ABHI DIAGNOSTICS REGULATION CONFERENCE

Date: 8th October, 2020

Time	Topic	Speaker
14:00	**Chair's welcome**	• **Stephen Lee, Director, Diagnostics Regulation, ABHI**
14:05	**System readiness**	*Speakers to provide an overview of the readiness of the new IVD regulatory system and impact of Brexit* • **Elizabeth Harrison, Technical Team Manager, IVDs, BSI** • **Celia Mortimer & Jenny Keating, Senior Regulatory Policy Managers, MHRA** • **Oliver Bisazza, Director Regulations & Industrial Policy, MedTech Europe** • **Anna Hallersten, Director, Head of Regulatory Policy Europe, Roche Diagnostics**
14:45	**Q&A**	
15:10	**Embedding IVDR through the organisation**	*Speakers to describe how they are embedding IVDR requirements into their organisation: product development, market access and commercial* *Developing Regulatory Data and Notified Body relationships* • **James Shearn, Head of Regulatory Affairs, Oncimmune** *Regulation from a multi-national lens* • **Julia Riedlinger, IVDR Program Lead, Roche Diagnostics** *The IVDR/MDR experience – 2 years out* • **Phil Brown, Director, Regulatory and Compliance, ABHI**
16:00	**Q&A**	
16:15	**Chair's closing comments**	
16:30	**Event Close**	