

Essentials of In-Vitro Diagnostics Regulatory Affairs



3 July 2024

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	Ashleigh Batchen, TUV SUD
09.15	Intro session: General principles of regulation/regulatory science and regulatory structure - what is an IVD, QMS, business impact, regulatory strategy for geographies	Stuart Angell, IVDeology
10.15	Break	
10.30	Intended purpose (with 30 minutes of workshop)	Ashleigh Batchen, TUV SUD
11.30	Classification / conformity assessment (with 30 minutes of workshop)	Tom Beale, Agilent Technologies
13.00	Lunch	
14.00	Risk management	Stuart Angell, IVDeology
14:45	Break	
15.00	PMS	Ashleigh Batchen, IVDeology (or Tom?)
15.30	Future UK changes	Joseph Burt, MHRA
16.15	Ask the experts panel session	All
16.30	Close of Meeting	