MODULE 2 7FHH1099

Agenda

Regulatory Strategy for a New Active Substance:

Non-clinical Development

TOPRA, 5-6 City Reach, London, E14 9 NN, UK

11 – 13 February 2025

Day 1 – Tuesday 11th February		
13:30– 14:00	**Registration**	
14:05	**Start of Module**	
	Chairperson:	*Lesley Reeve* *Module Leader*
14:05 – 14:20	**Welcome and Introduction**	
14:25 – 15:15 (50 minutes)	**Non-clinical Studies in Drug Development**	*Elisa Passini* *NC3Rs*
15:20 – 16.10 (50 minutes)	**Selection of a Candidate Compound: Studies to Identify Likely Candidates**	*Tom Hammond* *AstraZeneca*
16:10 – 16:30	**Tea Break**	
16:30 – 17:15 (45 minutes)	**Safety Pharmacology Studies**	*Andrea Greiter-Wilke* *Roche, Switzerland*
17:15 – 17:30	**Introduction to The Case Study** (Case study questions available for collection)	*Lesley Reeve* *Module Leader*
17:30	**Close of Day 1**	

Day 2 – Wednesday 12th February		
Chairpersons:	Lesley Reeve and Andy Gibbs	
09:00 – 10:00 (1 hour)	**Introduction to Pharmacokinetics and Application to Drug Development**	*Peter Kilford* *Simulations Plus*
10:05 – 10:25 (20 minutes)	**Coffee Break**	
10:25 – 11:25 (1 hour)	**General Toxicology Studies**	*Andy Gibbs* *LabCorp*
11:30 – 12:20 (50 minutes)	**Genotoxicity and Carcinogenicity**	*Lesley Reeve* *Fortrea*
12:25 – 13:25 (1 hour)	**LUNCH**	
13:30 – 14:30 (1 hour)	**Reproductive Toxicology Testing – What and Why?**	*Jane Stewart* *Apconix*
14:35 – 14:55 (20 minutes)	**Tea Break**	
15:00 – 15:45 (45 minutes)	**Environmental Risk Assessment**	*Sarah Bull* *Tara Consulting*
15:50 – 19:00 (~3 hours)	**Case Study (Group work)**	*Lesley Reeve* & *Andy Gibbs* *Module Leaders*
19:00	**Close of Day 2**	

Day 3 – Thursday 13th February		
Chairpersons:	Andy Gibbs and Lesley Reeve	
09:00 – 09:45 (45 minutes)	**Toxicology Support for Paediatric Development**	*Paul Baldrick Fortrea*
09:50 – 10:40 (50 minutes)	**Overall Assessment of the Non-clinical Package and Strategic Planning**	*Lesley Reeve Fortrea*
10:40 – 11:00	**Coffee break**	
11:00 – 11:50 (50 minutes)	**Specific Nonclinical Considerations Associated with Biotechnology Products**	*Andy Gibbs* LabCorp
11:55 – 12:45 (50 minutes)	**Specific Nonclinical Considerations Associated with Cell and Gene Therapy Products**	*Michaela Sharpe Moare Solutions Ltd.*
12:45 – 13:45 (1 hour)	**LUNCH**	
13:45 – 14:45 (1 hour)	**Agency Review Process / Data Presentation Problems**	*Julianna Berrie MHRA*
14:45 – 15:45 (1 hour)	**Case study and Feedback (includes TEA)**	*All*
15:45 - 16:00	**Close of Module**	