Essentials of EU Pharmaceutical Regulatory Affairs

14th July 2026
TOPRA offices and Remote

Time	Presentation	Speaker
09:00	Introduction to TOPRA	**TOPRA presenter**
09:15	Introductions – Presenters and Delegates	**Andrew (Andy) Thornley**
09:30	Setting the Scene	**Kit Evans, G&L Scientific**
10:20	Overview of Drug Development	**Victor Goncharuk, Opella**
11:00	Break (20 minutes)	
11.20	Regulatory Control of Clinical Trials	**David Solomon, RA consultant**
11.50	Quiz 1 (learning reinforcement)	**Andy**
12:00	The Marketing Authorisation Application Dossier	**Philip Kerr, G&L Scientific**
12:30	Product Information (Labelling)	**Andy**
13:00	Break (40 minutes)	
13.40	SmPC Game	**Andy and David**
14:00	European Marketing Authorisation Procedures	**Alina Nikiforova, G&L Scientific**
14:40	Marketing Authorisation Strategy	**Alina**
14.50	Quiz 2 (learning reinforcement)	**Andy**
15:00	Post- Authorisation Activities	**Bronagh Brolly, G&L Scientific**
15:25	Product Safety (Pharmacovigilance)	**David Solomon**
15:35	Current and Planned Changes in the EU with a Look at the Impact of AI	**Victor Goncharuk**
15.50	Quiz 3 (learning reinforcement) Review of Learning Objectives	**Andy and co-presenters**
16:00	Delegate Feedback and Wrap-up	**All Presenters/ TOPRA**
16.:20	Course ends	