

Essentials of Pharmaceutical Regulatory Affairs



Thursday June 2023 Brussels, Belgium

Programme

Time	Presentation	Speaker
09:30	Introduction to TOPRA	TBC
09:40	Introductions – presenters and delegates	Charlene Muscat
09:55	Setting the Scene	Claire McDonald
10:20	Break (15 minutes)	
10:35	Overview of Drug Development	Charlene Muscat
11:05	Regulatory Control of Clinical Trials	Claire McDonald
11:25	Break (10 minutes)	
11:35	Marketing Authorisation Applications	Charlene Muscat
11:55	Product Information (Labelling)	Charlene Muscat
12:10	Homework (SmPC) and Morning Quiz	Charlene Muscat
12:40	Break (1 hour)	
13:40	European Marketing Authorisation Procedures	Bruno Speder
14:30	Marketing Authorisation Strategy	Bruno Speder
14:40	Break (20 minutes)	
15:00	Post- Authorisation Activities	Claire McDonald
15:35	Review of learning objectives	All
16:30	Career development / Q&A on the day's topics	All
16:45	Wrap up and feedback	All