EU Regulatory Essentials, Medical Device and IVDs: Demystifying the EU MDR and IVDR: From Transition to Implementation (1 October 2018)

Day 1 – Basic to Intermediate

8:00 am	**Registration and Continental Breakfast**		
9:00 am	**Welcome and Overview of the New Regulations (Joint MD & IVD Session)** • Outline of MDR and IVDR • Key differences with current MDD/AIMDD and IVDD **Sabina Hoekstra-van den Bosch, PharmD, FRAPS,** scientific staff member medical devices, Central Committee on Research Involving Human Subjects (CCMO)		
9:30 am	**Implementation of the New Regulations at the Authorities (Joint MD & IVD Session)** • Implementation at the designating authorities: what needs still to be done? • Outcomes of the joint CAMD/EU Commission Implementation WG • Outcome of the Transition ad-hoc Group • Timelines **John Wilkinson,** OBE, Director of Devices, MHRA		
10:15 am	**How to Implement the New Legal Obligations of Economic Operators in EU MDR** **Erik Vollebregt, LLM,** partner, Axon Lawyers		
10:45 am	**Refreshment Break**		
11:00 am	**EU MDR Track**	**11:00 am**	**EU IVDR Track**
11:00 am	**Conformity Assessment in the MDR** • Routes to CE marking and conformity assessment with MDR • GAP analysis between ISO 13485:2016 and the MDR QMS requirements **Gert Bos, PhD , FRAPS,** executive director & partner, Qserve Group	**11:00 am**	**Classification Concepts and Up Classifications; Products Newly Covered Under the Regulation** • Change from the list based approach classifications to the rules based approach linked to risk under the IVDR • Products newly covered by the IVDR **Connie Del Buono,** founder**,** director regulatory and compliance, Synoptyx
11:30 am	**What is New with the MDR General Safety and Performance Requirements and the New Classification Rules** • Annex I general safety and performance requirements • New classification rules **Joachim Wilke, PhD,** director regulatory affairs & policy EMEA, Medtronic	**11:30 am**	**Conformity Assessment Now and Then** • Routes to CE marking and conformity assessment procedures with the IVDR, the IVDD and the value of ISO 13485:2016 • Additional IVDR QMS requirements • Additional QMS processes Certificate Structures – Scopes and the difference between full QA and ISO scope (to be refined by Sue)

			Andreas Stange, vice president, TÜV SÜD
12:00 pm	**Clinical Requirements during the Transition Period and the new Paradigm under the MDR** • Usage of MEDDEV Rev. 4 as preparation method • Clinical evidence and clinical evaluation required under the MDR **Bassil Akra, PhD,** director, Clinical Centre of Excellence, TÜV SÜD Product Service GmbH	**12:00 pm**	**IVDR General Safety and Performance Requirements** • Annex I general safety performance requirements • Labeling requirements **Julien Senac, PhD,** certification project manager, LNE/G-MED North America Inc.
12:30 pm	**Lunch**		
1:30 pm	**Technical Documentation for Compliance** • MDR Annex II technical documentation requirements • Notified Body evaluation of technical documentation **Mindy McCann,** VP regulatory compliance, Qserve Consultancy B.V.	**1:30 pm**	**Technical Documentation for Compliance** • IVDR Annex II technical documentation requirements • Notified Body evaluation of technical documentation **Julien Senac, PhD,** certification project manager, LNE/G-MED North America Inc.
2:45 pm	**Refreshment Break**		
3:00 pm	**Postmarket Expectations, Including Postmarket Clinical Follow-up** • Active and systematic Post-market Surveillance requirements • Postmarket clinical follow-up (PMCF) under the MDR • Periodic safety update report (PSUR) • Summary on safety and clinical performance (SSCP) • Reporting and Trending **Caroline Dore Geraghty,** chief clinical evaluator for Medical Devices, National Standards Authority of Ireland	**3:00 pm**	**Postmarket Expectations and Postmarket Performance Follow-up** • Active and systematic Post -market Surveillance requirements • PMS Plan and PMS Report • Vigilance incident and Trend reporting • Vigilance incident under the IVDD through Transition • Postmarket Performance Follow Up (PMPF) • Periodic safety update report (PSUR) **Philippe Auclair, PharmD, PhD, FRAPS,** senior director, regulatory strategy and advocacy, EMEA, Abbott
4:00 pm	**Closing Panel Discussion and Q&A** **All Speakers**		
5:00 pm	**Adjourn**		