

Essentials of In-Vitro Diagnostics Regulatory Affairs



5 July 2023

Programme

All timings are UK local time (BST/GMT+1)

Time	Presentation	Presenter
09.00	Welcome from TOPRA	
09.05	Introduction from the Chair	Ashleigh Batchen British In Vitro Diagnostics Association
09.15	Intro session: General principles of regulation/regulatory science and regulatory structure - what is an IVD, QMS	Jonathan Ripley Imed Consultancy
10.15	Break	
10.30	Intended purpose (with 30 minutes of workshop)	Stuart Angell IVDeology
11.30	Classification / conformity assessment (with 30 minutes of workshop)	Ashleigh Batchen Tom Beale Aglient Technologies
13.00	Lunch	
14.00	Risk management (with 30 minutes of workshop)	Eamon Doherty Oxford Immunotec
15.00	Break	
15.15	Business impact of regulatory affairs	Jude O'Donnell Qserve Group
15.45	Regulatory strategy: How does all this information apply when deciding regulatory strategy (e.g. geographies)?	Tom Beale
16.15	Ask the experts panel session	All
16.30	Close of Meeting	