



**UNSW**  
SYDNEY



# **PHAR9111**

## **Pharmaceutics**

**Course Outline**

**Term 3, 2022**

**School of Medical Sciences  
Faculty of Medicine & Health**

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## 1. Staff

Position	Name	Affiliation	Email	Phone
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Lecturer	Yuri Morgulis	Project Management, GSK		
	David Wilson	Director, Pacific Life Sciences		
	Dr Akinola Adisa	Principal Evaluator, Biochemistry Section, TGA		
	Dr Glenn Smith	Director, Biological Science Section, TGA		
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Student Admin enquiries	Education Support Team	School of Medical Sciences, UNSW Australia	<a href="mailto:pharm.med@unsw.edu.au">pharm.med@unsw.edu.au</a>	+612-9385-2464

All inquiries and study questions should be directed in the first instance to the course convenor who, if required, will direct your matters to an appropriate tutor or UNSW department.

## 2. Course information:

Units of credit: 6

Pre-requisite(s): There are no Pre-requisite(s) for this course

**Credit points:** This course has 6 Units of Credit. The course has been planned so that the average student should study for approximately 15 hours per week throughout the 10-week course. These hours cover all aspects of the workload including reading set material, watching pre-recorded videos, doing assignment work, preparing for and participating in online classes and participating in groupwork and discussion forums. Students differ in background; consequently, the amount of work will vary greatly between individuals, and, for particular students, it will vary between courses.

### 2.1 Course summary

PHAR9111 Pharmaceuticals deals with the science of making a chemical or biological entity suitable for delivery to humans as a therapeutic product. It therefore covers formulation and manufacture of these products. This course will give students the skills to understand how different types of medicines are formulated and the effect of different formulations on the properties of the medicine and the manufacturing processes for the medicine. It will cover

advanced formulations such as extended and modified release tablets, patches, injectables, biologicals (such as cell and tissue therapies) and delivery devices, as well as diagnostics. Stability, bioavailability, bioequivalence and sterility requirements for medicines will be covered as will repurposing of medicines for new uses and development of new formulations.

The course site in Moodle has been organised around the following Sections:

- Section 1 – Introduction to Product Development
- Section 2 – Good Manufacturing Practice (GMP)
- Section 3 – Product Quality and Stability
- Section 4 – Dosage Forms
- Section 5 – Dosage Form – Injectable Biotech Products
- Section 6 – Biologicals, Blood and Tissue Products
- Section 7 - Medical Devices
- Section 8 - In Vitro Diagnostics (IVDs)

## **2.2 Course aims**

This course aims to extend and develop the student's understanding of the pharmaceutical development of medicines and how to maintain product stability, sterility, availability and equivalence to assist delivery of the product to its site of action. It is focused on the aspects of chemistry and manufacturing controls of medicine production.

## **2.3 Course learning outcomes (CLO)**

At the conclusion of this course the student will be able to:

1. Interpret data required for making a judgement on the quality of a therapeutic product with regards to its formulation and manufacturing process
2. Analyse the effect of different formulations on the functional properties of a therapeutic product
3. Evaluate the manufacturing requirements for different types of therapeutic products
4. Perform activities associated with the role of the regulatory affair specialist within a therapeutics or medical device company
5. Integrate knowledge, skills and experience of pharmaceuticals using reflective practice

## **3. Strategies and approaches to learning**

### **3.1 Learning and teaching activities**

The course is delivered fully online. Reading materials are accessible via the Moodle Learning Management System. Resources to help you learn the course topics include course notes, websites, videos, lecture recordings, relevant books and journal articles. Many of the resources are accessible in Moodle or via the UNSW Library (UNSW VPN and student credentials required).

Weekly online classes are held via Blackboard with presentations on relevant topics by guest lecturers.

Online discussion forums are set up for individual course sections and facilitated by guest lecturers or course convenor.

### **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 50 hours throughout the term and students are expected (and strongly recommended) to do at least the same number of hours of additional study.

Students are expected to join synchronous online classes delivered via the Blackboard system and contribute to online discussion forums asynchronously. Please notify the Course Convenor if you are unable to attend the online class with a legitimate reason.

Participation and contribution to online discussion forums are required and assessed as a n assessment of the course.

Students are required to participate actively in group tasks and activities.

## **4. Course schedule and structure**

Online classes are scheduled weekly on Tuesdays at 8:00pm to 9:30pm (Sydney Time) (See course timetable for detail). Guest lecturers will present on specific topics and run class discussions of case studies. Tutorials are arranged for assessment tasks. Students are encouraged to complete prereading as required. Online sessions are conducted via the Blackboard Collaborate system accessible through the course site on Moodle. Google Chrome or Firefox are the preferred browser. Class recording is available overnight in Blackboard.

Asynchronous online discussion forums are set up for individual course sections. Students can post on set topics or put forward your own topics if they are relevant to the Section. Course lecturers and convenor will facilitate the discussion forums on a weekly basis.

## **5. Assessment**

### **5.1 Assessment tasks**

The course is assessed by completion of a mixture of assignments, online discussion forums, groupwork, participation in and leading online class discussions and a self-reflection journal.

Assessment	Task Length	Weight	CLO*	Due Date
<b>Task #1</b> Groupwork project	3000 words	35%	1, 2	23 Oct (23:59) Peer review: 30 Oct (23:59)
<b>Task #2</b> Individual assignment	2500 words	35%	3, 4	14 Nov (23:59)
<b>Task #3</b> Discussion Forums	<ul style="list-style-type: none"> <li>• 200 words/post</li> <li>• Turnitin submission: 1000 words (3 posts plus justification)</li> </ul>	15%	1, 2, 3, 4	<ul style="list-style-type: none"> <li>• Weekly throughout the term</li> <li>• Turnitin: 21 Nov (23:59)</li> </ul>
<b>Task #4</b> Reflective Journal	1500 words (at least 6 entries)	15%	5	<ul style="list-style-type: none"> <li>• Weekly throughout the term</li> <li>• Turnitin: 21 Nov (23:59)</li> </ul>

\*CLO: Course Learning Outcome

### **Assessment Task #1 – Group Wiki project (35%)**

**Due Date:** 23 Oct (23:59); Peer marking: 30 Oct (23:59)

**Task length:** 3000 words (excluding table, figure and references)

Students are assigned to groups. Each group is required to select a specific drug from the list below. You are required to compare and contrast two specific dosage forms of the drug by addressing a series of questions in this task, such as comparing their application and benefits, identifying manufacturing API, physiochemical properties and excipients, and addressing issues concerning stability, bioequivalence, packaging and sterility.

Topic drugs:

- Phenytoin: Solution for injection versus paediatric suspension
- Ventolin: inhalation aerosol versus oral solution
- Aspirin: capsule versus effervescent tablet
- Venlafaxine: immediate release tablet versus extended release tablet

The assessment task will be presented as a Wiki project that is accessible at the Moodle course site.

You can send over a draft outline for feedback by 9 Oct, but this is optional.

**Peer marking:** Each student is required to assess the contribution and performance of your group members using the rubric provided on Moodle. This will be worth 10% of the final marks of task. In addition, each student is required to assess ONE Wiki of other groups using the rubric provided on Moodle, which accounts for 10% of the final marks. You will lose 5% of your marks automatically if you do not complete peer review. Note: Please do not just give all colleagues full marks, but review them carefully and come to a decision based on the assessment criteria indicated in the rubrics.

Further detail of this task is available on the Moodle course site.

**Submission:** In addition to the completion of the Wiki page on Moodle, each student must submit a PDF copy of your group Wiki via the Turnitin system individually by the due date to receive your individual marks and peer feedback.

### **Assessment Task #2 – Individual assignment (35%)**

**Due Date:** 14 Nov (23:59)

**Task length:** 2500 words (excluding table, figure and references)

This assessment task is designed to demonstrate your understanding of the development of biosimilars of biotech medicines. Students will be provided formulation and manufacturing data package of two fictional humanised monoclonal antibodies for the treatment of acute myeloid leukaemia. Students are asked to analyse the data and prepare a report to address the following questions:

1. To compare these data, highlighting where the biosimilar is similar and where it is different to its reference product.
2. To discuss whether the magnitude and consequences of these differences constitute a significant risk to a patient to whom this product would be administered.
3. To make a recommendation whether the biosimilar should be registered for clinical use, exploring the risks and weighting then against benefits.

You can send over a draft outline for feedback by 6 Nov (23:59), but it is optional.

Details of the assignment are available on the Moodle course site.

**Submission:** You must submit your assignment via Turnitin before the due date. You must self-check the similarity score and originality report of your submission before the due date to avoid plagiarism. You will be contacted for corrective actions if your report is unacceptable.

### **Assessment Task #3 – Discussion Forums (15%)**

**Due Date:**

- Weekly throughout the Term for individual forums by the due dates indicated on Moodle
- Final submission of selected posts: Mon 21 Nov (23:59)

**Task length:**

- 200 words/post excluding references, table or figure)
- Final Turnitin submission: 1000 words (3 posts plus justification)

There are 6 section-specific discussion forums for this course. Students are required to contribute at least ONE post to each of these forums by the individual due dates as advertised on Moodle. Additional posts and response to peers are encouraged.

Your posts should contribute a body of knowledge to the discussion topics. You may contribute to the set topics or your own topic that is related to the course topics. It could be a link to an article you have read with your critical review of the article, a link to a video resource you have viewed with a critical review of the video, substantive answers to any questions posted by others. You can post own topic as long as it is related to the theme of the Section.

**Submission via Turnitin:**

In addition to the regular posting to the forums as required above, you need to select your top 3 posts and submit it through Turnitin as a single MS Word or pdf document. You must also include a justification on why you have chosen those particular 3 posts and why you consider them to be your best ones. Your justification should be around 200 words.

**Marking:**

To be eligible for marking, you must post at least one post online to the discussion forum.

The record of your posting on Moodle will be assessed in addition to your Turnitin submission. The total number and timing of your posts will be considered when marking (see the marking rubric for detail), as posting regularly and timely is essential to achieving the objectives of this task, i.e., to promote self-learning, peer learning and peer engagement.

**Assessment Task #4 – Reflective journal (15%)****Date due:**

- Throughout the term on weekly basis.
- Final submission: Mon 21 Nov (23:59)

**Length:** 1500 words excluding references (at least 6 entries)

The Reflective Journal is a core component to the development of your personal and professional skills and involves a reflective online learning process. You are required to create a reflective journal. Note: You cannot submit the same journal that you may have created for other courses or the program.

Students are required to write at least 6 entries for your journal on a regular basis. You can reflect on weekly learning, completing assessment tasks and other personal development as appropriate, but your entry should be focused on the weekly learning in this course.

The purpose of reflective writing is to review:

- **What?** – What have I learned this [week, fortnight]? What most surprised you? What did you relate to the most? Or the least?



- **So what?** - How does my learning relate to my program and professional/career goals? What am I confused about? What links can I make between my learning and my career? What areas of my personal growth do I need to focus on? What skills do I need to focus on? Are there any gaps in my knowledge and skills in the subject area?
- **Now what?** What do I need to do to achieve my learning/career goals? What are my next steps? How can I integrate what I have learnt into my professional life? How has feedback on my performance influenced my career choices? What actions does your reflection lead you to implementing? How do you address the gaps identified?

In writing a reflection you can:

- write brief notes or point form phrases
- write about yourself, for example, your feelings and attitudes, values and reactions
- observe others (fellow students or employees) and describe what you can learn from them eg, presentation skills, expressing your point of view with evidence
- see every situation as providing material for reflection and new learning
- listen/read what your peer/colleagues have to say and use the different perspectives given to deepen your personal reflection
- cover the various assessment tasks you are undertaking (group work, individual essays, discussion forums) and discuss skills you have gained or want to develop as a result of your studies

**Submission:** The reflective journal will be submitted and assessed specifically for this course. If you use a public blogging site for your journal, please download a pdf or word version of your reflection for this course for submission. You must conduct self-check of your similarity score in your originality report in Turnitin before submission to ensure the compliance and avoid plagiarism.

## 5.2 Assessment criteria and standards

The assessment criteria and standards for individual tasks are available as marking rubrics in the Assessment Section on Moodle course site. It is highly recommended to preview the marking rubrics when completing the tasks.

## 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 earned 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](#).

### **Turnitin and plagiarism check**

All assignments must be submitted through Turnitin via the Moodle course site. Submission via Email attachment to the Course Convenor is not acceptable unless specifically instructed otherwise. Assignments submitted on Moodle are automatically scanned using Turnitin to check for plagiarism against known work submitted by other students, your own previous submissions (self-plagiarism), literature and articles from the internet.

You must self-check your originality report including the similarity score to ensure your compliance before your final submission. As a rule, the Turnitin system allows for unlimited times of resubmission and it can produce the originality report immediately after each submission before the due date, but it will take 24 hours to generate the report after 3 resubmissions. The pass threshold of your originality report will be discussed in the class and at Moodle site.

Students should always retain a copy of each assessment task (including posts in Discussion forums) for their own records. Please review the guidelines on academic integrity in the following sections of the course outline.

## **5.4 Feedback on assessment**

You can submit a draft outline of Assessment Task 1 and Assessment Task 2 to the Course Convenor by the specified due date for feedback, but this is optional.

Student submissions in Turnitin will be marked online. Once the marks and comments of your assessment are available, students should log back into Turnitin and download their marked assignment and review comments. Students should include their thoughts on the feedback in their reflective journals, including plans for future assignments to address any deficiencies.

Final result for the course will be emailed to student email address on the UNSW's Release of Results date. Results can also be viewed online by logging into myUNSW and selecting "View Results" under "My Student Profile".

Definitions of grades used at UNSW are available here: <https://student.unsw.edu.au/grades>.

## 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 found at <https://student.unsw.edu.au/referencing>.

References should be cited in the text and referenced at the end of the assignment. Vancouver referencing style is recommended for this course. An example can be found in *Nature Medicine*. Briefly, in-text citations are numbered and the bibliography at the end of the assignment are numbered correspondingly.

Note: The exact formatting is flexible, but you must keep consistency across your references.

A general guide can be found [here](#) for citing sources using Vancouver referencing style, including journal article, book chapter, newspaper article, industry report or websites.

**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*. 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 <http://subjectguides.library.unsw.edu.au/elise/presenting>

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>

- <https://www.gs.unsw.edu.au/policy/documents/studentmisconductprocedures.pdf>
- <https://student.unsw.edu.au/plagiarism>
- <https://www.gs.unsw.edu.au/policy/documents/plagiarismpolicy.pdf>

The University will not tolerate plagiarism in submitted written work and regard this as an academic misconduct. Evidence of plagiarism in submitted assignments will be thoroughly investigated by the Conduct and Integrity Office. Evidence of plagiarism may result in disciplinary outcomes and a record being made in the Central Plagiarism Register, and the Faculty Student Integrity Advisor being notified. Please note that employers have the right to ask the University for evidence of student misconduct.

## 7. Readings and resources

In addition to the materials provided on Moodle course site, including course notes, references and book chapters, students will need to consult the following websites when completing learning activities and assessment tasks during their course study.

**Regulatory authorities:** For most assessments, you will need to check information posted on the websites of various regulatory bodies; the following will help you start:

- Therapeutic Goods Administration (TGA): <http://www.tga.gov.au>
- Food and Drug Administration (FDA): <http://www.fda.gov>
- European Medicines Agency (EMA): <http://www.ema.europa.eu>

**Governmental and industrial websites:**

- Pharmaceutical Benefits Scheme (PBS): <http://www.health.gov.au/pbs>
- National Prescribing Service (NPS): <http://www.nps.org.au>. An invaluable source of accurate, balanced, evidence-based information about medicines and a pillar of the federal government's National Medicines Policy.
- Australian Government Department of Health: <http://www.health.gov.au>. This site will lead you to many types of useful information, for example, Australian statistics on medicine (useful if you want to state the health burden of a particular disease)
- International Conference on Harmonisation: <http://www.ich.org>
- International Standards Organisation: <http://www.iso.ch>

**The Product Information (PI)** is the Therapeutic Goods Administration (TGA) approved information supplied by Sponsors of pharmaceutical products. It is written for healthcare professionals. The consumer-focused document is called the Consumer Medicine Information (CMI). The PI is essential reading for assignments dealing with specific therapeutics. PIs and CMIs are available on the TGA website (<https://www.ebs.tga.gov.au/>). Reformatted versions of approved PIs are available in MIMS. It is important to emphasise that MIMS may not have the latest PI updates and that they have been subject to editorial modification (usually minor). You should contact the sponsor if you want the latest PI. If you quote the information in MIMS, you should state this as your source.

**BioMedTracker** is a database of therapeutic product regulatory decisions, focused on the USA. It is available through the UNSW Library via the Subject Guide page for Pharmacology and Pharmaceutical Medicine <http://subjectguides.library.unsw.edu.au/medicine/pharmacology>. Ensure you can view pop-ups as the login and password are on a pop-up screen once you access the database (username: unsw; password: unsw1).

**The Medical Dictionary for Regulatory Activities** is available through UNSW Library and is accessible via the Subject Guides page for Pharmacology and Pharmaceutical Medicine <http://subjectguides.library.unsw.edu.au/medicine/pharmacology>. Ensure you can view pop-ups as the login and passwords are on a pop-up screen once you access the database.

**US Pharmacopoeia and National Formulary (USP-NF)** is a combination of the United States Pharmacopoeia (USP) and the National Formulary (NF). It contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. USP-NF is available through UNSW

Library and is accessible via the Subject Guides page for Pharmacology and pharmaceutical medicine <http://subjectguides.library.unsw.edu.au/medicine/pharmacology>.

## 8. Administrative matters

General student enquiries should be submitted via student portal <https://portal.insight.unsw.edu.au/web-forms/>

### Official communication

UNSW student email and class announcements on course Moodle site are the main tools for course-related communications. Please include the course code in the subject line of all emails. If you use non-UNSW email, you must arrange redirection from your student email.

### Program leave and withdrawal

For matters of program leave and discontinuation of the course, please contact the Admin Team first at [pharm.med@unsw.edu.au](mailto:pharm.med@unsw.edu.au) for advice.

### Grievance resolution officer

If you have any problem or grievance about the course, you should try to resolve it with the coordinator (Dr Johnson Liu- Tel: 02 9385 9086; [johnson.liu@unsw.edu.au](mailto:johnson.liu@unsw.edu.au)) or the Head of Pharmacology/Program Authority (Professor Margaret Morris - Tel: 02 9385 1560; [m.morris@unsw.edu.au](mailto:m.morris@unsw.edu.au)). If the grievance cannot be resolved in this way, you should contact the School of Medical Sciences Grievance Officer, Professor Nick Di Girolamo (Tel: 02 9385 2538; [n.digirolamo@unsw.edu.au](mailto:n.digirolamo@unsw.edu.au)).

## 9. Additional support for students

- The Current Students Gateway: <https://student.unsw.edu.au/>
- Academic Skills: <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>
- *eLearning and IT Apps*: <https://student.unsw.edu.au/elearning>
- *Student Support 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>
- UNSW Student complaints: <https://student.unsw.edu.au/complaints>
- Postgraduate coursework student support: <https://student.unsw.edu.au/postgrad>
- Special Consideration: <https://student.unsw.edu.au/special-consideration>
- Student Wellness Counselling: <https://student.unsw.edu.au/counselling>

- Self-help guides: <https://student.unsw.edu.au/mindsmart>
- Academic Standing for postgraduates: <https://student.unsw.edu.au/academic-standing-postgrad>
- English language support: <https://student.unsw.edu.au/english>