

Essentials of Pharmaceutical Regulatory Affairs

6th August 2020



Programme

All timings are UK local time (BST/GMT+1)

Time	Presentation
09:30	Introduction to TOPRA
09:40	Introductions
09:55	Setting the Scene
10:20	Overview of Drug Development
10:50	Regulatory Control of Clinical Trials
11:10	Marketing Authorisation Applications
11:40	Break
12:10	Product Information (Labelling)
12:20	SmPC game
12:50	Break
13:20	European Marketing Authorisation Procedures
14:20	Marketing Authorisation Strategy
14:30	Break
14:50	Post- Authorisation Activities
15:10	Review
15:30	Millionaire Quiz
15:50	Wrap up (Close 16:00)