MODULE 2 7FHH1099 – Agenda

Regulatory Strategy for a New Active Substance: Non-clinical Development

TOPRA, 6th Floor, 3 Harbour Exchange, South Quay, London E14 9GE, UK

20 - 22 October 2021

Day 1 – Wednesday 20th October

13:30– 14:00	**Registration**	
14:05	**Start of Module**	
	Chairperson: *Lesley Reeve*	
14:05 – 14:20	**Welcome and Introduction**	*Laura Brown, Course Director* *Lesley Reeve, Module Leader*
14:25 – 15:15	**Non-clinical Studies in Drug Development**	*Natalie Burden* *NC3Rs*
15:20 – 16.10	**Selection of a Candidate Compound: Studies to Identify Likely Candidates**	*Liz Martin* *AstraZeneca*
16:10 – 16:30	**TEA**	
16:30 – 17:20	**Overall Non-clinical Package and Strategic Planning**	*Lesley Reeve* *Covance*
17.20 –	**Case study (Group work)**	*Lesley Reeve* *Covance*

Day 2 – Thursday 21st October

Chairperson: *Lesley Reeve*

09:30 – 10:30	**Safety Pharmacology Studies**	*Will Redfern* *Certara*
10:30 – 10:50	**COFFEE**	
10:55 – 11:55	**Introduction to Pharmacokinetics and Application to Drug Development**	*Peter Kilford* *Certara*
12:00 – 13:00	**General Toxicology and Carcinogenicity Testing**	*Andy Gibbs* *Covance*
13:00 – 13:50	**LUNCH**	
13:55 – 14:55	**Genotoxicity Testing**	*Jon Howe* *GSK*
15:00 – 16:00	**Reproductive Toxicology Testing – What and Why?**	*Jane Stewart* *Apconix*
16:05 -	**Case Study (Group work)** **(includes TEA)**	*Lesley Reeve* *Covance*

Day 3 – Friday 22nd October

Chairperson: *Lesley Reeve*

09:30– 10:00	**Environmental Risk Assessment**	*Ainsley Jones* *FERA*
10:05 – 10:45	**Toxicology Support for Paediatric Development**	*Paul Baldrick* *Covance*
10:45 – 11:05	**COFFEE**	
11:05 – 11:55	**Specific Nonclinical Considerations Associated with Biotechnology Products**	*Alison Wolfreys* *UCB*
12:00 – 12:50	**Specific Nonclinical Considerations Associated with Cell and Gene Therapy Products**	*Michaela Sharpe* *Moare Solutions Ltd.*
12:50 – 13:45	**LUNCH**	
13:45 – 14:45	**Agency Review Process / Data Presentation Problems**	*David Jones* *MHRA*
14:45 – 15:45	**Case study and Feedback** **(includes TEA)**	*All*
15:45 - 16:00	**Close of Module**	