PHAR9121

Pharmacovigilance

Course Outline

Term 3, 2022

School of Medical Sciences

Faculty of Medicine & Health

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1. Staff

Position	Name	Affiliation	Email	Phone
Course Convenor	Dr Johnson Liu	Senior Lecturer, School of Medical Sciences, UNSW Sydney	johnson.liu@unsw.edu.au	02-9385 9086
Lecturer	Josie Gabites	Director, Cpharm		
	Jessica Tidemann	Director, Pharmacovigilance Branch, TGA		
	Albert Mellick	A/Prof, Ingham Institute		
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Student Admin enquiries	Education Support Team	School of Medical Sciences, UNSW Sydney	pharm.med@unsw.edu.au	02-9385 2464

All inquiries and study questions should be directed in the first instance to the course convener 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

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. This course will cover the identification and quantification of risk associated with medicines, recognition and interpretation of adverse drug reactions (ADRs), the underlying toxicopathology, pharmacology and regulatory requirements for pre-clinical testing, including toxicological studies. Students will learn to write and interpret key documents associated with pharmacovigilance including Risk Management Plans (RMPs), Periodic Safety Update Reports (PSURs), Periodic Benefit-Risk Evaluation Report (PBRER), Development Safety Update Reports (DSURs). The international and Australian guidelines for

adverse event reporting, international (ICH) guidelines, European and US PV systems, the role of the qualified person and compliance will be addressed in the course.

The course is organised around the following Sections:

- Section 1 - Pre-clinical toxicology
- Section 2 - History and development of vigilance and how it fits into industry
- Section 3 - Definitions, classification and mechanisms of adverse effects
- Section 4 - Pharmacovigilance systems in Australia
- Section 5 - Risk management systems
- Section 6 - Audits, inspections and work partnerships with other functional units
- Section 7 - International pharmacovigilance system

2.2 Course aims

This course aims to teach students how to understand the science of pharmacovigilance, how adverse drug reactions are identified and analysed, and to be conversant with the risk management aspects of medical compliance.

2.3 Course learning outcomes (CLO)

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

1. Justify the importance of pre-clinical drug safety assessments and review current requirements for such testing
2. Expand knowledge of risks and analysis of therapeutic products
3. Understand the requirement for post-marketing compliance and pharmacovigilance activities and their contribution to the safety of a therapeutic product
4. Perform activities associated with the role of the pharmacovigilance specialist within a pharmaceutical company
5. Integrate knowledge, skills and experience of pharmacovigilance and risk profiles 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 Mondays 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 and tutorials are arranged for assessment tasks. Students are encouraged to complete prereading if 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
Task #1 Groupwork project	PPT Presentation, 12 slides (excluding title and references slides);	30%	1	Mon 17 Oct (8pm: • Presentation slides • PDF copy via Turnitin Peer review: 24 Oct (23:59)

	15 mins plus 5 mins questions			
Task #2 Individual Assignment	2500 words	40%	4	Wed 16 Nov (23:59)
Task #3 Discussion Forums	• 7 posts (200 words/post) • Top 3 posts plus justification (1000 words)	15%	1-4	Weekly throughout the term; Final submission: Tue 22 Nov (23:59)
Task #4 Reflective Journal	1500 words (6 entries)	15%	5	Weekly throughout the term; Final submission due: Tue 22 Nov (23:59)

*CLO: Course Learning Outcome

Assessment #1 – Group Presentation (30%)

Due Date:

- Slides: Mon 17 Oct, 8pm
- Presentations: Mon 17 Oct, 8pm to 9:30pm
- Peer review: Mon 24 Oct (23:59)

Students are assigned to groups. Each group is required to select one of the ICH Safety Guidelines and review it in light of the regulatory requirements for safety aspects of therapeutic products. They will work together and deliver their review as a presentation to the class in the Blackboard session.

Each group is allocated 15 minutes for their presentation plus 5 minutes for questions. No more than 12 slides (excluding title slide and references slide).

Peer marking:

Students are required to assess the contribution of each of your group members using the marking rubric for member's contribution. In addition, each student needs to mark one of other group's presentation using the corresponding marking rubric. Peer marking will contribute 20% towards your final marks of this task. Note: Do not just give all colleagues full marks for their contribution but review them carefully and come to a decision based on the assessment criteria provided.

Submission:

- Send your group slides to the pharm.med@unsw.edu.au and copy to the Course Convenor (with a subject line "PHAR9121 Group #) for presentation.

- Each student needs to submit a copy of your group slides to Turnitin.
- Send peer marking results to pharm.med@unsw.edu.au (with a subject line: 'PHAR9121 Peer marking').

Detailed task instructions are available at the course Moodle site.

Assessment #2 – Assignment (40%)

Due Date: Wed 16 November (23:59)

Length: 2500 words (excluding figure, table and references)

Students will be given a choice of products and expected to develop a pharmacovigilance plan for their chosen product. You need to make a selection of your topic product on the Moodle site.

Students may submit a draft outline for feedback on 30 October (optional).

Further information will be provided on the course Moodle site.

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: Tue 22 Nov (23:59)

Students are required to contribute at least ONE post to each of seven section-specific discussion forums (Section 1 to Section 7). Additional post and response to peers' post are highly recommended.

Your posts should contribute a body of knowledge to the Discussion Forum 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 that lecturers and students post in the Discussion Forums.

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.

Why are you required to complete this assessment task?

Participating in online discussion forums will develop your communication skills, which are critical in the pharmaceutical industry. I strongly believe that you can all contribute and support each other's learning through participating in these Discussion Forums. It is also a way of developing your relationships with each other, which you can maintain throughout your careers.

Assessment #4 – Reflective journal (15%)

Date due:

- Throughout the term on weekly basis.
- Final submission: Tue 22 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 curses 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.

Why am I asking you to complete this assessment task? This assessment task is designed to demonstrate an ability to integrate your course learning with your work environment, knowledge of the pharmaceutical industry and self-development. Self-reflection is a powerful learning tool and you can use it throughout your career to discern your own performance and where you would like to make improvements. Keeping a record of your achievements and areas for improvement will prepare you for job interviews and promotions

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

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 earnt is 24/30 and the task is two days late the student receives a grade of 24 − 3 marks = 21 marks.

Late submissions will be penalized at 5% per day capped at five days (120 hours). Students will not be permitted to submit their assessments after this date.

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 articles 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 originally 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* [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 *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.

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

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 Pharmacopeia (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 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) or the Head of Pharmacology/Program Authority (Professor Margaret Morris - Tel: 02 9385 1560; 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).

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