

# Essentials of Pharmaceutical Regulatory Affairs



Friday 31 May 2024, Hilton Hotel, Rotterdam, Netherlands

## **Programme**

<b>Time</b>	<b>Presentation</b>	<b>Speaker</b>
09:30	Introduction to TOPRA	<b>TBC</b>
09:40	Introductions – presenters and delegates	<b>Claire McDonald</b>
09:55	Setting the Scene	<b>Claire McDonald</b>
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>Bruno Speder</b>
11:55	Product Information (Labelling)	<b>Bruno Speder</b>
12:10	Homework (SmPC) and Morning Quiz	<b>Both</b>
12:40	Break (1 hour)	
13:40	European Marketing Authorisation Procedures	<b>Bruno Speder</b>
14:30	Marketing Authorisation Strategy	<b>Bruno Speder</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>