BIOM6490: Introduction to Drug Development
Winter 2019
DRAFT

Calendar Description:
Drug development is the process of integrating scientific data from several disciplines in order to demonstrate efficacy and safety of the candidate molecule for regulatory approval. This course will provide an overview of the drug development process including preclinical and clinical phases as well as regulatory aspects of drug development.

Course Coordinator:
Dr. Gordon Kirby
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Instructors:
Dr. Craig Bailey (Biomedical Sciences)
Dr. Cathy Bauman (Population Medicine)
Dr. Ron Johnson (Biomedical Sciences)
Dr. Jibran Khokhar (Biomedical Sciences)
Dr. Jim Petrik (Biomedical Sciences)

Guest lecturers:
Rodney Butt (Nutrasource Diagnostics Inc., Guelph, ON)
Dr. Jonathan Hare (Consultant, TelemarkVet, Toronto, ON)
Dr. David Hobson, (Research Innovation Office, University of Guelph)
Dr. Veronique Lauriault (Toxicology Consultant, San Francisco, CA)
Dr. Michael Schunk, (Executive Vice President, Operations, Medicago, Québec City, QC)

Course Objectives:
The objectives of the course are i) to understand the science surrounding the progression of novel drug candidates from early discovery to the marketplace, ii) to understand the regulation of the drug approval process.

Course Description:
The course will provide an overview of the key areas of drug development and approval, focusing on the science of drug development, regulation and industry perspectives. After successful completion of this course, the student will be able to:

1. Define and correctly use the vocabulary common to the drug development process.
2. Understand the timelines of the drug development process.
3. Understand concepts in drug design, synthesis and screening of early drug discovery.

4. Understand basic concepts of pharmacodynamics and pharmacokinetics of preclinical phases of drug development, including bioanalytical techniques and biomarkers.
5. Understand the toxicity tests used to assess drug safety in preclinical phases, the interpretation of preclinical data and the contribution to clinical trial design.
6. Understand the stages of clinical development (phase I-IV) required for drug approval.
7. Understand regulatory submissions and governance of the drug approval process.

Lecture Times & Location
Tuesday and Thursday 1:00-2:20 p.m., 3648 Biomedical Sciences, OVC

Recommended Reading Material:
Lecture notes will be available on CourseLink before lectures.

CALCULATION OF COURSE GRADES

Student Evaluation:
Students will be evaluated as follows:

- *A written report consisting of a current issue in drug development.* Students will choose topics from a list that will be provided in CourseLink. Example topics include: influenza vaccine development, making therapeutics in cells; orphan drug development; minimizing risk in drug development; ethical issues in drug development; harmonization of drug regulatory policy; use of big data in drug development etc. This report is due March 22 and is worth 40% of the final grade.
- *A ten-minute oral presentation on the selected issue in drug development.* Student presentation dates, along with topics, can be booked on a first-come-first-served basis in CourseLink. Presentations will be evaluated by 2 faculty members and are worth 25% of the final grade.
- *Mock regulatory review of an IND submission.* Students will be divided into a "submission" team and a "reviewer" team. Data will be provided from the pre-clinical stage of drug development. The "submission" team will select, present and defend the relevant data in a written IND submission and the "reviewer" team will provide a written response to the submission. Faculty coaches will be assigned to each team to provide support and advice. The oral component of the mock regulatory review (worth 30%) will take place during the final lecture timeslot. This will consist of a deliberation between the two teams involving questions and answers related to the IND submission and the reviewers' report. The submission will be judged by 3 faculty members and will be based on the quality of the written reports and the deliberation. The structure, timelines and logistics of the written reports and the deliberation will be discussed in class.
- *Student participation* is based on contributions to group discussions and evaluation of seminars by student peers (5%).

BIOM*6490 Class Schedule (W2019)

Date	Topic	Faculty/Speaker
Jan 08	Introduction –overview of drug development process; workflow, phases, objectives, activities	Kirby
Jan 10	Introduction –drug regulation, government structure, legislation, policy development and implications	Kirby
Jan 15	Preclinical drug development –Good Laboratory Practice I	Hare
Jan 17	Preclinical drug development –Good Laboratory Practice II	Hare
Jan 22	Early discovery -Drug discovery activities	Khokhar
Jan 24	Early discovery -Targeted Drug Design	Petrik
Jan 31	Regulatory- Preclinical drug development-Fundamental Aspects	Kirby
Feb 05	Regulatory- Preclinical drug development -PK-ADME	Kirby
Feb 07	Regulatory- Preclinical drug development-Practical Aspects	Kirby
Feb 12	Regulatory- Submission and Regulatory Review-Canada	TBA
Feb 14	Regulatory- Submission and Regulatory Review -USA and EU	Lauriault
Feb 19	Winter break –No classes	
Feb 21	Winter break –No classes	
Feb 26	Student Presentations	
Feb 28	Student Presentations	
Mar 05	Clinical Trials - Design and statistics	Bauman
Mar 07	Clinical Trials - Structure and management	Butt
Mar 12	Clinical Trials -Practical Aspects: -Contract Research Organizations, Submission and Regulatory Review	Butt
Mar 14	Veterinary Drug Development –Food Animal Drugs-1	Johnson
Mar 19	Natural Health Products	Butt
Mar 21	Veterinary Drug Development –Food Animal Drugs-2	Johnson
Mar 26	Regulatory -Intellectual Property and Legal aspects	Hobson
Mar 28	Biologics (peptides and monoclonal antibodies), Vaccines, Antibody-drug conjugates	Schunk
Apr 2	Commercializing pharmaceuticals	TBA
Apr 4	Mock Regulatory Review of New Drug Submission	Students

Responsibilities of the Student:

E-mail Communication

As per university regulations, all students are required to check their <uoguelph.ca> e-mail account regularly: e-mail is the official route of communication between the University and its students. Communication will also occur via CourseLink.

When You Cannot Meet a Course Requirement

When you find yourself unable to meet an in-course requirement because of illness or compassionate reasons, please advise the course in writing, with your name, id#, and e-mail contact. See the graduate calendar for information on regulations and procedures for Academic Consideration:
http://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/sec_d0e1400.shtml

Drop Date

Refer to the Graduate Calendar for the schedule of dates for dropping one-semester and two-semester courses:
http://www.uoguelph.ca/registrar/calendars/graduate/current/sched/sched-dates-f10.shtml

Academic Misconduct

The University of Guelph is committed to upholding the highest standards of academic integrity and it is the responsibility of all members of the University community – faculty, staff, and students – to be aware of what constitutes academic misconduct and to do as much as possible to prevent academic offences from occurring. University of Guelph students have the responsibility of abiding by the University's policy on academic misconduct regardless of their location of study; faculty, staff and students have the responsibility of supporting an environment that discourages misconduct. Students need to remain aware that instructors have access to and the right to use electronic and other means of detection. The Academic Misconduct Policy is detailed in the Graduate Calendar:
http://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/sec_d0e1687.shtmlhttp://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/sec_d0e1702.shtml

Recording of Materials

Presentations which are made in relation to course work—including lectures—cannot be recorded in any electronic media without the permission of the presenter, whether the instructor, a classmate or guest lecturer.

Resources

The Graduate Calendar is the source of information about the University of Guelph's procedures, policies and regulations which apply to graduate programs:
http://www.uoguelph.ca/registrar/calendars/graduate/current/