

Practical Application of Toxicology in Drug Development

2019 Course Schedule

Day 1 - Monday, July 15

07:45-08:15	Registration and Check In
08:15-08:30	Welcome and Introduction <i>Ernie Harpur, Newcastle University</i>
08:30-10:00	Overview of Drug Discovery and Development; Part I <i>Ruth Roberts, Apconix</i>
10:00-10:20	Break
10:20-11:50	Overview of Drug Discovery and Development; Part II <i>Ruth Roberts, Apconix</i>
11:50-12:50	Lunch
12:50-13:40	Pharmacology <i>Rob Wallis, Safety Pharmacology Consultant</i>
13:45-14:45	Safety Pharmacology <i>Rob Wallis, Safety Pharmacology Consultant</i>
14:45-15:00	Break
15:00-16:30	Pharmacokinetics/ADME <i>Kunal Taskar, GSK</i>
16:00-16:15	Day 1 Wrap Up and Day 2 Workshop Instructions
16:30-18:30	Reception (followed by your own arrangements for dinner)

Day 2 - Tuesday, July 16

08:30-10:00	Organ Systems—Part I <i>Adam Hargreaves, Pharmcelerate</i>
10:00-10:15	Break
10:15-11:45	Organ Systems—Part II <i>Matt Jacobsen, AstraZeneca</i>
11:45-12:45	Lunch
12:45-14:15	Safety of Biotechnology Products <i>Lolke de Haan, MedImmune</i>
14:15-14:30	Break

14:30-16:00	Genetic Toxicology <i>George Johnson, Swansea University</i>
16:00-16:10	Day 2 Wrap Up and Day 3 Workshop Instructions
16:10-17:00	Breakout Group Discussion

Day 3 - Wednesday, July 17

08:30-08:45	Presentation from Day 2 Breakout Session
08:45-10:15	Carcinogenicity <i>Nigel Roome, Independent Expert</i>
10:15-10:30	Break
10:30-12:00	Pathology <i>Vasanthi Mowat, Envigo</i>
12:00-13:00	Lunch
13:00-14:30	Clinical Pathology <i>Jo Harding and Peter Cotton, AstraZeneca</i>
14:30-14:45	Break
14:45-16:15	Immunotoxicology <i>Marc Pallardy, Université Paris-Sud</i>
16:15-16:20	Day 3 Wrap Up and Day 4 Workshop Instructions
16:20-17:00	Breakout Group Discussion

Day 4 - Thursday, July 18

08:30-08:45	Presentations from Day 3 Breakout Sessions
08:45-10:15	Reproduction/Developmental Toxicology <i>Gary Chellman, Charles River</i>
10:15-10:30	Break
10:30-12:00	Risk Assessment <i>Ernie Harpur, Newcastle University</i>
12:00-13:00	Lunch
13:00-14:30	Regulatory Toxicology <i>David Jones, MHRA</i>
14:30-14:45	Break
14:45-16:45	Regulatory Case Studies <i>Tim McGovern, American College of Toxicology and David Jones MHRA</i>
16:45-17:00	Day 4 Wrap Up and Day 5 Workshop Instructions

Day 5 - Friday, July 19

09.00-09.10	Presentations from Day 4 Breakout Session Day 5 Workshop Instruction
09.10-10.10	Common Technical Document preparation and Standard for Exchange of Nonclinical Data <i>Trish Parris and Brett Coupland, AstraZeneca</i>
10.10-11.40	Breakout Group Discussion of Nonclinical Assessment of Drug F with Regulators <i>Tim McGovern, ACT, Tanya Chambers, MHRA and Leonora Simon, MHRA</i>
10.40-11.50	Break
11.50-12.50	Review of Nonclinical Assessment of Drug F: Regulatory Perspective <i>Tim McGovern, ACT</i>
12.50-12.55	Final Summary <i>Ernie Harpur, Newcastle University and Norman Kim, Immunovant</i>
12:55-14:00	Lunch and Adjourn