

BIOM6490: Introduction to Drug Development
Fall 2016
(0.5 Credits)

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 aspects of drug development.

Course Coordinator:

Dr. Ron Johnson, Biomedical Sciences, Room 1683, ext 54041, email:
rjohns03@uoguelph.ca

Instructors:

Dr. Craig Bailey (co-coordinator; Biomedical Sciences, University of Guelph)
Dr. Gord Kirby (Biomedical Sciences, University of Guelph)
Dr. John Dutcher (Physics, University of Guelph)
Dr. Jonathan Hare (Kingfisher International Inc, Stouffville, ON)
Rodney Butt (Nutrasource Diagnostics Inc, Guelph, ON)
Others (to be announced)

Course Objectives:

The objectives of the course are i) to understand the science surrounding the taking of novel drug (and medical device) candidates from early discovery to the marketplace, ii) to understand the regulation of the drug and medical device approval process.

Course Description:

The course will provide an overview of the key areas of drug (and medical device) 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 stages of clinical development (phase I-IV) for drug approvals.
6. Understand regulatory submissions and governance of the drug approval process.
7. Understand product manufacturing, commercialization, marketing and sales pertaining to drug molecules

Evaluation:

Students will be graded on seminar presentations (2 X 25%) and a critical review paper (50%).

Resources:

Notes will be available on D2L

BIOM6490 Class Schedule (F2016)

Schedule **All sessions in OVC 3648, Tues & Thurs: 10:00-11:20 am**

Date	Topic	Faculty/Speaker
Sept 15	Introduction to drug development	RB
Sept 17	Introduction to drug development	RB
Sept 22	Preclinical drug development-Good Lab Practice-I	JH
Sept 24	Preclinical drug development-Good Lab Practice-II	JH
Sept 29	Preclinical drug development-II	GK
Oct 01	Preclinical drug development-II	GK
Oct 06	Early discovery (Targeted Drug Design)	JD
Oct 08	Early discovery (Targeted Drug Design)	JD
Oct 13	No classes	
Oct 15	No classes	
Oct 20	Student Seminars-1	
Oct 22	Student Seminars-1	
Oct 27	Regulatory-I (IP and Legal)	CB
Oct 29	Regulatory-I (IP and Legal)	CB
Nov 03	Clinical Trials	RB
Nov 05	Clinical Trials	RB
Nov 10	Regulatory-II (Regulatory Review; Remote)	SA
Nov 12	Regulatory-II (Regulatory Review; Remote)	SA
Nov 17	Prod Manu/Commercialization/Mark/Sales	RP
Nov 19	Prod Manu/Commercialization/Mark/Sales	RP
Nov 24	Student Seminars-2	
Nov 27	Student Seminars-2	
Dec 01	Veterinary Drug Dev-Food Animal Drugs	RJ
Dec 03	Veterinary Drug Dev-Food Animal Drugs	RJ

Please note that the schedule may change

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.

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/>