

# Essentials of Pharmaceutical Regulatory Affairs



Thursday 4<sup>th</sup> August 2022

## **Programme**

<b>Time</b>	<b>Presentation</b>	<b>Speaker</b>
09:30	Introduction to TOPRA	<b>Raluca Radu</b> TOPRA
09:40	Introductions – presenters and delegates	<b>Andy Thornley</b> UCB
09:55	Setting the Scene	<b>Claire McDonald</b> GSK
10:20	Break (15 minutes)	
10:35	Overview of Drug Development	<b>Claire McDonald</b>
11:05	Regulatory Control of Clinical Trials	<b>Claire McDonald</b>
11:25	Break (10 minutes)	
11:35	Marketing Authorisation Applications	<b>Alexis Cockroft</b> Lex Regulatory Ltd
11:55	Product Information (Labelling)	<b>Andy Thornley</b>
12:10	SmPC Exercise	<b>Andy &amp; Claire</b>
12:40	Break (1 hour)	
13:40	European Marketing Authorisation Procedures	<b>Andy Thornley</b>
14:30	Marketing Authorisation Strategy	<b>Alexis &amp; Andy</b>
14:40	Break (15 minutes)	
14:55	Post- Authorisation Activities	<b>Claire McDonald</b>
15:30	Looking into the Future	<b>All</b>
15:35	Review of learning objectives / Q&A on today topics	<b>All</b>
16:30	Wrap up and Feedback	<b>All</b>
16:45	Career Panel Q&A	<b>All</b>