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

3rd – 5th July 2019

***De Vere Latimer Place, Chesham, Bucks, UK*** **Module Leader**: Lesley Reeve

**Date:** Wednesday 3rd July

| Time | Activity | Speaker |
|---|---|---|
| **15.30 – 16.00** | Registration | |
| **16.00 – 16.20** | Welcome & Introduction<br>Aims and objectives of the module | Lesley Reeve<br>Module Leader |
| **16.20 – 17.15** | Lecture 1: Non-clinical Studies in Drug Development | Natalie Burden<br>NC3Rs |
| **17.15 – 18.00** | Lecture 2: Selection of a Candidate Compound: Studies to Identify Likely Candidates | Liz Martin<br>AstraZeneca |
| **18.00 – 18.30** | New Student Tutorial | Laura Brown<br>Course Director |
| **19.00** | **Dinner** | |

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3rd – 5th July 2019

**Date**: Thursday 9th May 2019 Chairperson: Lesley Reeve

| Time | Activity | Speaker |
|---|---|---|
| **09.00 – 09.45** | Lecture 3: Safety Pharmacology Studies | Will Redfern<br>Certara |
| **09.45 – 10.50** | Lecture 4: Introduction to Pharmacokinetics and Application to Drug Development | Peter Kilford<br>Certara |
| **10.50 – 11.20** | **Refreshment Break** | |
| **11.20 - 12.30** | Lecture 5: General Toxicology and Carcinogenicity Testing | Andy Gibbs<br>Covance |
| 12.30 – 13.30 | Lunch | |
| 13.30 – 14.25 | Lecture 6: Candidate selection/ PK - tutorial | Peter Kilford and Lesley Reeve |
| 14.25 – 14.45 | Introduction to Case Study | Lesley Reeve<br>Covance |
| **14.45 – 15.15** | **Refreshment Break** | |
| 15.15 – 16.15 | Lecture 7: Genotoxicity Testing | Jon Howe<br>GSK |
| 16.15 – 16.50 | Lecture 8: Environmental Risk Assessment | Ainsley Jones<br>FERa |
| 16.55 – 18.30 | Case Study | Lesley Reeve<br>Covance |
| **19.00** | **Dinner** | |

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

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**Date:** Friday 5th July 2019

| | | **Chairperson: Lesley Reeve** |
|---|---|---|
| **09.00 – 10.00** | Lecture 9: Reproductive Toxicology Testing – What and Why? | Jane Stewart<br>Apconix |
| **10.30 – 10.35** | Lecture 10: Toxicology and Support for Paediatric Development | Paul Baldrick<br>Covance |
| **10:35 – 11.00** | **Refreshment Break and Check Out** | |
| **11.00 – 11.45** | Lecture 11: Specific Considerations Associated with Biotechnology Products | Alison Wolfreys<br>UCB |
| **11.45 – 12.35** | Lecture 12: Overall Assessment of the Non-clinical Package and Strategic Planning | Lesley Reeve<br>Covance |
| **12.35 – 13.35** | **Lunch** | |
| **13.35 – 14.45** | Lecture 13: Agency Review Process / Data Presentation Problems | David Jones<br>MHRA |
| **14.45 – 15.45** | **Case Studye and Feedback including Refreshment Break** | |
| **15.45 – 16.00** | Close of Module | |