

# Essentials of Pharmaceutical Regulatory Affairs



Tuesday 10<sup>th</sup> May 2022

## Programme

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