

Essentials of Pharmaceutical Regulatory Affairs



Programme

Time	Presentation	Speaker
09:30	Introduction to TOPRA	Raluca Radu TOPRA
09:40	Introductions – presenters and delegates	Chris Parkinson GlaxoSmithKline
09:55	Setting the Scene	Chris Parkinson
10:20	Break (15 minutes)	
10:35	Overview of Drug Development	Chris Parkinson
11:05	Regulatory Control of Clinical Trials	Chris Parkinson
11:25	Break (30 minutes)	
11:55	Marketing Authorisation Applications	Andy Thornley UCB Pharma
12:15	Product Information (Labelling)	Andy Thornley
12:30	Homework (SmPC) and Morning Quiz	Chris Parkinson
13:00	Break (40 minutes)	
13:40	European Marketing Authorisation Procedures	Andy Thornley
14:30	Marketing Authorisation Strategy	Andy & Chris
14:40	Break (20 minutes)	
15:00	Post- Authorisation Activities	Chris Parkinson
15:35	Review of learning objectives	All
16:30	Career development / Q&A on the day's topics	Andy & Chris
16:45	Wrap up and feedback	All