Essentials of Pharmaceutical Regulatory Affairs

11 June 2025, London, UK

Programme

Time	Presentation	Speaker
09:30	Introduction to TOPRA	**TBC**
09:40	Introductions – presenters and delegates	**Claire McDonald** **GSK**
09:55	Setting the Scene	**Claire McDonald**
10:20	Break (15 minutes)	
10:35	Overview of Drug Development	**Claire McDonald**
11:05	Regulatory Control of Clinical Trials	**Claire McDonald**
11:25	Break (10 minutes)	
11:35	Marketing Authorisation Applications	**Bruno Speder** Astrivax
11:55	Product Information (Labelling)	**Bruno Speder**
12:10	Homework (SmPC) and Morning Quiz	**Both**
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**