

# Essentials of In-Vitro Diagnostics Regulatory Affairs



**29 April 2020**

## Programme

Time	Presentation	Presenter
10.00	Registration and Coffee	
10.30	Welcome from TOPRA	
10.35	Introductions	
10.45	Module 1: What are IVDs and how did we get here?	Simon Richards, Abbott
11.15	Module 2: Basic concepts of Regulatory Affairs	Erin Wigglesworth, SPD
12.15	Module 3: How Regulatory Affairs works in an IVD Business	Simon Richards, Abbott
12.45	Lunch	
13.30	Module 4: Introduction to legislative and non-legislative documents	Richard Saunders, Ortho Clinical Diagnostics
14.15	Module 5: Classification and Conformity Assessment	Nancy Consterdine, IVDeology
15.00	Coffee break	
15.15	Module 6: Technical Documentation and IVD Labelling	Stuart Angell, IVDeology
16.00	Module 7: Post Market Activities	Gill Morgan, Sestria
16.45	Quiz	
17.00	Close of Meeting	