

Essentials of EU Pharmaceutical Regulatory Affairs



15th October 2026
Online

Time	Presentation	Speaker
09:00	Introduction to TOPRA	TOPRA presenter
09:15	Introductions – Presenters and Delegates	Andrew (Andy) Thornley
09:30	Setting the Scene	Andy
10:10	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)	Jasmine Rauf, G&L Scientific
13:00	Break (40 minutes)	
13:40	SmPC Game	Andy and Jasmine
14:00	European Marketing Authorisation Procedures	Alina Nikiforova, G&L Scientific
14:30	Marketing Authorisation Strategy	Shannon O'Rourke, G&L Scientific
14:50	Quiz 2 (learning reinforcement)	Andy
15:00	Post- Authorisation Activities	Sarah Imrie, G&L Scientific
15:25	Product Safety (Pharmacovigilance)	David Solomon
15:35	Current and Planned Changes in the EU with a Practical Look at the Impact of Artificial Intelligence	Victor Goncharuk
16:00	Quiz 3 (learning reinforcement) Review of Learning Objectives	Andy and co-presenters
16:15	Delegate Feedback and Wrap-up	All Presenters/ TOPRA
16.:30	Course ends	
Note: Times in BST (Central European summer time – 1hr)		