD, Medicines Evaluation Board, Netherlands
- Eric Klasen
- Armin Ritzhaupt, PhD, MPh, European Medicines Agency
- Micha Nuebling, PhD, Paul-Ehrlich-Institut
- Jayanth Katta, PhD, BSI
- Sophie Tabutin, PharmD, MSc, W.L. Gore & Associates
- Stephan Affolter, Ypsomed AG
- John Van Hoven, MS, Rocky Mountain Regulatory and Quality Partners

**10:15 – 10:45 CET**

*International Regulatory Changes: Member States — Legal Structure Changes: Pharma, Biotech and Medical Devices Back in DG Health; New German Law (BfArM Receiving Executive Power)*
- Rainer Voelksen, FRAPS, VOELKSEN Regulatory Affairs

**11:15 – 12:15 CET**

*Give Me Data: Challenges and Opportunities of Real-World Evidence*
- Michael Maier, MBA, RAC, Medidee Services SA
- Tim Farley, PhD, Medidee Services SA
- Sandra Klompmaker, PhD, Medidee Services SA

MDR Technical Documentation for Legacy Products: Practical Tips and Tricks
- Jan-Paul van Loon, MSc, PhD, Qserve Consultancy
- Jane Arnold-Round, B.Eng, MSc

**Tuesday, 27 Oct.**

**08:30 – 09:30 CET**

- Maria Donawa, MD, Donawa Lifescience
- Daniela Karner, Donawa Lifescience
- Matteo Mosso, Donawa Lifescience

*Beyond the Corrigendum: Strategies for Optimal Use of MDR Grace Period*
- Amanda Maxwell, BA, Medtech Insight
- Sabina Hoekstra-van den Bosch, PharmD, FRAPS, TÜV SÜD Product Service GmbH
- Gert Bos, PhD, FRAPS, Qserve Group
- Erik Vollebregt, Axon Lawyers

**COMBINATION PRODUCTS**
- Jayanth Katta, PhD, BSI
- Jane Arnold-Round, B.Eng, MSc
- Jonathan Sutch, PhD, BSI
- Armin Ritzhaupt, PhD, MPh, European Medicines Agency

**10:45 – 11:15 CET**

*Regulatory Hurdles to Overcome to Introduce Nanotechnology-based IVD and Medical Devices to the EU Market, A Safe-N-Medtech Concern*
- Luc Van Hove, MD, PhD, MARACA International bvba
- Menno Prins, PhD, Eindhoven University of Technology
- Angel Delpozo, MSC, BioKerality Research Institute
- Quentin Pankhurst

**11:15 – 12:15 CET**

*MDR: Lessons Learned*
- Sophie Tabutin, PharmD, MSc, W.L. Gore & Associates
- Jayanth Katta, PhD, BSI

**12:15 – 12:45 CET**

*International Regulatory Changes: Member States — Deal or No Deal: The Impact of the MRA Switzerland — EU on Medtech in Europe*
- Stephan Affolter, Ypsomed AG
- John Van Hoven, MS, Rocky Mountain Regulatory and Quality Partners

**12:45 – 13:15 CET**

*MDR: Technical Documentation for Legacy Products: Practical Tips and Tricks*
- Jan-Paul van Loon, MSc, PhD, Qserve Consultancy
- Jane Arnold-Round, B.Eng, MSc

**UDI/Labeling**
- Lena Cordie-Bancroft, Qualitas Professional Services, LLC
- Hans Strobel, dokspot GmbH
- Reinhart Seibl
13:30 – 14:30 CET
Implementing Practices to Comply with the In Vitro Diagnostics Regulation
• Hilary Baldwin, Caris Life Sciences
• Luc Van Hove, MD, PhD, MARACA International bvba
• Armin Ritzhaupt, PhD, MPH, European Medicines Agency

Challenges and Understanding of the Periodic Safety Update Report (PSUR)
• Alex Laan

Working with FDA: How to Get the Most Out of Your FDA Meetings and Interactions
• John Lockwood, CBA, RAC, CSQE, Pearl Pathways

14:45 – 15:45 CET
Performance Evaluation Reports — Planning and Preparation in Anticipation of IVDR Requirements
• Rachel Kennedy, RAC, LabCorp

Vigilance and Trend Reporting
• Keith Morel, PhD, Qserve Group

Working with FDA: Factors for Successful Approval
• Jason Krzeszak, MSE, MBA, NAMSA
• Deepa Arora, MD, Clinexel Life Sciences Private Limited
• Melissa Walker, MS, RAC, FRAPS, Graematter, Inc.

16:15 – 17:45 CET
Fireside Debate with IVDR Notified Body and Industry Representation
• Gert Bos, PhD, FRAPS, Qserve Group

Clinical Evaluation: Clinical Data Versus Non-clinical Data; How to Interpret Article 61.10
• Natascha Cuper, PhD, DARE Medical Certifications

MDR Implementation: Economic Operator Requirements
• Ludger Moeller, Medical Device Safety Service GmbH

11:15 – 12:15 CET
The WHO Prequalification (PQ) Program for IVD in the Light of the IVDR
• Michael Maier, MBA, RAC, Medidee Services SA
• Rima Padovani, PhD, Medidee Services SA
• Mark Lanigan, World Health Organization

Clinical Investigation under MDR
• Sabina Hoekstra-van den Bosch, PharmD, FRAPS, TÜV SÜD Product Service Gmbh

13:30 – 14:30 CET
What is Sufficient Clinical Evidence for IVDs in Preparation for the IVDR?
• Luc Van Hove, MD, PhD, MARACA International bvba

Creating and Implementing Effective Post-market Clinical Follow-up Under the EU Medical Devices Regulation
• Adrian Keene, BSc (Hons), NAMSA

09:00 – 10:45 CET
International Regulatory Landscape Changes: Asia (outside ASEAN) Effective Regulatory Strategy & Update in MedTech Product Registration Process
• Lena Cordie-Bancroft, Qualitas Professional Services
• Joalim Lim, BSc, MSc, PhDc, CCRP, Agape-Life Support System

European Union Reference Laboratory for IVD
• Anne Van Nerom, DVM, PhD, Sciensano

Innovators and Regulators: Time to Collaborate
• Lena Cordie-Bancroft, Qualitas Professional Services

Sufficient Clinical Evidence: What is sufficient clinical evidence for legacy, new and software medical devices?
• Leo Hovestadt, Elekta
• Gianni Di Rienzo, Qserve Consultancy

08:30 – 09:00 CET
International Regulatory Landscape Changes: Southeast Asia Medical Device Regulations changes and Challenges to Medical Device Industry
• Lena Cordie-Bancroft, Qualitas Professional Services

08:30 – 09:30 CET
IVDR Regulatory Strategy Plan: A Proper Regulatory Strategy is Key for IVD Manufacturers and Test-Labs with In-house Developed Tests/LDTs
• Anja Wiersma, PhD, mi-CE consultancy

08:30 – 09:30 CET
IVDR Regulatory Strategy Plan: A Proper Regulatory Strategy is Key for IVD Manufacturers and Test-Labs with In-house Developed Tests/LDTs
• Jacques JM van Dongen, MD, PhD, Leiden University Medical Center

09:45 – 10:45 CET
Impact of Notified Body Representative Technical Documentation Sampling — It Affects Your MDR Compliance Workload
• Matt Royle, PhD, NAMSA

Clinical Investigation under MDR
• Sabina Hoekstra-van den Bosch, PharmD, FRAPS, TÜV SÜD Product Service Gmbh

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13:30 – 14:30 CET
What is Sufficient Clinical Evidence for IVDs in Preparation for the IVDR?
• Luc Van Hove, MD, PhD, MARACA International bvba

Clinical Evaluation Reports (CERs)
• Diana Nogueira, MSc, PhD, Qserve Group

Software as a Medical Device: Comparison Between US and EU Approaches
• Pat Baird, MBA, MS, Philips

15:00 – 15:30 CET
SaMD/Cybersecurity — Case Study: Premarket Cybersecurity in Medical Devices
• Barry Ashar, MS, MBA, Makromed, Inc.
15:00 – 16:00 CET
Navigating the Pre-Market Approval Process for FDA
• Hilary Baldwin, Caris Life Sciences

Risk Management — Focal Point for Regulatory and Legal Purposes
• Kimberly Trautman, MS, NSF International
• Richard Bassett, LL.M, MSc, BSc, NAMSA

15:30 – 16:00 CET
SaMD/Cybersecurity — Regulatory Strategies for Machine Learning/AI and Software as a Medical Device (SaMD); Real World Case Studies
• James Monroe, MS, RAC, CQA, American Society for Quality

16:10 – 16:15 CET
Poster Presentation 1: Development of a Digital Tool for Risk Management, Post-Market Surveillance, Clinical Evaluation of Medical Devices
• Shristi Shrestha, MSc, Lübeck University of Applied Sciences

16:15 – 16:20 CET
Poster Presentation 2: Regulatory Challenges in the Non-EU Countries of the SEE Region
• Dragana Bundalo, MSc, PharmaSwiss

16:20 – 16:25 CET
Poster Presentation 3: eSubmissions: Regional Moving Towards Global Aspects
• Dzeparoski Marjan, PhD, Bionika Pharmaceuticals

16:40 – 16:45 CET
Poster Presentation 4: The Importance of a Regulatory Qualification and Continuous Professional Development in Career Progression and Advancement
• Olivia McDermott, PhD, Olivia McDermott Hayes

16:45 – 16:50 CET
Poster Presentation 5: The Importance of a Regulatory Qualification and Continuous Professional Development in Career Progression and Advancement
• Olivia McDermott, PhD, Olivia McDermott Hayes

16:50 – 16:55 CET
Poster Presentation 6: Can Legislation Evolve Along with Technology? Case Study: Software as Medical Device in Emerging Markets
• Monica Hernandez, BSc, Boston Scientific

16:55 – 17:00 CET
Poster Presentation 7: Considerations for Medicinal Products Approved for Use in Pediatric Populations Based on Labeling Claims
• Caitlin Skenyon, RPh, PharmD, Northeastern University

19:00 – 21:00 CET
Conference Dinner

09:45 – 10:15 CET
From Product Information to Promotional Material — Promotional Material and National Regulations in EU: How to Successfully Launch Your Product in Different Markets?
• Colette Shortt, MSc, PhD, MBA, Johnson & Johnson
• Camille Priiou, PharmD, BlueReg

10:30 – 11:00 CET
Orphan Drugs: Challenges and Differences for its Designation in the European Union and the United States of America
• Maria Bertoli, PhD
• Jennifer Neff, PhD, bess AG

11:00 – 11:30 CET
Orphan Drugs: Global Regulatory Landscape and Strategy for Orphan Drugs
• Mridula Shukla, MSc, Arcutis Biotherapeutics Inc.
• Jennifer Neff, PhD, bess AG
• Kristina Larsson, MSc, European Medicines Agency

12:00 – 13:00 CET
Supporting Innovation
• Siegfried Schmitt, PhD, CSci, CChem, FRSC, Parexel
• Anthony Humphreys

13:00 – 13:30 CET
Orphan Drugs: Challenges and Differences for its Designation in the European Union and the United States of America
• Maria Bertoli, PhD
• Jennifer Neff, PhD, bess AG

13:30 – 14:00 CET
From Product Information to Promotional Material — Promotional Material and National Regulations in EU: How to Successfully Launch Your Product in Different Markets?
• Colette Shortt, MSc, PhD, MBA, Johnson & Johnson
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14:00 – 14:30 CET
From Product Information to Promotional Material — Promotional Material and National Regulations in EU: How to Successfully Launch Your Product in Different Markets?
• Colette Shortt, MSc, PhD, MBA, Johnson & Johnson
• Camille Priiou, PharmD, BlueReg
• Stephanie Omokaro, MD, US Food & Drug Administration

14:45 – 15:15 CET
Navigating the Future of Regulatory Affairs — The Future of the Regulatory Affairs Profession
• Peter Lassoff, PharmD, Syneos Health
• John Klein, MSc, MBA, NorthCoast Clinical Consulting, LLC

15:15 – 15:45 CET
Navigating the Future of Regulatory Affairs — Getting Out More — How Regulatory Affairs Professionals Can Connect with the Shop Floor
• Siegfried Schmitt, PhD, CSci, CChem, FRSC, Parexel
• Peter Lassoff, PharmD, Syneos Health

15:45 – 16:15 CET
Navigating the Future of Regulatory Affairs — 10 Steps to Effective Outsourcing in Regulatory Operations: Lessons Learned from our Successes and Challenges
• Jen Multari, MSc, RAC, Boehringer Ingelheim
• Peter Lassoff, PharmD, Syneos Health

16:30 – 17:30 CET
RNA-Based Therapeutics: Opportunities and Challenges
• Tracy Meffen, MS, CQA, RAC, Genevant Sciences
• Andreas Kuhn, Dr, BioNTech RNA Pharmaceuticals GmbH

09:15 – 09:45 CET
From Product Information to Promotional Material — Electronic Product Information: Creating a Meaningful Future for Patient Information in Europe
• Ahmad Torqui, MSD
• Colette Shortt, MSc, PhD, MBA, Johnson & Johnson
• Elizabeth Scanlan

10:30 – 11:00 CET
Orphan Drugs: Challenges and Differences for its Designation in the European Union and the United States of America
• Maria Bertoli, PhD
• Jennifer Neff, PhD, bess AG

11:00 – 11:30 CET
Orphan Drugs: Global Regulatory Landscape and Strategy for Orphan Drugs
• Mridula Shukla, MSc, Arcutis Biotherapeutics Inc.
• Jennifer Neff, PhD, bess AG
• Kristina Larsson, MSc, European Medicines Agency
CONFERENCE DAY-5

09:15 – 09:45 CET
Changing Pharmaceutical Regulatory Landscape in China and Asia
• Yingying Liu, MSc, CSL Behring
• Pallavi Trivedi, MPH, RAC, Trident Pharmaceuticals Limited & Spinos Clinical Research UK

09:45 – 10:15 CET
Changing Pharmaceutical Regulatory Landscape in China and Asia – The Dynamics and Outlook of the ASEAN Regulatory Landscape
• Stefanie Faßhauer, MBA, PharmaLex
• Pallavi Trivedi, MPH, RAC, Trident Pharmaceuticals Limited & Spinos Clinical Research UK

10:30 – 11:00 CET
Dealing with Regulatory Requirements — Regulatory Requirements for Extractables and Leachables
• Devina Bhardwaj, Intervein Laboratories
• Hiren Berawala, Intervein Laboratories
• Mark Di Cioccio, Team Consulting

10:30 – 11:30 CET
Dealing with Regulatory Requirements - Regulatory Challenges Faced Successfully Taking a New Client out of MHRA Compliance Management Team (CMT) Measures (Data Integrity Issues)
• David Thompson, Clarity Compliance Solutions

12:00 – 13:00 CET
Regulatory Changes: Biosimilars
• Irena Milobratovic, MPharm, RAC, Arriello
• Claudia Louati, MS, US Food and Drug Administration
• Gabriela Marton, Arriello
• Jennifer Neff, PhD, bess AG

13:30 – 14:00 CET
MA Lifecycle Management — Towards an Agile Risk-based Variation Regulatory Framework
• Charlie Mortazavi, PharmD, Sanofi

14:00 – 14:30 CET
MA Lifecycle Management — The Trials and Tribulations of Handling Older Regulatory Applications
• Mark Slisz, RAC, Pearl Pathways
• Charlie Mortazavi, PharmD, Sanofi

14:45 – 15:15 CET
Working with FDA: How to Prepare a Well-received IND
• Mark Slisz, RAC, Pearl Pathways
• Robert Seevers, PhD, Pearl Pathways

15:15 – 15:45 CET
Working with FDA: Form FDA 1572 (Statement of Investigator) Signature Waivers at Non-US Sites
• Mark Di Cioccio, Team Consulting
• Philip Budashewitz, RPh, MA, US Food and Drug Administration

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