BIOM*6490 Introduction to Drug Development

Winter 2022
Section(s): 01

Department of Biomedical Sciences
Credit Weight: 0.50
Version 1.00 - December 21, 2021

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1 Course Details

1.1 Calendar Description

Drug development is the process of integrating scientific data from several disciplines in order to demonstrate efficacy and safety of the new chemical entity for regulatory approval. This course will provide an overview of the drug development process including preclinical and clinical aspects of drug development.

Restrictions: Restricted to Biomedical Sciences students.

1.2 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.

1.3 Timetable

Timetable is subject to change. Please see WebAdvisor for the latest information.

Date	Topic	Lecturer
Jan 11	Introduction –overview of drug development process; drug regulation, government legislation and policy development	Kirby
Jan 13	Early discovery -Drug discovery activities	Khokhar
Jan 18	Preclinical drug development -Good Laboratory Practice I	Davidson
Jan 20	Preclinical drug development -Good Laboratory Practice II	Davidson
Jan 25	Early discovery -Targeted Drug Design	Petrik
Jan 27	Regulatory- Preclinical drug development- Fundamental Aspects	Kirby
Feb 01	Regulatory- Preclinical drug development - Pharmacology	Kirby
Feb 03	Regulatory- Preclinical drug development - Practical Aspects	Kirby
Feb 08	Regulatory- Regulatory Review for market authorization-Canada	Cherry

Feb 10	Regulatory- Non-clinical Safety and Regulatory Review -USA	Lauriault
Feb 15	Toxicology Consultants: Issues in Drug Development	Haighton
Feb 17	Communicating Risk in Drug Development	Brecher
Feb 22	Winter break –No class	
Feb 24	Winter break –No class	
Mar 1	Clinical Trials – Study design and statistics	Bauman
Mar 3	Veterinary Drug Development	Johnson
Mar 08	Student Presentations	
Mar 10	Student Presentations	
Mar 15	Clinical Trials - Structure and management	Butt
Mar 17	Clinical Trials -Practical Aspects: -Contract Research Organizations, Submission and Regulatory Review	Butt
Mar 22	Natural Health Products	Butt
Mar 24	Biologics –Development and Regulation	Schunk
Mar 29	Regulatory -Intellectual Property and Legal aspects	Hobson
Mar 31	Commercializing pharmaceuticals	Babiak

Apr 2	Mock Regulatory Review of New Drug Submission	Students

1.4 Final Exam

There is no final exam.

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2 Instructional Support

2.1 Instructional Support Team

Instructor: Cathy Bauman Dr.
Email: cbauman@uoguelph.ca
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Instructor: Ron Johnson Dr.
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Instructor: Jibran Khokhar Dr.
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Office: OVCE 2608

Instructor: James Petrik Dr.
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Office: OVC 3627

Course Co-ordinator: Gordon Kirby Dr.
Email: gkirby@uoguelph.ca
Telephone: +1-519-824-4120 x54948
Office: OVC 2638C

2.2 Guest Lecturers

Paul Babiak (Affiliate Lead, Customer and Market Insights, Biogen Canada Inc. Toronto, ON)

Dr. Ron Brecher (Toxicology Risk Assessment and Risk Communication Specialist, Guelph, ON)

Rodney Butt (Nutrasource Diagnostics Inc., Guelph, ON)

Amy Davidson, (Kingfisher International Inc, Toronto, ON)

Lois Haighton (Intertek, Scientific and Regulatory Consultancy, Mississauga, ON)

Dr. David Hobson (Research Innovation Office, University of Guelph, Guelph, ON)

Heather Cherry (Therapeutic Products Directorate, Health Products and Foods Branch, Health Canada, Ottawa, ON)

Dr. Veronique Lauriault (ToxConsult LLC, San Francisco, CA, USA)

Dr. Michael Schunk, (Executive Vice-President, Operations [Retired], Medicago, Québec City, QC)

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3 Learning Resources

3.1 Recommended Resources

Lecture notes will be available on CourseLink before lectures. (Notes)

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4 Learning Outcomes

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.

4.1 Course Learning Outcomes

By the end of this course, you should be able to:

1. Understand the science surrounding the progression of novel drug candidates from early discovery to the marketplace.

2. Understand the regulation of the drug approval process.
3. Define and correctly use the vocabulary common to the drug development process.
4. Understand the timelines of the drug development process.
5. Understand concepts in drug design, synthesis and screening of early drug discovery.
6. Understand basic concepts of pharmacodynamics and pharmacokinetics of preclinical phases of drug development, including bioanalytical techniques and biomarkers.
7. Understand the toxicity tests used to assess drug safety in preclinical phases, the interpretation of preclinical data and the contribution to clinical trial design.
8. Understand the stages of clinical development (phase I-IV) required for drug approval.
9. Understand regulatory submissions and governance of the drug approval process.

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5 Teaching and Learning Activities

Lecture Times & Location

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

5.1 Lecture

Tue, Jan 7, 1:00 PM

Topics: Introduction –overview of drug development process; drug regulation, government legislation and policy development

Lecturer: Kirby

Thu, Jan 9, 1:00 PM

Topics: Early discovery -Drug discovery activities

Lecturer: Khokhar

Tue, Jan 14, 1:00 PM

Topics: Preclinical drug development –Good Laboratory Practice I

Lecturer: Hare

Wed, Jan 17, 1:00 PM

Topics: Preclinical drug development –Good Laboratory Practice II

Lecturer: Hare

Tue, Jan 21, 1:00 PM

Topics: Regulatory- Preclinical drug development-Fundamental Aspects

Lecturer: Kirby

Thu, Jan 23, 1:00 PM

Topics: Early discovery -Targeted Drug Design

Lecturer: Petrik

Tue, Jan 28, 1:00 PM

Topics: Regulatory- Preclinical drug development-Practical Aspects

Lecturer: Kirby

Thu, Jan 30, 1:00 PM

Topics: Regulatory- Preclinical drug development –Pharmacology

Lecturer: Kirby

Tue, Feb 4, 1:00 PM

Topics: Regulatory- Non-clinical Safety and Regulatory Review - USA

Lecturer: Lauriault

Thu, Feb 6, 1:00 PM

Topics: Regulatory- Regulatory Review for market authorization- Canada

Lecturer: Hui

Tue, Feb 11, 1:00 PM

Topics: Communicating Risk in Drug Development

Lecturer: Brecher

Thu, Feb 13, 1:00 PM

Topics: Toxicology Consultants: Issues in Drug Development

Lecturer: Haighton

Tue, Feb 18

Topics: Winter break –No classes

Thu, Feb 20

Topics: Winter break: no classes

Tue, Feb 25, 1:00 PM

Topics: Student Presentations

Thu, Feb 27, 1:00 PM

Topics: Student Presentations

Tue, Mar 3, 1:00 PM

Topics: Student presentations

Thu, Mar 5, 1:00 PM

Topics: Clinical Trials – Study design and statistics

Lecturer: Baumann

Tue, Mar 10, 1:00 PM

Topics: Clinical Trials - Structure and management

Lecturer: Butt

Thu, Mar 12, 1:00 PM

Topics: Clinical Trials -Practical Aspects: -Contract Research Organizations, Submission and Regulatory Review

Lecturer: Butt

Tue, Mar 17, 1:00 PM

Topics: Natural Health Products

Lecturer: Butt

Thu, Mar 19, 1:00 PM

Topics: Veterinary Drug Development

Lecturer: Johnson

Tue, Mar 24, 1:00 PM

Topics: Regulatory -Intellectual Property and Legal aspects

Lecturer: Hobson

Thu, Mar 26, 1:00 PM

Topics: Biologics –Development and Regulation

Lecturer: Schunk

Tue, Mar 31, 1:00 PM

Topics: Commercializing pharmaceuticals

Lecturer: Babiak

Thu, Apr 2, 1:00 PM

Topics: Mock Regulatory Review of New Drug Submission

Students presentations

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6 Assessments

6.1 Assessment Details

A written report consisting of a current issue in drug development (40%)
Due: Mon, Mar 23
Students will choose topics from a list that will be provided in CourseLink. Example topics include: 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.

A ten-minute oral presentation on the selected issue in drug development (25%)
Date: Week 9
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. Comments will also be provided by student colleagues.

Mock regulatory review of an IND submission (30%)

Students will be divided into groups and provided with nonclinical toxicology data to be used in two different hypothetical IND submissions. Students will review the data and respond to a series of questions related to the IND submissions including identifying the relevant toxicities and determining the starting dose to be used in human clinical trials. On the last day of lecture, students will present their reports as a team to the class. Reports/presentations will be evaluated by the course coordinator and another faculty member.

Student participation (5%)

Student participation is based on contributions to group discussions and evaluation of seminars by student peers.

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7 University Statements

7.1 Email Communication

As per university regulations, all students are required to check their e-mail account regularly: e-mail is the official route of communication between the University and its students.

7.2 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 instructor (or designated person, such as a teaching assistant) in writing, with your name, id#, and e-mail contact. The grounds for Academic Consideration are detailed in the Undergraduate and Graduate Calendars.

Undergraduate Calendar - Academic Consideration and Appeals
https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-ac.shtml

Graduate Calendar - Grounds for Academic Consideration
https://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/index.shtml

Associate Diploma Calendar - Academic Consideration, Appeals and Petitions
https://www.uoguelph.ca/registrar/calendars/diploma/current/index.shtml

7.3 Drop Date

Students will have until the last day of classes to drop courses without academic penalty. The deadline to drop two-semester courses will be the last day of classes in the second semester. This applies to all students (undergraduate, graduate and diploma) except for Doctor of Veterinary Medicine and Associate Diploma in Veterinary Technology (conventional and alternative delivery) students. The regulations and procedures for course registration are available in their respective Academic Calendars.

Undergraduate Calendar - Dropping Courses
https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-drop.shtml

Graduate Calendar - Registration Changes
https://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/genreg-reg-regchg.shtml

Associate Diploma Calendar - Dropping Courses
https://www.uoguelph.ca/registrar/calendars/diploma/current/c08/c08-drop.shtml

7.4 Copies of Out-of-class Assignments

Keep paper and/or other reliable back-up copies of all out-of-class assignments: you may be asked to resubmit work at any time.

7.5 Accessibility

The University promotes the full participation of students who experience disabilities in their academic programs. To that end, the provision of academic accommodation is a shared responsibility between the University and the student.

When accommodations are needed, the student is required to first register with Student Accessibility Services (SAS). Documentation to substantiate the existence of a disability is required; however, interim accommodations may be possible while that process is underway.

Accommodations are available for both permanent and temporary disabilities. It should be noted that common illnesses such as a cold or the flu do not constitute a disability.

Use of the SAS Exam Centre requires students to make a booking at least 14 days in advance, and no later than November 1 (fall), March 1 (winter) or July 1 (summer). Similarly, new or changed accommodations for online quizzes, tests and exams must be approved at least a week ahead of time.

For Guelph students, information can be found on the SAS website
https://www.uoguelph.ca/sas

For Ridgetown students, information can be found on the Ridgetown SAS website
https://www.ridgetownc.com/services/accessibilityservices.cfm

7.6 Academic Integrity

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 encourages academic integrity. Students need to remain aware that instructors have access to and the right to use electronic and other means of detection.

Please note: Whether or not a student intended to commit academic misconduct is not relevant for a finding of guilt. Hurried or careless submission of assignments does not excuse

students from responsibility for verifying the academic integrity of their work before submitting it. Students who are in any doubt as to whether an action on their part could be construed as an academic offence should consult with a faculty member or faculty advisor.

Undergraduate Calendar - Academic Misconduct
https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-amisconduct.shtml

Graduate Calendar - Academic Misconduct
https://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/index.shtml

7.7 Recording of Materials

Presentations that are made in relation to course work - including lectures - cannot be recorded or copied without the permission of the presenter, whether the instructor, a student, or guest lecturer. Material recorded with permission is restricted to use for that course unless further permission is granted.

7.8 Resources

The Academic Calendars are the source of information about the University of Guelph's procedures, policies, and regulations that apply to undergraduate, graduate, and diploma programs.

Academic Calendars
https://www.uoguelph.ca/academics/calendars

7.9 Disclaimer

Please note that the ongoing COVID-19 pandemic may necessitate a revision of the format of course offerings, changes in classroom protocols, and academic schedules. Any such changes will be announced via CourseLink and/or class email.

This includes on-campus scheduling during the semester, mid-terms and final examination schedules. All University-wide decisions will be posted on the COVID-19 website (https://news.uoguelph.ca/2019-novel-coronavirus-information/) and circulated by email.

7.10 Illness

Medical notes will not normally be required for singular instances of academic consideration, although students may be required to provide supporting documentation for multiple missed assessments or when involving a large part of a course (e.g.. final exam or major assignment).

7.11 Covid-19 Safety Protocols

For information on current safety protocols, follow these links:

- https://news.uoguelph.ca/return-to-campuses/how-u-of-g-is-preparing-for-your-safe-return/
- https://news.uoguelph.ca/return-to-campuses/spaces/#ClassroomSpaces

Please note, these guidelines may be updated as required in response to evolving University, Public Health or government directives.
