CRED IVD Regulatory Affairs for Global Markets
27-29 April 2022
Hybrid

Day 1

Time	Presentation	Presenter
8:30	**Online registration**	
9:00	**Welcome from TOPRA**	**Joe Jennings** TOPRA
9:05	**Welcome from Chairman** Overview of the day	**Simon Richards** Abbott
9:20	**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	**Simon Richards** Abbott
10.30	**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	**Simon Richards** Abbott
12:15	**Lunch**	
13:15	**USA** • Overview of US IVD regulations and Authorities • Best practices for achieving registration in the US • Emerging Issues ○ Valid Act • Q and A	**Cheng Zhang** Abbott
14:45	**Break**	
15:00	**Canada** • Overview of Canadian IVD regulations • Best practices for achieving registration in the US • Emerging Issues • Q and A	**Simon Richards** Abbott
16:15	**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** BIVDA
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** (BIVDA)
10:30	**Break**	
10:45	**Workshop** • Open house discussion on submission issues and how to address them – Attendees to bring items or examples. • Discussion on "Universal" submissions	**Simon Richards** Abbott
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	**Robyn Meurant** (ACT-IVD Consultant)
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 Morales** Silva de Moraes Associés
16:30	**Wrap up and Close of the day**	

Day 3

Time	Presentation	Presenter
08:30	**Online registration**	
09:00	**Welcome from Chairman** • Overview of the day	**Simon Richards** Abbott
09:15	**Japan** • Overview of key regulations and Authorities in Japan • Best practices for achieving registration in Japan • Q and A	**Andreas Stange** TUV SUD
10:30	**Break**	
10:45	**Saudi Arabia** • Overview of Saudi Arabian regulations and Authority • Best practices for achieving registration in Saudi Arabia • Emerging Issues • Q and A	**Simon Richards** Abbott
12:00	**Final Q&A and Wrap up**	
12:30	**Close of Workshop**	

Delegates will be encouraged to ask questions throughout the day so as to ensure the meeting is as interactive as possible.