

# Essentials of Pharmaceutical Regulatory Affairs



**14th July 2026**

**TOPRA offices and Online**

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