

Essentials of Pharmaceutical Regulatory Affairs



28 October 2025

TOPRA office

Time	Presentation	Speaker
09:00	Introduction to TOPRA	TOPRA
09:20	Introductions – presenters and delegates	Andrew (Andy) Thornley
09:40	Setting the Scene	Victor Goncharuk
10:35	Overview of Drug Development	Victor Goncharuk
11:05	Break (20 minutes)	
11:25	Regulatory Control of Clinical Trials	David Solomon
11:50	The Marketing Authorisation Application Dossier	G&L Healthcare
12:15	Product Information (Labelling)	Andy Thornley
12:30	SmPC Game	Andy and David
13:00	Break (40 minutes)	
13:40	European Marketing Authorisation Procedures	G&L Healthcare
14:20	Marketing Authorisation Strategy	Yevheniia and Andy
14:30	Break (20 minutes)	
14:50	Post- Authorisation Activities	G&L Healthcare
15:15	Product Safety (Pharmacovigilance)	David Solomon
15:30	Current and Planned Changes in the EU	Victor Goncharuk
15:35	Review of learning objectives and Quiz	All Presenters
17:00	Delegate Feedback and Wrap-up	All Presenters/ TOPRA