

# Essentials of Pharmaceutical Regulatory Affairs

Thursday 3<sup>rd</sup> August 2023



## Programme

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