

BIVDA Regulatory Affairs Seminar

Agenda - Day One

11 February 2025

Time	Subject	Speakers
09:30	Registration	
10:00	Welcome and Introduction to Regulatory Strategy	Stuart Angell, BIVDA Regulatory Affairs Working Party Chair Neil Plumridge, BIVDA Regulatory Affairs Manager
10:15	BIVDA Regulatory Strategy - How BIVDA will advocate and support members during their regulatory journey	Professor Mike Messenger, Head of Regulatory Strategy, BIVDA
10:30	Keynote	TBC
11:00	2024 - 2025 MHRA update - A forward look to activity in 2025 and a reflection on 2024	Dr Rob Reid, Deputy Director - Innovative Devices, MHRA
11:30	Qualification of IVDs - Navigating borderline products and AI software	Megha Deviprasad Iyer, Director Global Strategic Regulatory Affairs, Thermo Fisher
12:00	Classification of IVDs - MDCG guidance and the challenges of international divergence	Liz Harrison, Global Head - IVD devices, BSI
12:30	LUNCH	
13:30	Conformity Assessments - How to manage the process and reflecting on lessons learned	Ashleigh Batchen, Regulatory Strategy Principal (UK), TÜV SÜD
14:00	Workshop - UK as an international launchpad: break-out sessions	Team AB
15:00	BREAK	
15:15	Technical Documentation and Performance Evaluation	Dr. Pieter Bogaert, Senior IVD Regulatory Affairs Consultant, Qarad
15:45	Panel Session	An opportunity to pose questions to the speakers of the day
16:45	Closing remarks	

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Agenda - Day Two

12 February 2025

Time	Subject	Speakers
09:00	Pre-market Preparation – Reviewing the challenges of international registration	Claire Thompson, Associate Director, Regulatory Affairs, Abbott
09:30	Post-market Surveillance (PMS) - Update to UK PMS and Vigilance following the PMS SI 2024	Robyn Meurant, Principal Consultant, ACT-IVD
10:00	Workshop - Post-market Surveillance	Ivan Perez Chamorro, Founder and CEO, Medboard, Robyn Meurant, ACT-IVD, & Nadine Neale - Device Regulatory Specialist, MHRA
11:00	BREAK	
11:30	Regulatory Intelligence Strategy - How to stay on top of a moving world of regulatory change	Ivan Perez Chamorro, Founder and CEO - Medboard
12:00	National/International - International Recognition vs International Reliance, MDSAP, IMDRF	Petra Zollner, Director Regulatory Affairs (IVDR & MDR), MedTech Europe
12:30	LUNCH	
13:30	Abridgment to Access Markets	Professor Mike Messenger, Head of Regulatory Strategy, BIVDA
14:00	Panel Session - Regulation in a global market	TBC
15:00	Closing remarks	David Lawson, Director of Medical Technology, Department of Health and Social Care
15:30	Event closes	