

Essentials of Pharmaceutical Regulatory Affairs

Tuesday 21st March 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 Thornley
10:20	Break (15 minutes)	
10:35	Overview of Drug Development	Sheetal Vaidya G&L Scientific
11:05	Regulatory Control of Clinical Trials	Sarah Tindall Consultant Reg Information
11:30	Break (20 minutes)	
11:50	The Marketing Authorisation Application Dossier	Sheetal Vaidya
12:15	Product Information (Labelling)	Andy Thornley
12:30	SmPC Game	Andy and Sheetal
13:00	Break (40 minutes)	
13:40	European Marketing Authorisation Procedures	Sarah Tindall
14:20	Marketing Authorisation Strategy	Mohit Sunkersett G&L Scientific
14:40	Break (20 minutes)	
15:00	Post- Authorisation Activities	Mohit and Andy
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)	Claire McDonald GSK

ENABLING AND PROMOTING EXCELLENCE IN THE HEALTHCARE REGULATORY PROFESSION