BRITISH PHARMACOLOGICAL SOCIETY

Launching a new medicine – Training workshop

Thursday 26th October 2023

10.00 - 10.15	**Welcome and plan for the day** *Renata Scalco – Global Development Leader, Roche*
10.15 - 10.45	**What critical attributes make a drug a drug** *Lutz Mueller – Toxicology Project Leader, Roche*
10.45 - 11.15	**Regulatory perspective of drug development** *Lesley Narburgh – Global Franchise Regulatory Head, Rare diseases and Neurodegeneration, Roche*
11.15 - 11.45	**Breakout tutorial session (attributes of a drug)** *Lutz Mueller and Lesley Narburgh, Roche*
11.45 - 12.00	**Break**
12.00 - 12.30	**Review and decision – When is it safe to go into humans?** *David Jones – Consultant Pharmaco-Toxicologist*
12.30 - 13.00	**Clinical pharmacology evidence building** *Helen Tomkinson – Managing Director, Limina Clinical Pharmacology*
13.00 - 13.45	**Lunch**
13.45 - 14.15	**Breakout tutorial session (Clinical PK)** *Helen Tomkinson – Managing Director, Limina Clinical Pharmacology*
14.15 - 14.45	**Indication selection – proactive and reactive risks** *Aaron Deveney – Vice President Clinical Development, Weatherden*
14.45 - 15.15	**Breakout tutorial session (indication selection problem)** *Aaron Deveney – Vice President Clinical Development, Weatherden*
15.15 - 15.25	**Break**
15.25 - 15.55	**The clinical regulatory perspective** *Kirsty Wydenbach – Head of Regulatory Strategy, Weatherden*
15.55 - 16.25	**Breakout tutorial session (regulators discussion - labels)** *Kirsty Wydenbach – Head of Regulatory Strategy, Weatherden*
16.25 - 16.30	**Wrap-up and confirmation of the Learning Outcomes** *Renata Scalco - Project lead, Roche*