

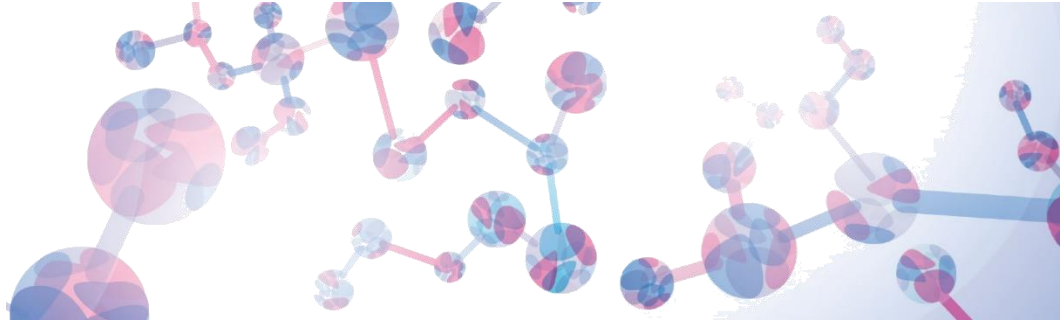
BIVDA REGULATORY AFFAIRS VIRTUAL SEMINAR 2021

[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 | Sarah Johns (Qiagen) |
| 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 | |