

Essentials of Pharmaceutical Regulatory Affairs

24 November 2020



Programme

Presenters:

Andy Thornley, FMD K&L and Regulink

Chris Parkinson, GSK

All timings are UK local time (GMT)

Time	Presentation	Presenter
09:30	Introduction to TOPRA	Cristina Dragan, TOPRA
09:40	Introductions	Andy Thornley & Chris Parkinson
09:55	Setting the Scene	Andy Thornley
10:20	Overview of Drug Development	Chris Parkinson
10:50	Regulatory Control of Clinical Trials	Chris Parkinson
11:10	Marketing Authorisation Applications	Andy Thornley
11:40	Break	
12:10	Product Information (Labelling)	Andy Thornley
12:20	SmPC game	Chris Parkinson
12:50	Break	
13:20	European Marketing Authorisation Procedures	Andy Thornley
14:20	Marketing Authorisation Strategy	Andy Thornley
14:30	Break	
14:50	Post- Authorisation Activities	Chris Parkinson
15:10	Review of learning objectives (including quiz!)	Andy Thornley & Chris Parkinson
15:50	Wrap up and feedback (Close 16:00)	