PHAR3101

Drug Design Discovery & Development

Course Outline

Term 3, 2022

School of Medical Sciences

Faculty of Medicine & Health

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1. Staff

Course contact details: DrugDiscovery@unsw.edu.au

Position	Name	Email	Consultation times and locations
Course Convenor	Angela Finch	a.finch@unsw.edu.au	By appointment
Course Convenor	Marty Le Nedelec	m.lenedelec@unsw.edu.au	By appointment
Course Convenor	Matthew Perry	m.d.perry@unsw.edu.au	By appointment
Lecturer	Nicole Jones	n.jones@unsw.edu.au	By appointment
Lecturer	Valentina Naumovski	v.naumovski@unsw.edu.au	By appointment

2. Course information

Units of credit: 6

Pre-requisite(s): PHAR2011

Teaching times and locations: http://timetable.unsw.edu.au/2022/PHAR3101.html

2.1 Course summary

This course will explore the process of drug development, from target identification to final drug registration. It will present drug development as a process involving target selection, hit discovery using computer-based methods and combinatorial chemistry/high-throughput screening. Lead identification and optimisation via the use of structure-activity series and computational methods will be covered. Safety evaluation, bioavailability, clinical trials, and the essentials of intellectual property, regulatory affairs and commercialisation will also be discussed. Along the way, you will learn about screening assays, computer-aided drug design, and toxicology as applied to the development of new medicines.

2.2 Course aims

Building on basic pharmacology skills learned in PHAR2011, the objectives of this course are for you to:

- gain an understanding of the processes involved in developing a new therapeutic
- develop an appreciation of the complex and expensive nature of the drug discovery and development process
- explore the role of teamwork and the different models and approaches to teamwork and project management that are used in the pharmaceutical industry
- develop skills in the interpretation and analysis of scientific data and literature, problem-solving, and the communication of information in an accessible manner.

2.3 Course learning outcomes (CLO)

At the successful completion of this course you (the student) should be able to:

1. Demonstrate an understanding of the steps involved in drug development from bench to bedside.
2. Apply knowledge of the drug development process and identify challenges and benefits of different approaches to address novel scenarios.
3. Critically analyse scientific literature and experimental data and communicate their findings.
4. Show an understanding of teamwork and the contributions of different discipline areas to drug development.

2.4 Relationship between course learning outcomes and assessments

Course Learning Outcome (CLO)	LO Statement	Related Tasks & Assessment
CLO 1	Demonstrate an understanding of the steps involved in drug development from bench to bedside.	Progress Exam Therapeutic Product Development History End of session examination
CLO 2	Apply knowledge of the drug development process and identify challenges and benefits of different approaches to address novel scenarios.	Progress Exam Research Report Therapeutic Product Development History End of session examination
CLO 3	Critically analyse scientific literature and experimental data and communicate their findings.	Research Report Therapeutic Product Development History End of session examination
CLO 4	Show an understanding of teamwork and the contributions of different discipline areas to drug development.	Therapeutic Product Development History

3. Strategies and approaches to learning

3.1 Learning and teaching activities

The learning and teaching philosophy underpinning this course is centred on student learning and aims to create an environment that interests and challenges students. The teaching is designed to be relevant and engaging in order to prepare students for future careers.

Although the primary source of information for this course is the material covered in lectures, tutorials, and practical classes, effective learning can be enhanced through self-directed use of other resources such as textbooks and Web-based sources. Your practical classes will be directly related to the lectures, and it is essential and required to prepare for practical classes before attendance. It is up to you to ensure you perform well in each part of the course: preparing for classes; completing assignments; studying for exams and seeking assistance to clarify your understanding.

Learning activities occur on the following days and times:

Lectures: Topics being covered each week can be found on the course timetable. The topics will be covered via pre-recorded lectures or online modules and will be available online prior to the week scheduled.

Tutorials: You should attend one session per week, delivered face to face on Wednesday at either 12-1 pm or 1-2 pm

Laboratory practicals: You should attend the laboratory practicals to be held face to face on Monday 1-4 pm. The practicals are a core part of your learning experience in the sciences.

Q & A sessions: Online via Teams on Friday at 1 pm.

Progress Exam (Mid-session test): Week 5 (covers content from weeks 1-4) and will be held during the Q & A time slot of week 5 (Friday 1 pm).

Information regarding weekly activities will be available via the interactive timetable on Moodle and in weekly announcements via Moodle.

3.2 Expectations of students

Students are reminded that UNSW recommends that a 6 units-of-credit course should involve about 150 hours of study and learning activities. The formal learning activities total approximately 53 hours throughout the term and students are expected (and strongly recommended) to do at least the same number of hours of additional study. This equates to ~15 hours per week dedicated to this course.

The *Q&A sessions* are provided to allow you the opportunity to clarify points covered in each week's topics. You should review the week's topics and make notes well in advance of the Q&A session. You should then review your notes and write down any questions you have about these topics and post them to the Q&A discussion board or bring those questions along to the Q&A session.

The *practicals* are provided to support lecture material and practise analytical skills. There will be opportunities to request and receive feedback on the tasks performed during practical classes each week via your electronic laboratory notebook.

In the *tutorials*, you will work in teams to evaluate projects at different stages of the drug discovery process, deciding if the project should progress or not and planning the approach that you will take to progress the project. The tutorials will provide you with ongoing feedback on your ability to apply your drug discovery knowledge as well as opportunities to develop your communication, time management and teamwork skills.

If you wish to contact the course convenors or staff, you can do so by e-mail or Microsoft Teams, using the details provided in section 1 of this document and on the course Moodle page. We are committed to providing the best experience and outcome for all students and will therefore endeavour to respond to e-mails as soon as possible, but please consider the following:

- Standard work hours are Monday to Friday from 8:30 am to 5:30 pm. E-mail correspondence received outside of this time may be dealt with from the next working day.
- All staff and students have busy schedules and multiple commitments, so while staff will endeavour to answer e-mail correspondence as quickly as possible, please apply appropriate expectations in this regard (*i.e.*, within 48 hours and on a workday).
- Please only use Teams messaging to communicate with the course staff during class. Outside of class please use the course e-mail (drugdiscovery@unsw.edu.au)

- All digital correspondence, including e-mail, Teams messages, and messages on discussion forums should be respectful, courteous, and polite.

To help us improve the course, please consider providing us with feedback by acting as a student liaison, and/or by completing the MyExperience survey later in the term.

4. Course schedule and structure

This course consists of 35 hours of class contact hours plus 18 hours of recorded material covering course topics. You are expected to take an additional 99 hours of hours to complete assessments, prepare for tutorials and practicals, and revision and exam preparation activities.

Week	Topic	Activity [Learning opportunity]	Related CLO
Week 1	• The drug discovery process: Choosing the project • Novel target identification & validation	*Practical*: Teamwork in the pharma industry *Tutorial*: The drug discovery process-Choosing the project *Q&A:* Choosing the project / Novel target I.D.	CLO 1 CLO 2 CLO 4
Week 2	• Target Selection • Assay Development	*Practical:* Target identification *Tutorial*: Target Selection and validation *Q&A*: Target Selection / Assay Development	CLO 1 CLO 2 CLO 3
Week 3	• High-throughput screening • Sources of active compounds	*Practical*: Assay Development I *Tutorial*: Assay Development & HTS screening *Q&A*: High-throughput screening / Sources of active compounds	CLO 1 CLO 2 CLO 3
Week 4	• Ligand-based drug design • Structure-based drug design	*Tutorial*: Sources of active compounds & Structure-based drug discovery *Q&A*: Ligand-based drug design / Structure-based drug design	CLO 1 CLO 2
Week 5	• Bioavailability • Intellectual property	*Practical*: Assay Development II *Tutorial*: Ligand-based drug discovery & Bioavailability	CLO 1 CLO 2 CLO 3
Week 7	• Pre-clinical toxicology –*in vitro* • Pre-clinical toxicology – *in vivo*	*Workshop*: Careers in Drug Discovery *Tutorial*: Intellectual property *Q&A*: Bioavailability / Intellectual property / pre-clinical toxicology, in vitro & in vivo	CLO 1 CLO 2 CLO 4
Week 8	• Clinical trials • Clinical trial design	*Practical*: Preclinical toxicology I *Tutorial*: Pre-clinical toxicology *Q&A*: Clinical trials / Clinical trial design	CLO 1 CLO 2 CLO 3
Week 9	• Ethics of human & animal experimentation • Biopharmaceuticals	*Practical*: Preclinical toxicology II /Clinical Trials I *Tutorial*: Clinical trial design *Q&A*: Ethics of human & animal experimentation	CLO 1 CLO 2 CLO 3
Week 10	• Regulatory Affairs • Commercialization	*Practical*: Clinical Trials *Tutorial*: Regulatory Affairs & Commercialization *Q&A*: Biopharmaceuticals/Regulatory Affairs / Commercialization	CLO 1 CLO 2 CLO 3

Exam Period: 25 November – 8 December
Supplementary Exam Period: 9 January – 13 January

5. Assessment

5.1 Assessment tasks

Assessment task	Length	Weight	Mark	Due date and time
Assessment 1: Progress Exam	50 min	10%	100	Friday 1 pm week 5
Assessment 2: Research Report	1000 words	20%	100	Monday week 7
Assessment 3: Therapeutic Product Development History	≤6 minutes each See task description for details	15%	100	Part 1: Tuesday week 4 Part 2: Monday week 10
Assessment 4: End of session examination	2 h	55%	100	Exam Period:

Assessment 1: Progress Exam. This exam will give you feedback on how you are succeeding in the course. It will test your ability to apply the knowledge you have acquired from multiple learning activities to drug discovery and development scenarios. The examinations may be in the format of, short and/or long answer questions. The questions will be based on the material covered in the lectures, practical classes, and tutorials. The material covered prior to the progress exam may again be examined in the final exam.

Assessment 2: Research Report. Technical or study reports play a critical role in the drug development process. providing a summary of research findings succinctly and unambiguously and can be used by team members, team leaders and senior management to inform 'go/no-go' decisions for a drug or even an entire research program. You will submit a written report covering three of the practical sessions. The report should be in the form of a technical report.

Assessment 3: Therapeutic Product Development History

Part 1: Each team will produce an infographic to educate a peer audience that explores teamwork and/or project management in the pharmaceutical industry. An infographic is a visual representation of data or information that is intended to quickly communicate information to a reader. An infographic should be easily comprehended and read in less than a minute. (6%).

Part 2: Each team will produce an educational resource covering the drug discovery and development process of their assigned drug, highlighting the major milestones and challenges the development team faced in the journey that the drug took from bench to bedside. The educational resource can take any form, including but not limited to an infographic, an animation, a website, a video, or a podcast. It should take the audience no more than 6 minutes (it can be less) to interact with the resource and come away educated about the drug discovery and development process and the teamwork required for success. (9%)

Assessment 4: End of session examination. The end-of-term examination will test your ability to apply the knowledge you have acquired from multiple learning activities to drug discovery and development scenarios. The examinations may be in the format of short and long answer questions. The questions will be based on the material covered in the lectures, practical classes and collaborative learning sessions.

Further information

UNSW grading system: https://student.unsw.edu.au/grades

UNSW assessment policy: https://student.unsw.edu.au/assessment

5.2 Assessment criteria and standards

Practice exam questions will be made available to you via Moodle, as well as during the tutorials.

Details regarding the assessment tasks will be provided to you during the first laboratory practical session in week 1, as well as being available on the course Moodle page. A detailed marking rubric for each task will be provided to you via the course Moodle page.

5.3 Submission of assessment tasks

Late Submission

UNSW has standard late submission penalties as outlined in the UNSW Assessment Implementation Procedure, with no permitted variation. All late assignments (unless extension or exemption previously agreed) will be penalised by 5% of the maximum mark per day (including Saturday, Sunday and public holidays). For example, if an assessment task is worth 30 marks, then 1.5 marks will be lost per day (5% of 30) for each day it is late. So, if the grade earnt is 24/30 and the task is two days late the student receives a grade of 24 – 3 marks = 21 marks.

Late submission is capped at 5 days (120 hours). This means that a student cannot submit an assessment more than 5 days (120 hours) after the due date for that assessment.

Special Consideration

If you experience a short-term event beyond your control (exceptional circumstances) that impacts your performance in a particular assessment task, you can apply for Special Considerations.

You must apply for Special Consideration **before** the start of your exam or due date for your assessment, except where your circumstances of illness or misadventure stop you from doing so.

If your circumstances stop you from applying before your exam or assessment due date, you must **apply within 3 working days** of the assessment, or the period covered by your supporting documentation.

More information can be found on the Special Consideration website.

5.4. Feedback on assessment.

Assessment 1: Progress Exam Individual marks are provided via Inspera once the exams have been graded. Cohort feedback is provided in the form of a post or podcast via the course Moodle page in week 7.

Assessment 2: Research Report. A marking rubric will be used to evaluate the research report and provide feedback along with written feedback on your report.

Assessment 3: Therapeutic Product Development History Part 1: A marking rubric will be used to evaluate the infographic and provide feedback along with written feedback on your team's infographic.

Part 2: A marking rubric will be used to evaluate the educational resource and provide feedback along with written feedback on your team's resource.

Assessment 4: End of session examination. Cohort feedback is provided once the exams are completed in the form of a post in Moodle.

6. Academic integrity, referencing and plagiarism

Referencing is a way of acknowledging the sources of information that you use to research your assignments. You need to provide a reference whenever you draw on someone else's words, ideas or research. Not referencing other people's work can constitute plagiarism.

Further information about referencing styles can be located at https://student.unsw.edu.au/referencing

Academic integrity *is fundamental to success at university. Academic integrity can be defined as a commitment to six fundamental values in academic pursuits: honesty, trust, fairness, respect, responsibility and courage.*[1] *At UNSW, this means that your work must be your own, and others' ideas should be appropriately acknowledged. If you don't follow these rules, plagiarism may be detected in your work.*

Further information about academic integrity and ***plagiarism*** *can be located at:*

- *The Current Students site* https://student.unsw.edu.au/plagiarism*, and*
- *The ELISE training site* https://subjectguides.library.unsw.edu.au/elise

The Conduct and Integrity Unit provides further resources to assist you to understand your conduct obligations as a student: https://student.unsw.edu.au/conduct.

7. Readings and resources

Recommended Primary Texts:

- Drug Discovery and Development - Technology in Transition. Hill & Rang. Elsevier Ltd 2nd edition 2013.
- Pharmacology in Drug Discovery: understanding drug response T. P. Kenakin. Elsevier, 2nd Edition 2012.

These textbooks will be available at the UNSW bookshop. They are also available in print and online formats from the library.

Other Resources:

The following electronic journals are accessible via the UNSW library.

- Nature Reviews: Drug Discovery.
- Drug discovery today.
- Pharmacology & Pharmaceutical Medicine Study guide

Links to additional sources to supplement the material covered in the lectures will be placed on the lecture pages on Moodle.

8. Administrative matters

Student enquiries should be submitted via the student portal https://portal.insight.unsw.edu.au/web-forms/

[1] International Center for Academic Integrity, 'The Fundamental Values of Academic Integrity', T. Fishman (ed), Clemson University, 2013.

9. Additional support for students

- The Current Students Gateway: https://student.unsw.edu.au/
- Academic Skills and Support: https://student.unsw.edu.au/academic-skills
- *Student Wellbeing and Health* https://www.student.unsw.edu.au/wellbeing
- UNSW IT Service Centre: https://www.myit.unsw.edu.au/services/students
- *UNSW Student Life Hub:* https://student.unsw.edu.au/hub#main-content
- *Student Support and Development:* https://student.unsw.edu.au/support
- *IT, eLearning and Apps:* https://student.unsw.edu.au/elearning
- *Student Support and Success Advisors:* https://student.unsw.edu.au/advisors
- *Equitable Learning Services (Formerly Disability Support Unit):* https://student.unsw.edu.au/els
- *Transitioning to Online Learning* https://www.covid19studyonline.unsw.edu.au/
- *Guide to Online Study* https://student.unsw.edu.au/online-study