CRED IVD Regulatory Affairs for Global Markets
22-24 November 2021
Online

Day 1

Time	Presentation	Presenter
8:30	**Online registration**	
9:00	**Welcome from 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+A	**TBC**
10.30	**Break**	
10.50	**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 • Q+A	**TBC**
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
	  • COVID EUA?
	• Q+A
		TBC

14:45	**Break**	
15:00	**Canada** • Overview of Canadian IVD regulations • Best practices for achieving registration in the Canada • Emerging Issues • Health Canada current activities • Q+A	**TBC**
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	**Simon Richards** Abbott
9:15	**Russia and the Eurasian Economic Union** • Overview of Russian/EEU IVD regulations and Authorities • Best practices for achieving registration in Russia • Emerging Issues • EEU regulations and impact • Q+A	**TBC**
10:30	**Break**	
10:45	**Unique Device Identification impacts worldwide** • Overview of UDI with focus on GS1 • Established UDI systems and databases • Emerging issues • Q+A	**TBC**
12:00	**Lunch**	
13:00	**Software as a Medical device** • What is software as a medical device? • How is SaMD regulated with a focus on the US market • Good practices for SaMD registration • Q+A	**TBC**
14:30	**Break**	
14:50	**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+A	**TBC**
16:15	**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	**Asia Pacific with a focus on Japan** • Overview of key AP regulations and Authorities with a focus on Japan • Emerging Issues ○ Wider AP regulatory development • Q+A	**TBC**
10:30	**Break**	
10:45	**Saudi Arabia** • Overview of Saudi Arabian regulations and Authority • Best practices for achieving registration in Saudi Arabia • Emerging Issues • Wider regulatory development in the Middle East • Q+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.