EU Regulatory Essentials, Medical Device and IVDs: Transitioning From Current Directives Into Future Regulations
Sunday, 10 September 2017

<table>
<tr><td>7:00 am</td><td colspan="3">Registration and Continental Breakfast</td></tr>
<tr><td>8:00 am</td><td colspan="3">Welcome and Overview of EU process, the Current New Approach Directives and the Need for Evolution to New Regulations (Joint MD & IVD Session)
Current European regulation of devices and the new approach—Active Implantable Medical Device Directive (AIMD), Medical Device Directive (MDD) and In Vitro Diagnostics Directive (IVDD)
Why and what is changing in Europe?
Introduction to the Medical Device Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR)
Sabina Hoekstra-van den Bosch, MSc, PharmD, FRAPS, senior manager global regulations and standards, Philips</td></tr>
<tr><td>8:45 am</td><td colspan="3">How to Implement the New Legal Obligations of Economic Operators in EU MDR

Erik Vollebregt, LLM, partner, Axon Lawyers</td></tr>
<tr><td>9:15 am</td><td>EU MDD/MDR Track</td><td>9:15 am</td><td>EU IVDD/IVDR Track</td></tr>
<tr><td rowspan="2">9:20 am</td><td rowspan="2">Conformity Assessment With the New MDR
Routes to CE marking and conformity assessment today and with MDR
GAP analysis between ISO 13485:2016 and the MDR QMS requirements
Glenda Marsh, senior director, global policy implementation, Johnson & Johnson</td><td>9:20 am</td><td>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
Stefan Burde, PhD, IVD product expert, BSI Americas</td></tr>
<tr><td>9:40 am</td><td>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
Stefan Burde, PhD, IVD product expert, BSI Americas</td></tr>
<tr><td>10:00 am</td><td colspan="3">Refreshment Break</td></tr>
</table>

10:30 am	**What is New With MDR General Safety and Performance Requirements and the New Classification Rules** • Annex I general safety performance requirements • Hazardous substances • New classification rules **Sabina Hoekstra-van den Bosch, MSc, PharmD, FRAPS,** senior manager global regulations and standards, Philips	**10:30 am**	**Expansion of the Essential Requirements in the IVDR General Safety and Performance Requirements** • Annex I general safety performance requirements • Labeling requirements **Connie Del Buono,** founder**,** director regulatory and compliance, Synoptyx
11:15 am	**Clinical Requirements During the Transition Period and the New Paradigm Under the MDR** • MDD clinical evaluation per MEDDEV Rev. 4 expectations • Clinical evidence and clinical evaluation required under the MDR • General postmarket clinical expectations **Bassil Akra, PhD,** director, Clinical Centre of Excellence, TÜV SÜD Product Service GmbH	**11:15 am**	**Performance Evaluation Requirements; a New Paradigm Under the IVDR** • Clinical validity report • IVDR performance evaluations • Clinical evidence and performance evaluation required under the IVDR **Sue Spencer,** head of global medical device services, UL
12:00 pm	**Lunch**		
1:00 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.	**1:00 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.
1:45 pm	**Postmarket Expectations, Including Postmarket Clinical Follow-up** • Postmarket clinical follow-up (PMCF) under the MDR • Periodic safety update report (PSUR) • Summary on safety and clinical performance (SSCP) • Reporting and Trending **Philippe Auclair, PharmD, PhD, FRAPS,** senior director, regulatory strategy and advocacy, EMEA, Abbott	**1:45 pm**	**Postmarket Expectations and Postmarket Performance Follow-up** • Postmarket surveillance under the IVDR • Vigilance and incident reporting under the IVDD through the transition • Postmarket Performance Follow Up (PMPF) • Periodic safety update report (PSUR) **Anja Wiersma, PhD,** CEO and senior consultant, mi-CE consultancy

2:30 pm	**Refreshment Break**
3:00 pm	**Plenary Summary of the Day** • Impact of the changes of the MDR on the Notified Body daily work • Impact of the changes of the MDR on the manufacturer daily work • Impact of the changes of the IVDR on the Notified Body daily work • Impact of the changes of the IVDR on the manufacturer daily work **Bassil Akra, PhD,** director, Clinical Centre of Excellence, TÜV SÜD Product Service GmbH **Connie Del Buono,** founder**,** director regulatory and compliance, Synoptyx **Sabina Hoekstra-van den Bosch, MSc, PharmD, FRAPS,** senior manager global regulations and standards, Philips **Sue Spencer,** head of global medical device services, UL
4:00 pm	**Adjourn**