CRED European IVD Regulatory Affairs
17-19 March 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	**EU IVD Regulation overview**
	• Overview of IVDR regulations including:
	• Overview of IVDR and what it requires.
	• Risk management overview.
	  ○ Risk classification of IVDs
	  ○ Conformity assessment pathways for each device class
	  ○ Technical documentation requirements including labelling and UDI
	  ○ Overview of PRRC responsibilities including performance studies
	  ○ Responsibilities of economic operator, including key obligations and registration
	  ○ Overview of PMS and Vigilance requirements
	• Case study
		Petra Zoellner/ Oliver Bisazza
		MedTech Europe

12:30	**Break**	
13:00	**QMS Requirements of IVDR** • QMS requirements for manufacturers • QMS requirements for other EO's • Assessment of QMS • Assessment of product Quality • Case study	**Tom Clarke** ISO Sense Consulting Ltd.
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	**Simon Richards** Abbott
9:05	**Classification and NB approval (EU focus)** • Classification of IVDs • Interactions with CA and NB within the EU - different types of interactions, including examples and strategies for success • Differences in classifications between EU and ROW • IUS - How to write an Intended Use Statement, what needs to be included and key considerations. • Management of advertising/Promotional material	**Erica Conway** BSI **Stephen Lee** ABHI
12:30	**Break**	
13:00	**General design and development** • Overview of the general design and development QMS process, including design stages • Regulatory approach plans and identification of applicable regulations • Overview of ISO 14971 and risk management and application to D&D • Case study	**Fiona Gould** Abbott
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
09:05	**Post Market Surveillance and Vigilance requirements for IVDs** • Vigilance Reporting - decision process and reporting requirements, including reporting to different CA • FSN and FSCA • PMPF planning and execution • PMS Planning, Execution and Reporting (PSUR), including key objectives, relevant sources of information to include in reviews, and where to find this information • Case study	**Gill Morgan** Sestria Ltd.
12:00	**Break**	
12:30	**Q&A and Wrap up of the day**	
13:00	**Close of Workshop**	

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