



CRED European IVD Regulatory Affairs 23-25 February 2022 Online

Day 1

Time	Presentation	Presenter
8:30	Online registration	
9:00	Welcome from TOPRA 	Cristina Dragan Regulatory Intelligence and Symposium Manager
9:05	Welcome from Chairman Overview of the day	Simon Richards Abbott
9:20	EU IVD Regulation overview <i>(including a 15 minute break)</i> <ul style="list-style-type: none"> • Overview of IVDR regulations including: <ul style="list-style-type: none"> ○ Recent changes ○ Overview of core elements: <ul style="list-style-type: none"> ▪ 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 • Workshop 	Petra Zoellner MedTech Europe
12:45	Lunch	
13:30	QMS Requirements of IVDR <ul style="list-style-type: none"> • QMS requirements for manufacturers • Group Session • Conformity Assessment of QMS and Product Quality • QMS requirements for other EO's 	Tom Clarke ISO Sense Consulting Ltd.
17:15	Wrap up and Close of the day	



Day 2

Time	Presentation	Presenter
8:30	Online registration	
9:00	Welcome from Chairman <ul style="list-style-type: none"> • Overview of the day 	Simon Richards Abbott
9:05	Interactions with competent authorities and Notified Bodies <i>(including a 15 minute break)</i> <ul style="list-style-type: none"> • Intended use and classification • Interactions with competent authorities • Workshop 1 	Stephen Lee ABHI
	<ul style="list-style-type: none"> • Interaction with Notified Bodies • IVDR transitional arrangements • Workshop 2 	Erica Conway BSI
12:30	Lunch	
13:15	Compilation of the Technical Documentation <i>(including a 15 minute break)</i> <ul style="list-style-type: none"> • Overview of Technical Documentation requirements and Breakout Session • Guidance on how to present the Technical Documentation • Relevant standards and guidance's to support your Technical Documentation • Strategies for UK/EU/STED • Open forum to discuss contents, approach and ongoing maintenance including Performance Evaluation documents 	Fiona Gould FKG Consultancy
16:45	Wrap up and Close of the day	



Day 3

Time	Presentation	Presenter
08:30	Online registration	
09:00	Welcome from Chairman <ul style="list-style-type: none">• Overview of the day	Simon Richards Abbott
09:05	Post Market Surveillance and Vigilance requirements for IVDs <ul style="list-style-type: none">• Vigilance Reporting - decision process and reporting requirements, including reporting to different CA• FSN and FSCA• PMS Planning, Execution and Reporting (PSUR), including key objectives, relevant sources of information to include in reviews, and where to find this information• PMPF planning and execution• Workshop	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.