Module 2: Regulatory Strategy for a New Active Substance: Non-clinical Development

Date: 15 – 17 March 2023

LOCATION: TOPRA OFFICE, LONDON, UK

Module Leader(s): Lesley Reeve & Andy Gibbs

Day 1: Wednesday 15th March 2023

Time	Activity	Speaker
14:00 – 14:20	1. Welcome and Introduction to Module	Lesley Reeve, Module Leader
14:20 – 15:15	2. Non-clinical Studies in Drug Development	Natalie Burden, NC3Rs
15:15 – 16:10	3. Selection of a Candidate Compound: Studies to Identify Likely Candidates	Liz Martin, Astra Zeneca
16:10 – 16:30	Afternoon break	
16:30 – 17:20	4. Overall Non-clinical Package and Strategic Planning	Lesley Reeve, Covance
17:20 -	5. Case Study (Group work)	Lesley Reeve, Covance

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Day 2: Thursday 16th March 2023

Time	Activity	Speaker
09.30 – 10.30	6. Safety Pharmacology Studies	Will Redfern, Certara
10.30 – 10.50	Morning break	
10.50 – 11.55	7. Introduction to Pharmacokinetics and Application to Drug Development	Peter Kilford, Certara
11.55 – 13:00	8. General Toxicology and Carcinogenicity Testing	Andy Gibbs, Covance
13:00 – 13:50	Lunch	
13.50 – 14:55	9. Genotoxicity Testing	Jon Howe, GSK
14:55 – 16:00	10. Reproductive Toxicology Testing – What and Why?	Jane Stewart, Apconix
16:00 –	Case Study (Group work, includes afternoon break)	Lesley Reeve, Covance

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Day 3: Friday 17th March 2023

Time	Activity	Speaker
09.30 – 10:00	11. Environmental Risk Assessment	Ainsley Jones, FERA
10:00 – 10.45	12. Toxicology Support for Paediatric Development	Paul Baldrick, Covance
10.45 – 11.05	Morning break	
11.05 – 11:55	13. Specific Nonclinical Considerations Associated with Biotechnology Products	Alison Wolfreys, UCB
11:55 – 12.50	14. Specific Nonclinical Considerations Associated with Cell and Gene Therapy Products	Michaela Sharpe, Moare Solutions Ltd.
12.50 – 13.45	Lunch	
13:45 – 14.45	15. Agency Review Process / Data Presentation Problems	David Jones, MHRA
14.45 – 15.45	Case Study and Feedback (includes afternoon break)	All
15.45 – 16.00	Close of Module	