

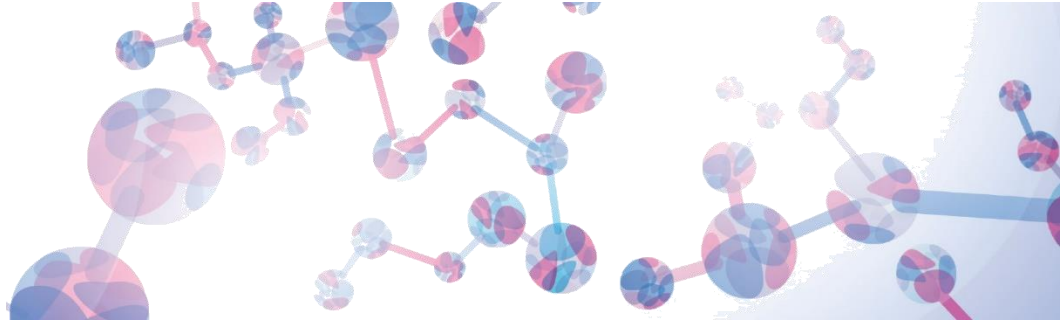
BIVDA REGULATORY AFFAIRS VIRTUAL SEMINAR 2021

[Liverpool City Marriott Hotel](#) – 11th/13th October

Day 1 Tuesday 12th October 2021

AGENDA

Time	Topic	Speaker
IVDR Implementation		
08:30	1. Chairman's Welcome & Competition Law	Doris-Ann Williams (BIVDA) Richard Saunders (Ortho-Clinical Diagnostics)
Day 1 - Opening Poll Question		
08:45	2. IVDR "Where are we with 6 months to Go?" and Industry Advocacy 3. Medical Devices Coordination Group (MDCG) / Key Activities of the MTE Working Groups (Labelling/ Clinical Evidence & Technical Forum)	Oliver Bisazza (MedTech Europe) Petra Zoellner (MedTech Europe)
10:00	BREAK	
10:30	4. A notified bodies perspective on working with manufacturers under the IVDR – the pitfalls and challenges.	Erica Conway (BSi)
11:15	5. A large and small companies' perspective on working with a notified body under the IVDR – the pitfalls and challenges	Richard Saunders (Large - Ortho-Clinical Diagnostics) James Shearn (Small – Oncimmune)
12:15	6. Economic Operators under the IVDR – the challenges	Alison Dennis (Taylor Wessing)
13:00	LUNCH BREAK	
Intended Purpose & PRRC		
14:00	7. The challenges of writing a good, intended purpose / use statement <ul style="list-style-type: none"> • The regulatory requirements • Real-life examples 	Petra Zoellner (MedTech Europe) Facilitator -
15:30	BREAK	
16:00	8. PRRC – Open Session	Stuart Angell (Stuart Angell)
16:45	9. Open Panel Q&A	Presenters
Day 1 - Closing Poll Question		
17:30	CLOSE OF DAY 1	



Evening Dinner and Entertainment

18:30
to
22:00

Shankly Hotel Millennium House, 60 Victoria Street, Liverpool, L1 6JD

Day 2

Wednesday 13th October 2021

AGENDA

Practical IVDR Implementation		
Time	Topic	Speaker
08:30	1. Introduction to Day 2	Doris-Ann Williams (BIVDA)
30-minute Breakout Sessions (3 sessions before break) – 08:45 to 10:30		
08:45	2. CDx	TBC (TBC)
08:45	3. Software	TBC (TBC)
08:45	4. Near Patient Testing and Self-Tests	Erin Wigglesworth (Cepheid)
08:45	5. Literature Reviews	Sue Spencer (QServe)
08.45	6. SS&P / PSUR	Richard Saunders (Ortho-Clinical Diagnostics)
10:30	BREAK	
11:00	7. MHRA consultation for UK CA marking – A Practical Discussion	Steve Lee (ABHI/Consultant) Facilitator – Stuart Angell (IVDeology)
13:00	LUNCH BREAK	
UK Regulatory Activities		
14:00	8. DEFRA	TBC (TBC)
14:30	9. HSE	TBC (TBC)
Regulatory Affairs Working Party		
14:30	Minutes and Action Follow-up (25 th June 2021)	Richard Saunders / Doris-Ann Williams
15:00	Closing Remarks	Richard Saunders
Day 2 – Closing Poll Question		
15:15	CLOSE OF DAY 2 –SEMINAR ENDS	