

Essentials of Pharmaceutical Regulatory Affairs

3 August 2023



Programme

Time	Presentation	Speaker
09:30	Introduction to TOPRA	TOPRA
09:40	Introductions – presenters and delegates	Andrew (Andy) Thornley UCB Pharma
09:55	Setting the Scene	Andy (tbc)
10:20	Break (15 minutes)	
10:35	Overview of Drug Development	Alexis Cockroft Lex Regulatory
11:05	Regulatory Control of Clinical Trials	Alexis
11:30	Break (20 minutes)	
11:50	The Marketing Authorisation Application Dossier	tbc
12:15	Product Information (Labelling)	Andy Thornley
12:30	SmPC Game	Andy Thornley
13:00	Break (40 minutes)	
13:40	European Marketing Authorisation Procedures	tbc
14:20	Marketing Authorisation Strategy	Alexis and Andy
14:40	Break (20 minutes)	
15:00	Post- Authorisation Activities	Alexis (with Andy for PV aspects tbc)
15:35	Review of learning objectives and Quiz	All Presenters
16:50	Delegate Feedback and Wrap-up	Kay Platt TOPRA
17:00	Course ends	
17:10	Career development in Regulatory Affairs (optional for any delegate who wishes to stay on)	tbc

ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION

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