

Essentials of In-Vitro Diagnostics Regulatory Affairs



Programme

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

Time	Presentation	Presenter
09.00	Welcome from TOPRA	TOPRA representative
09.05	Introduction from the Chair	
09.15	Intro session: General principles of regulation/regulatory science and regulatory structure - what is an IVD, QMS, business impact, regulatory strategy for geographies	
10.15	Break	
10.30	Intended purpose (with 30 minutes of workshop)	
11.15	Classification / conformity assessment (with 30 minutes of workshop)	
13.00	Lunch	
14.00	Risk management	
14:45	Break	
15.00	PMS	
15.30	Future UK changes	
16.15	Ask the experts panel session	
16.30	Close of Meeting	