

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

11 – 13 February 2025

Lincoln Plaza Hotel, 2 Lincoln Plaza, London E14 9BN



Module Leader(s): Lesley Reeve and Andy Gibbs

Date: Tuesday 11th February

| Time (CET) | Activity | Speaker |
|----------------------|--|--|
| 13.30 – 14.00 | Lunch and registration | |
| 14:05 – 14.20 | Welcome & Introduction to Module | Lesley Reeve Module Leader |
| 14.25 – 15.15 | Lecture 1: Non-clinical Studies in Drug Development | Elisa Passini NC3Rs |
| 15.20 – 16.10 | Lecture 2: Selection of a Candidate Compound: Studies to Identify Likely Candidates | Tom Hammond AstraZeneca |
| 16.10 – 16.30 | Refreshment Break | |
| 16.30 – 17.15 | Lecture 3: Safety Pharmacology Studies | Andrea Greiter-Wilke Roche, Switzerland |
| 17.30 | Close of day 1 | |



Date: Wednesday 12th February

| Time (CET) | Activity | Speaker |
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| 09.00 – 10.00 | Lecture 4: Introduction to Pharmacokinetics and Application of Drug Development | Peter Kilford Simulations Plus |
| 10.05 – 10.25 | Refreshment Break | |
| 10.25 – 11.25 | Lecture 5: General Toxicology Studies | Lesley Reeve Fortrea |
| 11.30 – 12.20 | Lecture 6: Genotoxicity and Carcinogenicity | Lesley Reeve Fortrea |
| 12.25 – 13.25 | Lunch | |
| 13.30 – 14.30 | Lecture 7 : Reproductive Toxicology Testing – What and Why | Jane Stewart Apconix |
| 14.35 – 14.55 | Lecture 8: Environmental Risk Assessment | Sarah Bull Tara Consulting |
| 15.00 – 15.45 | Refreshment Break | |
| 15.50 – 18.30 | Case Study and feedback | Lesley Reeve and Andy Gibbs Module Leaders |



Date: Thursday 13th February

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| 09.00 – 09.45 | Lecture 9: Toxicology Support for Paediatric Development | Paul Baldrick Fortrea |
| 09.50 – 10.40 | Lecture 10: Overall Assessment of the Non-clinical Package and Strategic Planning | Lesley Reeve Fortrea |
| 10.40 – 11.00 | Refreshment Break | |
| 11.00 – 11.50 | Lecture 11: Specific Non-clinical Considerations Associated with Biotechnology Products | Andy Gibbs LabCorp |
| 11.55 – 12.45 | Lecture 12: Specific Non-clinical Considerations Associated with Cell and Gene Therapy Products | Michaela Sharpe Moare Solutions Ltd |
| 12.45 – 13.45 | Lunch | |
| 13.45 – 15.45 | Lecture 13: Agency Review Process / Data Presentation Problems | Julianne Berrie MHRA |
| 15.45 – 16.00 | Close of Module | |