EU Regulatory Essentials, Medical Device and IVDs: Demystifying the EU MDR and IVDR: From Transition to Implementation (2 October 2018)

Day 2 – Intermediate to Advanced

7:00 am	**Registration and Continental Breakfast**		
8:00 am	**Welcome and Housekeeping Notes**		
8:15 am	**EU MDR Track**	**8:15 am**	**EU IVDR Track**
8:15 am	**Up-Classification** The new medical device regulation includes 4 new classification rules and modified wording of already available rules which may lead to the up-classification of various devices. The intention of this workshop is to work with interested experts at different medical device manufacturers on a list of main changes to the wording/requirements which will clearly lead to a change in regulatory expectations. **Peter Schroeer,** senior director regulatory affairs, policy and innovation, Johnson & Johnson **Joachim Wilke, PhD,** director regulatory affairs & policy EMEA, Medtronic	**8:15 am**	***Prospective*** **Performance Evaluation and Data Requirements** • Data collection/relevance of the data quality of legacy data **Alex Laan,** principal certification manager, project manager certification medical devices business line medical, DEKRA Certification B.V.
9:00 am	**Clinical Premarket** Approximately 50% of the different chapters, articles and annexes of the new medical device regulation are covering clinical aspects. During this workshop we would like to explain the impact of the new requirements on the various medical devices and work with the attendees on examples enabling them to understand how to fulfill these requirements.	**9:15 am**	***Retrospective*** **Workshop on Clinical Evidence and Performance Evaluation Required Under the IVDR** • Scientific validity report • Clinical Evaluation: Using postmarket performance data • Creditable data • Clinical performance studies • GDPR • PMPF

	Melissa Day, RN, MBA, senior director, medical operations, Johnson & Johnson **David Rutledge, PharmD, FCCP, FAHA,** director, global regulatory operations, clinical evaluation & clinical risk management, Abbott Medical Devices		**Erica Conway, PhD,** global head IVDs, BSI
10:30 am	**Refreshment Break**		
10:45 am	**PMS/PMCF** According to article 83 of the medical device regulation, the post-market surveillance system shall be suited to actively and systematically gathering, recording and analyzing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions. Further on in this regulation, it is mentioned that PMCF is a continuous process to update the clinical evaluation and is part of the PMS plan. During this workshop, we would like to explain to the attendees based on examples the way to comply with the new regulation by using various methodologies. **Keith Morel, PhD,** US VP regulatory compliance, Qserve Group **Maduagwu Oji,** senior manager regulatory affairs EMEA, Baxter Healthcare Limited		**Workshop on Legacy Products** • How to deal with legacy software • Product examples **Simon Richards,** vice president regulatory affairs, Alere
12:15 pm	**Lunch**		

<table>
<tr><td>1:15 pm</td><td rowspan="2">Successful Reporting PSUR, PMCFR, CER and SSCP

The new medical device regulation increases the transparency for regulators and public. The intention of this workshop is to clarify the rules on reporting for the various device classification and to explain the necessity of strong QM Processes and training to comply with the new reporting requirements.

Bassil Akra, PhD, director, Clinical Centre of Excellence, TÜV SÜD Product Service GmbH

Sabina Hoekstra-van den Bosch, PharmD, FRAPS, scientific staff member medical devices, Central Committee on Research Involving Human Subjects (CCMO)</td><td>1:15 pm</td><td>Workshop on Self-Test, Near Patient Testing and Human Factors/Usability

• Requirements
• What are the differences?
• Case studies

Anja Wiersma, PhD, CEO and senior consultant, mi-CE consultancy</td></tr>
<tr><td></td><td>2:00 pm</td><td>Transition Strategy

• Certification structure
• Will you do a type exam?
• Scopes of the certificates
• What does your notified body want from you?

Sue Spencer, head of global medical device services, UL</td></tr>
<tr><td>2:45 pm</td><td colspan="3">Refreshment Break</td></tr>
<tr><td>3:00 pm</td><td colspan="3">Closing Panel Discussion and Q&A

All Speakers</td></tr>
<tr><td>4:00 pm</td><td colspan="3">Adjourn</td></tr>
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