

Essentials of Pharmaceutical Regulatory Affairs

27th February 2020



Programme

Time	Presentation
10:00	Introduction to TOPRA
10:10	Introductions
10:35	Setting the Scene
11:00	Overview of Drug Development
11:30	Coffee
11:40	Regulatory Control of Clinical Trials
12:00	Marketing Authorisation Applications
12.30	Product Information (Labelling)
12:40	SmPC game
13:10	Lunch
14:10	European Marketing Authorisation Procedures
15:10	Marketing Authorisation Strategy
15.40	Post- Authorisation Activities
16:10	Review
15:40	Millionaire Quiz
16:20	Wrap up (Close 16:30)