

# DRUG DISCOVERY AND DEVELOPMENT

## 16:963:509

### Course Directors:

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**Course Description:** The purpose of this 1-credit elective course is to provide students an understanding of the drug discovery and development paradigm, from target validation and lead optimization to the numerous preclinical studies conducted to ensure drug safety. To emphasize the multidisciplinary approach needed to accomplish this task, students will learn from and engage instructors with a wide array of expertise, and will participate in case studies designed to improve their understanding of the course material.

### Course Objectives:

Upon completion of this course, the learner is expected to:

- Describe the stages of drug development and the timing of various safety studies.
- Demonstrate an understanding of the types of tests performed for regulatory submissions to global regulators.
- Review ICH Safety guidelines that describe the battery of studies needed for the safety testing of pharmaceuticals.
- Compare and contrast the safety testing of small molecules and therapeutic biologic molecules.
- Apply knowledge from lectures to solve case study questions.

## LECTURE SCHEDULE

Topics	Instructors
<b><i>Drug Discovery and Development – Overview</i></b> <ul style="list-style-type: none"> <li>• General timeline of drug development</li> <li>• Considerations for small molecules versus biologics</li> <li>• Pharmacodynamics versus toxicology</li> <li>• Overview of group roles</li> <li>• Regulatory requirements</li> </ul>	M. Davis H. Haggerty
<b><i>Target Validation and Lead Optimization</i></b> <ul style="list-style-type: none"> <li>• Principles of target screening</li> <li>• Technologies utilized</li> <li>• <i>In vitro</i> to <i>in vivo</i> screenings and model selection</li> </ul>	M. Fereshteh L. Zhang
<b><i>Discovery and Investigative Toxicology</i></b> <ul style="list-style-type: none"> <li>• Identification of early liabilities</li> <li>• Animal model selection rationale</li> <li>• Criteria for conducting investigative studies</li> </ul>	E. Janovitz J. Loy
<b><i>CASE STUDY: Investigative Toxicology</i></b>	S. Ruepp
<b><i>Pharmacokinetics / Toxicokinetics / Biotransformation</i></b> <ul style="list-style-type: none"> <li>• Basic Principles of PK/TK</li> <li>• Calculating exposure multiples to human dose</li> <li>• ADME</li> <li>• Regulatory requirements and study design</li> </ul>	A. Batog
<b><i>Genetic Toxicology / Occupational Toxicology</i></b> <ul style="list-style-type: none"> <li>• Mechanisms of genotoxicity</li> <li>• <i>In silico</i> / <i>in vitro</i> / <i>in vivo</i> assays</li> <li>• Identifying occupational hazards</li> </ul>	P. Leavitt J. Hillegass

<ul style="list-style-type: none"> <li>• Setting occupational exposure limits and permitted daily exposures for patient safety</li> </ul>	
<b><i>CASE STUDY: Genetic Toxicology</i></b>	L. Custer
<b><i>Safety / Cardiovascular Pharmacology</i></b> <ul style="list-style-type: none"> <li>• Basics of safety pharmacology</li> <li>• Cardiovascular safety assessments</li> <li>• Regulatory requirements</li> </ul>	P. Levesque
<b><i>Immunotoxicology</i></b> <ul style="list-style-type: none"> <li>• Classic assays of immunotoxicology</li> <li>• Incorporating pharmacodynamic assessments into toxicology studies</li> <li>• Utilizing vaccine models to assess pharmacodynamics</li> </ul>	J. Wheeler
<b><i>CASE STUDY: Immunotoxicology</i></b>	J. Sathish
<b><i>Toxicologic Pathology</i></b> <ul style="list-style-type: none"> <li>• Application of specialized techniques in toxicological pathology</li> <li>• Distinguishing spontaneous from test article-related lesions</li> <li>• Determination of adverse vs non-adverse findings</li> <li>• Extrapolation of animal data to human risk assessment</li> </ul>	L. Berman-Booty T. Brodie
<b><i>Reproductive Toxicology</i></b> <ul style="list-style-type: none"> <li>• <i>In vitro</i> screening in early discovery</li> <li>• Regulatory requirements</li> <li>• Impact on clinical trials and product labeling</li> </ul>	C. Villano K. Augustine
<b><i>CASE STUDY: Reproductive Toxicology</i></b>	K. Thompson
<b><i>Veterinary Science / Animal Models</i></b> <ul style="list-style-type: none"> <li>• Role of Institutional Animal Care and Use Committee</li> <li>• Proper design, conduct and reporting of experiments</li> <li>• Validation and use of specialized animal models</li> <li>• Animal welfare regulations</li> </ul>	H. Burr M. Kundu