ALL-IRELAND IVD SYMPOSIUM AGENDA

VENUE: CityWest Hotel, Dublin DATE: Thursday 4th May 2017

08:30-09:00	Registration/tea/coffee
09:00-09:15	Chairs welcome/Keynote Address (**Seamus Kearney**, Principal Consultant, ARC Regulatory)
09:15-10:15	Presentation 1: Overview of regulation (**Sue Spencer**, UL)
10:15-10:45	Presentation 2: Changes from a Notified Body Perspective (**Susan Murphy**, NSAI)
10:45-11:00	Panel Discussion - Open Q&A; (ARC, UL, NSAI – **Please submit specific questions in advance**)
11:00-11:15	Tea/Coffee & Networking
11:15-12:00	Presentation 3 & Workshop - Assessing the Impact of the changes (facilitator – **Sue Spencer**, UL)
12:00-12:30	Presentation 4 - Standard Development: Key to market knowledge & access (**Linda Hendy**, NSAI)
12:30-13:30	LUNCH & Networking
13:30-14:00	Presentation 5 - Additional Regulations: Biocidals, REACH (**Doris-Ann Williams**, BIVDA)
14:00-14:30	Presentation 6 - General Data Protection Regulation (**Gavin D'Alton**, BSi Cybersecurity and Information Resilience)
14:30-15:00	Presentation 7 - Clinical Performance Studies per ISO 20916 DRAFT Standard (**Jo Love**, Senior Clinical Conslutant, ARC Regulatory and member of TC212 WG3 developing the international standard)

Workshops - 15:00-16:30 (Registration required)

Stream 1	General IVD's – Led by **Sue Spencer, Head of Global Medical Device Services, UL**. Sue will lead discussions and activities aimed at understanding the impact on legacy/on-market products along with a deep dive into clinical evidence requirements and PMCPF.
Stream 2	Companion Diagnostics – Led by **Seamus Kearney, Principal Consultant, ARC Regulatory**. Seamus will lead an assessment of the changing requirements for Companion Dx products and how the changes fit with existing requirements in the US & Japan and in the accompanying therapuetic development timelines.
Stream 3	LDT's – Led by **Jo Love, Senior Clinical Consultant, ARC Regulatory**. Jo will look at the changes affecting the LDT market in the EU and the impact on the use of LDT's in medicinal clinical trials.
16:30	Wrap up

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