

# Essentials of In-Vitro Diagnostics Regulatory Affairs



**23 June 2022**

## Programme

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

Time	Presentation	Presenter
09.00	Welcome from TOPRA	Joseph Jennings, Associate Director of Engagement, TOPRA
09.05	Introductions	Simon Richards, Abbott
09.15	Module 1: What are IVD's and how did we get here?	Simon Richards, Abbott
09.45	Module 2: Introduction to legislative and non-legislative documents	Steve Lee, ABHI
10.45	Break	
11.00	Module 3: Basic concepts of Regulatory Affairs	Colleen Watson, Thermo Fisher Scientific Inc.
11.45	Module 4: How Regulatory Affairs works in an IVD Business	Erin Wigglesworth, SPD
12.30	Lunch	
13.30	Module 5: Classification and Conformity Assessment	Nancy Consterdine, IVDeology
14.15	Module 6: Technical Documentation and IVD Labelling	Stuart Angell, IVDeology
15.00	Break	
15.15	Module 7: Post Market Activities	Gill Morgan, Sestria
16.15	Quiz	Simon Richards, Abbott
16.30	Close of Meeting	