Transitioning to the New EU MDR and IVDR: A Workshop on Real World Implementation Experiences

16 – 17 May 2018

Thon Hotel, Brussels, Belgium

Our confirmed panel of experts includes:

- Bassil Akra, PhD, director, Clinical Center of Excellence, TÜV SÜD Product Service GmbH
- Nick Baker, FIBMS, head of IVD Notified Bodies, LRQA
- Oliver Bisazza, director, regulations & industrial policy, MedTech Europe
- Gert Bos, PhD, FRAPS, executive director and partner, Qserve Group
- Paul Brooks, executive director, Regulatory Affairs Professionals Society
- Erik Hansson, directorate general, GROW, European Commission
- Liz Harrison, technical team manager - IVD, BSI
- Sabina Hoekstra-van den Bosch, PharmD, FRAPS, lead for European regulation, Philips - Global Regulations & Standards
- Alex Laan, principal certification manager, project manager certification medical devices, DEKRA Certification B.V.
- Niall MacAleenan, deputy director, head of medical devices department, Health Products Regulatory Authority (HPRA)
- Michael Maier, senior partner, Medidee Services SA
- Ludger Möeller, president, Medical Device Safety Service GmbH
- Rima Padovani, PhD, senior associate, Medidee Services SA
- Makesh Ramalingam, deputy general manager-regulatory, HCL Technologies Ltd
- Salvatore Scalzo, policy and legal officer, European Commission
- Sophie Tabutin, PharmD, notified body regulatory lead, BSI
- Luc Van Hove, MD, PhD, ceo, Maraca International Consulting Services
- Rainer Voelksen, FRAPS, vice president, regulatory affairs/quality management, Occlutech
- Erik Vollebregt, advocaat, Axon Science Based Lawyers
- Anja Wiersma, PhD, ceo, mi-CE Consultancy

Day One - Wednesday 16 May 2018

8.30 Registration

9.00 Welcome and Introduction to Training Program – Paul Brooks

9.15 MDR/IVDR Regulations Changes: One Year Later

Session Leader: Gert Bos

Panelists: Oliver Bisazza and Sabina Hoekstra

	MDR Track	IVDR Track
9.45	Clinical requirements *Session Leader*: Sabina Hoekstra *Panelists:* Gert Bos and Sophie Tabutin	Performance evaluation *Session Leader*: Nick Baker *Panelists*: Luc van Hove, Liz Harrison, and Nick Baker
10.45	REFRESHMENT BREAK	
11.15	Managing legacy devices (clinical data) *Session Leader*: Gert Bos *Panelists*: Bassil Akra and Sophie Tabutin	Managing legacy devices (performance evaluation) *Session Leader*: Liz Harrison *Panelists*: Anja Wiersma and Nick Baker
12.00	LUNCH	
13.00	Changes introduced by the new General Safety and Performance Requirements *Session* Leader: Bassil Akra *Panelists*: Michael Maier, Sabina Hoekstra, and Makesh Ramaligam	Changes introduced by the new General Safety and Performance Requirements *Session Leader*: Luc van Hove *Panelists*: Rima Padovana
13.30		IVDR and GDPR *Session Leader*: Rima Padovana *Panelist*: Erik Vollebregt
14.00	Updating technical documentation and labelling *Session Leader*: Ludger Möeller *Panelists*: Michael Maier and Bassil Akra	Updating technical documentation and labelling *Session Leader*: Anja Wiersma *Panelists*: Rima Padovana and Nick Baker
15.00	REFRESHMENT BREAK	
15.30	Post-market expectations *Session Leader*: Michael Maier *Panelists*: Sophie Tabutin and Ludger Möeller	Post-market expectations *Session Leader*: Gert Bos *Panelists*: Anja Wiersma, Rima Padovana and Liz Harrison
16.30	Roundtable discussions *Session Leader*: Gert Bos *Panelists*: Rainer Voelksen, Sophie Tabutin, Sabina Hoekstra, and Oliver Bisazza	Roundtable discussions *Session Leader*: Erik Vollebregt *Panelists*: Rima Padovana, Liz Harrison, Luc van Hove, Anja Wiersma, and Nick Baker
17.00	Day Close	
17.30	DRINKS RECEPTION	
	Join the RAPS team for an optional post event drink & nibbles to round off day one. Representatives from RAPS European Council will be in attendance and look forward to meeting you.	

Day Two – Thursday 17 May 2018

9.00 Recap day one

9.15 Keynote Presentation: Commission representative (including an update on implementing and delegated acts)

Presenter: Erik Hansson, EC

10:00 Keynote Discussion: CAMD Roadmap Update

Presenter: Niall MacAleenan

10.45 Q & A EU Commission & CAMD

Panelists: Erik Hansson, Niall MacAleenan, and Salvatore Scalzo

11.15 Refreshment break

11:45 Notified body perspectives

MDR Track

Session Leader: Paul Brooks
Panelists: Bassil Akra and Sophie Tabutin

IVDR Track

Session Leaders: Alex Laan and Anja Wiersman
Panelists: Alex Laan, Nick Baker, and Gert Bos

12.30 Lunch

13.30 Impact on economic operators

Session Leader: Michael Maier
Panelists: Ludger Möeller, Gert Bos, and Erik Vollebregt

	MDR Track	IVDR Track
14.30	Introduction to transition strategies *Session Leader*: Gert Bos *Panelists*: Michael Maier, Sophie Tabutin, Bassil Akra, and Ludger Möeller	Introduction to transition strategies *Session Leader*: Luc van Hove *Panelists*: Anja Wiersma and Rima Padovana
15.00	REFRESHMENT BREAK	
15.30	Transition strategies *Session Leader*: Gert Bos *Panelists*: Michael Maier, Sophie Tabutin, Bassil Akra, and Ludger Möeller	Transition strategies *Session Leader*: Luc van Hove *Panelists*: Erik Vollebregt, Anja Wiersma and Rima Padovana
16.00	Final Roundtable *Session Leader*: Rainer Voelksen *Panelists*: Sophie Tabutin, Sabina Hoekstra, and Michael Maier	Final Roundtable *Session Leader*: Anja Wiersma *Panelists*: Rima Padovana, Luc van Hove, Alex Laan, Nick Baker, and Erik Vollebregt
17.00	Close	