

Essentials of Pharmaceutical Regulatory Affairs



6th August 2024

Time	Presentation	Speaker
09:30	Introduction to TOPRA	TOPRA
09:40	Introductions – presenters and delegates	Andrew (Andy) Thornley
09:55	Setting the Scene	Andy Thornley
10:20	Break (15 minutes)	
10:35	Overview of Drug Development	Lizzy Heads GL Healthcare
11:05	Regulatory Control of Clinical Trials	Alexis Cockroft Lex Regulatory
11:30	Break (20 minutes)	
11:50	The Marketing Authorisation Application Dossier	Yevheniia Prysiakhna G&L Healthcare
12:15	Product Information (Labelling)	David Solomon
12:30	SmPC Game	Andy and David
13:00	Break (40 minutes)	
13:40	European Marketing Authorisation Procedures	Yevheniia Prysiakhna
14:20	Marketing Authorisation Strategy	Alexis and Andy
14:30	Break (20 minutes)	
14:50	Post- Authorisation Activities	Lizzy Heads
15:15	Product Safety (Pharmacovigilance)	David Solomon
15:30	Current and Planned Changes in the EU	Andy
15:35	Review of learning objectives and Quiz	All Presenters
16:00	Delegate Feedback and Wrap-up	All Presenters/ TOPRA

16.30	Course ends	
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Tuesday 6th August 2024
TOPRA Office and online