CRED IVD Regulatory Affairs for Global Markets

19th – 20th November 2024

ONLINE

Day 1

Time	Presentation/Activity	Presenters
8:30	**Online registration**	
9:00	**Welcome from TOPRA**	**TOPRA**
9:05	**Welcome from Chairman** Overview of the day	**Stuart Angell** Ivdeologly
9:15	**MD SAP** **Australia** • Overview of Australian IVD regulations and MDSAP requirements • Best practices for achieving registration in Australia • Emerging issues • Use of IVDR approvals to speed registration in Australia **Canada** • Overview of Canadian IVD regulations • Best practices for achieving registration in the US • Emerging Issues • Q and A	**Stuart Angell** Ivdeologly **Nadine Cabellero** Thermofisher
10:30	**Break**	
10:45	**USA** • Overview of US IVD regulations and Authorities • Best practices for achieving registration in the US • Emerging Issues • Valid Act • Q and A	**Eamon Docherty** Biocartis NV
12:15	**Lunch**	
13:15	**Japan** • Overview of key regulations and Authorities in Japan • Best practices for achieving registration in Japan • Q and A	**Andreas Stange** TUV SUD
14:30	**Break**	
14:45	**Saudi Arabia and Middle East** • Overview of Saudi Arabian regulations and Authority • Best practices for achieving registration in Saudi Arabia • Emerging Issues Q and A	**TBC**
16:30	**Wrap up and Close of the day**	

Day 2

Time	Presentation	Presenter
8:30	**Online registration**	
9:00	**Welcome from Chairman** • Overview of the day	**Ashleigh Batchen** TUV SUD
9:15	**UK** • Overview of UK IVD regulations and Authorities • Best practices for achieving registration in UK • Emerging Issues • Updates to the regulations post Brexit • Q and A	**Ashleigh Batchen** TUVSUD
10:30	**Break**	
10:45	**China** • Overview of Chinese IVD regulations and Authorities • Best practices for achieving registration in China • Emerging issues • The impact of recent changes in China on IVDs • Q and A	**Hamish King** Cisema
12:00	**Lunch**	
13:00	**WHO – World Health Organisation** • Overview of WHO approvals/pre-qualification for diagnostics • Best practices for achieving approvals with WHO • Maintaining WHO approval. • Q+A	**TBC**
14:30	**Break**	
14:45	**Brazil and Latin America** • Overview of Brazilian regulations and Authority • Best practices for achieving registration in Brazil • Emerging Issues • Wider Latin America regulatory development • Q and A	**Eliana Moraes** Silva de Moraes Associés
16:30	**Final Q&A and Wrap up**	