Essentials of Pharmaceutical Regulatory Affairs

Time	Presentation	Speaker
09:15	Introduction to TOPRA	
09:20	Introductions – presenters and delegates	
09:40	Setting the Scene	
10:35	Overview of Drug Development	
11:05	Break (20 minutes)	
11:25	Regulatory Control of Clinical Trials	
11:50	The Marketing Authorisation Application Dossier	
12:15	Product Information (Labelling)	
12:30	SmPC Game	
13:00	Break (40 minutes)	
13:40	European Marketing Authorisation Procedures	
14:20	Marketing Authorisation Strategy	
14:30	Break (20 minutes)	
14:50	Post- Authorisation Activities	
15:15	Product Safety (Pharmacovigilance)	
15:30	Current and Planned Changes in the EU	
15:35	Review of learning objectives and Quiz	
16:00	Delegate Feedback and Wrap-up	