UNSW AUSTRALIA

# Prospectus 2013



## Postgraduate Coursework:

# Pharmaceutical Medicine Drug Development

Postgraduate Courses in Pharmaceutical Medicine and Drug Development were established with support from The Drug Information Association (DIA), and ARCS Australia, and the Therapeutic Goods Administration (TGA).

The programs have been supported financially by:
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Further enquiries on any of the Pharmaceutical Medicine and Drug Development Programs should be directed to the Drug Development Unit at the University of New South Wales.

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# Contents



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# About Us

## The University of New South Wales

The University of New South Wales (UNSW) is one of Australia's leading teaching and research Universities, known for the quality of its graduates and excellence in creative approaches to education.

Established in 1949, UNSW now has close to 40,000 students including over 7,000 international students. The University offers more than 600 undergraduate and 300 postgraduate programs. UNSW has a broad range of high quality teaching programs. Its teaching gains strength from its research activities, and international nature. UNSW has created an academic environment that promotes development of new ideas and lasting knowledge, and where students can be inspired to excel.


The main UNSW campus is located on a 38 hectare site at Kensington, seven kilometres from the centre of Sydney. The University is a founding member of the prestigious Group of Eight research intensive universities in Australia and a member of the Universitas 21 International Consortium.

## The School of Medical Sciences

The School of Medical Sciences (SoMS) is the largest School in UNSW Medicine,


and one of the largest at UNSW. It is a vibrant school, with over 200 teaching and research staff, more than 100 higher degree research students, and many thousands of undergraduates.

The School is largely based within the Wallace Wurth Medical Building on the Kensington Campus, but has significant contribution from various hospitals and Medical Research Institutes affiliated with UNSW.

# Pharmaceutical Medicine and Drug Development at UNSW



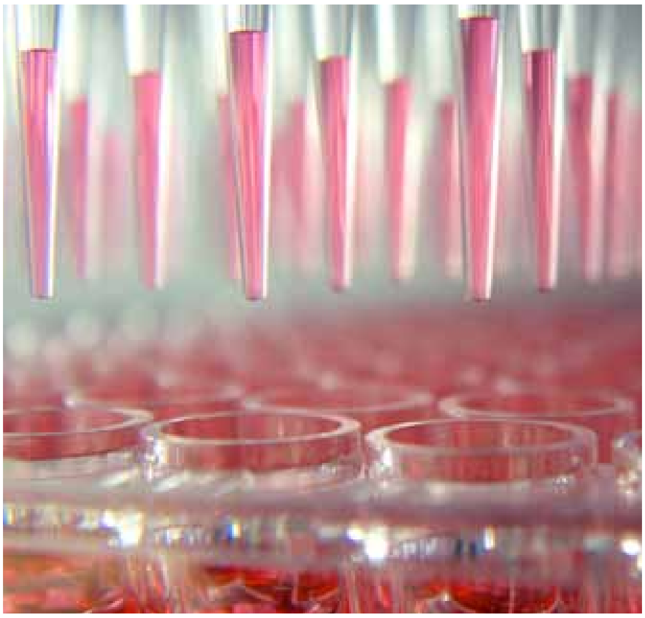
## Background

Pharmaceutical Medicine and Drug Development postgraduate programs fall within the Department of Pharmacology at SoMS. The postgraduate programs offer students an excellent opportunity to upgrade current skills which can be used as a stepping stone to further professional development in the pharmaceutical industry. Opportunities may take students to careers in drug discovery and product development; preclinical or clinical drug safety testing; regulatory control with the Therapeutic Goods Administration or regulatory compliance in a pharmaceutical company; part of a team evaluating new drugs; clinical trial management; medical and scientific communications; or senior managerial positions within biopharmaceutical businesses.

### Strength in Training

For Australia to play its full role in the development of new medicines, particularly in the early phase of drug development, and to maintain high standards of delivery of drugs to the market, it is essential that Australian Pharmaceutical Companies have staff adequately trained and skilled to perform in these areas. Training in these skills must meet assessable standards which are compatible with international scientific, clinical, legal and regulatory conventions. This is important for Australia to compete in local and international drug development activities and for the career development of those involved.

Those working in various roles within the pharmaceutical industry are responsible for the discovery and selection of new drugs for development, their evaluation for efficacy and safety in nonclinical and clinical studies, pharmacovigilance (e.g. monitoring and reporting of adverse drug reactions), registration of new drugs and associated regulatory activities, pharmacoeconomic studies, and other activities.



### Career Enhancement

The UNSW programs in Pharmaceutical Medicine and Drug Development have been designed to ensure students are well equipped with the skills, knowledge and insights needed to competently perform their roles and future leadership responsibilities in the industry.

The programs also provide an excellent opportunity for recent graduates in Medical Sciences, and those in a variety of research positions to upgrade skills, and to gain a deep understanding of the process of development of new medicines and devices.

## Unique Learning

The courses offered are unique because they have been designed, built and upgraded based on the needs of the pharmaceutical industry and regulatory sectors. Advisors from Therapeutic Goods Administration (TGA), Medicines Australia (MA), Australian Self-Medication Industry Association (ASMI), Association of Clinical and Regulatory Scientists (ARCS) and the International Drug Information Association (DIA) provide input to the courses regarding content and approaches. Course convenors and tutors are drawn from the Pharmaceutical Industry and Regulatory Agencies in addition to academia giving “real world” practicality to the educational experience. Active participation in solving problems relevant to a career in the Industry, and being able to communicate the findings clearly are rated as highly important course activities.

## Graduate Attributes

The Drug Development and Pharmaceutical Medicine Programs at UNSW foster the following graduate attributes:

**Personal**

— Apply analytical and critical thinking leading to creative problem solving.
— Commit to ethical practice and social responsibility.
— Engage in lifelong learning and reflective practice.

**Interactional Skills**

— Communicate across a range of disciplines.
— Work within and contribute to local and international processes in the development of new medicines and devices.
— Enhance collaborative and multidisciplinary teamwork.

**Applied Knowledge and Skills**

— Utilise information for decision making in the development of medicines and companion diagnostics and devices.
— Strategically plan and manage resources for projects associated with the development of new medicines and devices.
— Manage quality in the development of new medicines and devices.
— Manage risk associated with the development of new medicines and devices.

# Teaching Methods

The postgraduate coursework programs have been designed to meet the needs of students undertaking part-time education and training while still in employment. A key feature of our learning and teaching is delivery of material allowing identification and mastering of core principles and skills.

Our approach is to provide quality learning that is relevant to the real world. This is enhanced by students having access to tutors with specialist knowledge and experience in drug development.

Students are provided with course notes rather than having to attend lectures and taking notes. Students work through material in the manual at their own pace. Self-directed learning exercies are included within each course. Key milestones are suggested to help you plan your study schedule and work. Each course has a convenor, who may be assisted by one or more tutors. If students have difficulties with the manual material or assignment work they are able to contact the course convenor and/or tutors.

Additional study resource material in the form of supplementary literature and current news articles relevant to the courses are provided to enhance the learning experiences, web-links, weekend school lecture presentations etc. are made available through the UNSW e-learning system (Blackboard). Student self assessments are also made available through Blackboard as preparation for online tutorials and for revision purposes.


The streamlining of the provision of information means that more time can be spent on mastering concepts and learning to apply these concepts.

Students normally undertake 2 courses running in parallel per semester. No more than 2 courses can be taken per semester. Each course is only delivered once per year. All Pharmaceutical Medicine and Drug Development courses (core and elective) are worth six Units of Credit.

## Weekend Schools

During each semester there are 2 weekend schools, towards the beginning and end of each semester. Weekend schools are held at the UNSW Kensington Campus.

One day of each weekend school will be devoted to each course. Attendance at weekend school is required for all courses. These interactive sessions provide students with the opportunity to discuss issues with tutors, meet fellow students, and work through scenario-based problems directed to real-life situations in drug development.

Students regard the weekend schools as a valuable opportunity to exchange ideas and bring all components of the course together.

An optional 2 day on-site, interactive session at the Therapeutic Goods Administration facilities in Canberra is organised once per year to coincide with the Regulatory Affairs course (PHAR9104), and is highly recommended.

## Tutorials

Tutorials are held out of normal business hours. Tutorials are usually delivered online. Tutorials are held between 8 and 9:30 p.m. Sydney time on weekdays. Tutorials provide students with the opportunity to ask questions, and resolve problems they have faced working through the course materials.

## Assessments

Each course is assessed by a combination of assignment work, on-line mid-session exams and a written examination.

Assessments are structured around learning outcomes to ensure all competencies in the objectives have been mastered.

The proportion of marks allocated to the written examination varies with each course, but generally is between 45-50% of the final aggregate.

End of course examinations are held out of normal business hours on a Saturday. Interstate or international students can undertake the examination locally and don't have to travel to Sydney.

Assignments form a major part of the assessment procedure and require students to research, evaluate and apply information from primary literature, with an emphasis on using the most current information.

Students are encouraged to concentrate on topics that excite their interest, and go beyond the set materials. Students can utilise the specialist tutors in the relevant areas of drug development and pharmaceutical medicine to help achieve their goals.

## Course Evaluation and Development

Each year feedback is sought from students about the courses offered in Drug Development and Pharmaceutical Medicine, and continual improvements are made based on this feedback. The Course and Teaching Evaluation and Improvement (CATEI) process of UNSW is used to evaluate student feedback and add improvement to courses. Regular program reviews also provide advice regarding the content and context around courses. Students are invited to become a class representative to seek feedback from colleagues and meet with academic staff to discuss issues that arise. These channels allow the Program Authority and Course Convenors to become aware of problems and implement improvements, as well as provide insight into important trends and information relevant to the Industry.

## The Academic Year

The academic year in Pharmaceutical Medicine and Drug Development is divided into two semesters. Semester 1 (T1) and Semester 2 (T2), each consisting of 12 teaching weeks plus 2 weeks revision and examination period.

There is a short mid-semester break of one week in each teaching period. There is a mid-year break of approximately 4-5 weeks in June/July.

# Academic Staff

## Academic Advisor

***Richard Day*** *is Professor of Clinical Pharmacology at UNSW and St Vincent's Hospital Sydney.*

He has a clinical practice in Clinical Pharmacology, Clinical Toxicology, and Rheumatology. He has particular interests in promoting the quality of use of medicines (QUM) broadly and research into QUM and the rational and effective treatment of the rheumatic disorders. He was chair of PHARM for the Federal Government 1999-08, was a director of MBF, is the immediate past-President of the International Drug Information Association (DIA), was a member of the Medication Safety Task-force for the Australian Safety and Quality Council, is chair of NSW Health Medication Safety Expert Advisory, was chair of the NPS (National Prescribing Service) R&D committee and is co-chair of the electronic medication management reference committee for the National e-Health Transition Authority.

## Program Tutors

Mr Allan Anforth

Dr. Lyndall Brennan

Dr. John Churchill

Professor Richard Day

Dr. Catherina Dillenbeck

Ms Tracey Edinburg

Ms. Penny Field

Dr. Angela Finch

Dr. Jacinta Flattery-O'Brien

Dr. Madlen Gazarian

Mr. Adam Gordois

Assoc. Prof. Renate Griffith

Dr. Nicole Jones

Dr. Michael Kennedy

Dr David Kingston

Dr. Franziska Loehrer

Dr. Fabio Luciani

Dr. Mark McDonald

Dr. Michael Ortiz

Ms . Natalia Price

Dr. Alex Proudfoot

Dr. Eugene Salole

Dr. Glen Smith

Assoc. Prof. Kenneth Williams

Ms. Hong-Van Dang-Beck

Dr. Peter Vervaart

Dr. Devonie Waaka

Dr. Peter Yeates

# Feedback From Current and Past Students

*"The UNSW Drug Development course was a significant and rewarding course that has fast-tracked my career in the pharmaceutical and biotech industry. There is no other course in Australia that offers such a contemporary coverage of the industry, from 'bench-top to bedside". I knew that I wanted to progress through the pharmaceutical industry and without a varied and in-depth knowledge of the entire pharmaceutical industry, I couldn't have done so as confidently as I have.*

*The information has been invaluable to my career. It's meant that, although I may have a specific role in a pharma or biotech company, I'm able to think laterally across all other parts of the business and take into consideration key factors to ensure that my advice, decisions and strategies are well thought through.*

*Additionally, the course offers the opportunity to interact with many different people from across all different parts of the pharmaceutical industry - from research, regulatory and clinical areas and business people. Everyone has something to add and unique experiences to share, providing a well-rounded insight of any concept or issue that's being investigated or discussed." [Peter Norster, M.Med.Sci (Drug Dev)]*

*"I did not target my undergraduate studies towards having a career in the pharmaceutical industry, but upon finding myself working within that arena, I discovered the industry was an exciting and challenging place in which to work. I wanted to undertake a course that could bridge my knowledge gap by providing me with a deeper understanding of all the steps necessary to bring a drug from conception to market. I found that the UNSW Masters of Medical Science (Drug Development) program thoroughly met this expectation.*

*The quality of teaching was of a high standard throughout the Masters program, with all of the teaching staff having substantial and relevant experience. I appreciated that the course was well structured with plenty of 'real-life' examples. I also really enjoyed the opportunity to meet the other students at weekend schools and the friendships I've made as a result. Most of my student group were also working within the pharmaceutical industry whilst studying, and this meant we were able to thoroughly discuss the course material and constantly relate it back to real examples.*

*Based on what I learnt through the UNSW Masters program, I believe I have been able to operate more effectively and confidently in the various roles I have held in the pharmaceutical industry to date. I have found my understanding of the drug development process and the way different departmental functions link together particularly invaluable for my current position within Regulatory Affairs. I thoroughly enjoyed this course and I recommend it to anyone else who wishes to gain a greater understanding of the pharmaceutical industry!" [Larissa Hammer M.Med.Sci (Drug Dev)].*

*"This Masters Program has given me very comprehensive knowledge of the drug development process right through from drug discovery to post-market surveillance. Of most benefit for me in my role as a Lead CRA was the molecular and therapeutic subjects giving me a broad and well rounded understanding that can easily be translated across therapeutic areas. The subjects are both relevant and progressive, giving me the skills I need to ensure that I can excel in my role." [Sarah Loomes, M.Med.Sci (Drug Dev)]*

*"The Pharm Med and Drug Dev program at UNSW was really a superb program and a decision well made! It not only broadened my knowledge-base on a number of important clinical and non-clinical aspects but also gave me a chance to explore the career path that I would like to undertake. I had a real passion to enter the regulatory arena and with this Masters course my interest had really flourished in the area, thanks to the great industry experts teaching in the course. I have managed to change my career path from a Pharmaceutical Development Chemist to a Regulatory Affairs Associate in a very short time. This course can make a real difference." [Praneel Sharma, M.Med.Sci (Drug Dev)]*

*"I found the drug development course to be very helpful in establishing a broad knowledge base for the pharmaceutical industry. I found the course to be practical in nature and very relevant to the industry and my role. It also helped me further my career through a transfer to a new role within my company. Also, the option to do a couple of MBA subjects adds an extra dimension of variety to the course. I am very grateful for the time spent doing the course and would recommend it to anyone who is new to the industry." [Brandon Jones, M.Med.Sci (Drug Dev)]*

# Pharmaceutical Medicine Program (5511)

## Program 5511

The Graduate Diploma in Pharmaceutical Medicine offered at UNSW is a full-fee-paying, part-time, coursework-only program.

The objective of the program is to provide registered medical practitioners who work, or hope to work, in the pharmaceutical industry; participate in running clinical trials; or would like to work in industry organisations such as TGA, PBS, Natural Medicines Policy, or Medicines Australia, and seek the core competencies needed to practice as pharmaceutical physicians.

The program is compliant (yet to be accredited) with the syllabus required for accreditation as a Pharmaceutical Physician by the International Federation of Associations of Pharmaceutical Physicians (IFAPP).

Pharmaceutical physicians are responsible for the conduct of clinical trials, registration of new drugs and associated regulatory activities, pharmacoeconomic studies, supply of drug-related information, pharmacovigilance studies (e.g. monitoring and reporting of adverse drug reactions), and other similar activities.

Physicians wishing to advance within the pharmaceutical industry need to develop high levels of skill in the areas mentioned above. It is not only important that students meet assessable standards compatible with international scientific, legal and regulatory conventions, but also appreciate the broader context in which medicines and devices are developed and marketed. This is important for local and international activities and for career development.

## Program at a Glance

The Diploma consists of eight core courses, all of which have six Units of Credit (UOC) each.

[One UOC = approximately 25 hours of work in total.] Courses are delivered mainly by distance education with one on-campus weekend workshop per course. The teaching year consists of two Sessions (semesters) each of 14 weeks.

The award of the Graduate Diploma in Pharmaceutical Medicine requires the successful completion of the following eight courses. There are no electives in this program.

This program is suitable for people in full-time employment and is taken on a part-time basis.

## Time Frame

The minimum and maximum time frames for the program are:
— 2 to 4 years (4 to 8 Semesters)

## Starting Date

Semester 1: 4 March 2013
(Year 1 Orientation Weekend School
2-3 March 2013)
Semester 2: 29 July 2013

## Learning Outcomes

Assessment is based on the ability to apply principles to problem solving. There is minimal emphasis on memorisation of factual material. The emphasis is both in written examinations and assignments based on 'scenarios', i.e. case-type situations that require the exercise of comprehension, judgment, and an understanding of the issues involved.

Education and assessment is based on high-quality information delivery, application of this information through assignment work, on-line quizzes, presentations at weekend schools and written examinations. Students are provided with manuals consisting of about 300 pages of specially-commissioned text for each course. This forms the platform for the assignment work that should be based mainly on the primary (i.e. research) literature.

A key feature of assignment work is the development of critical appraisal skills for evaluating research papers. Students are issued with handbooks and workbooks for each course that set out assignment work and other tasks. This is supported by the UNSW e-learning system (Blackboard) which provides all course information including assignment work, student questions and answers, chat rooms, etc. Tutorials are delivered via Blackboard allowing discussion and presentation of materials. Students study the manuals at their own pace within allocated time periods. There are generally three telephone tutorials and two days of weekend school for each course. Tutors are available for Q & A by email.

## Mentorship

Our goal is that students be allocated a mentor within the medical department of a pharmaceutical company. The mentor is chosen from a pharmaceutical company that is a member of Medicines Australia (the industry association of the Australian pharmaceutical industry). Students are required to spend a minimum of 12-18 hours with the mentor's medical department. During this time, students will perform specified tasks and submit reports on these tasks to their mentor. The mentor will report to the Program Authority on the student's progress.

## Entry

Entry to the Graduate Diploma in Pharmaceutical Medicine is restricted to qualified medical practitioners having degrees requisite for registration as a medical practitioner in Australia or other jurisdictions considered of comparable standard by the Higher Degree Committee of UNSW Medicine.

## Program Articulation

Program 5511 is not articulated with other programs. However graduates of this program who wish to proceed to the award of Master of Medical Sciences in Drug Development may be given advanced standing in accordance with the UNSW Guidelines for Credit Transfer in Postgraduate Coursework Degrees, Diplomas and Certificates. For students enrolling for 2011 and beyond, a requirement for entry to the Master of Medical Science in Drug Development program is that students have achieved an average of 65% across the 8 core courses undertaken.

# Graduate Diploma In Pharmaceutical Medicine (5511)

| Year | Course Code | Course Title |
|---|---|---|
| 1 | PHAR9101 | Principles of Drug Action |
| | PHAR9120 | Clinical Development of Medicines |
| | PHAR9127 | Efficacy and Safety of Medicines |
| | PHAR9104 | Law, Ethics and the Regulation of Medicines |
| 2 | PHAR9102 | Pharmaceutical Drug Development of Medicines |
| | PHAR9121 | Post-marketing Development of Medicines |
| | PHAR9103 | Biostatistics and Trial Design |
| | PHAR9124 | Economic Drivers of the Pharmaceutical Industry and Medical Department Management |

— There are two weekend schools at the UNSW campus each semester.

— The teaching year consists of two 14 week semesters.

— Course assessments include on-line quizzes, assignments and a final examination.

— A maximum of two courses can be undertaken each semester.

# Drug Development Programs

## Programs 7370, 5504 and 9060

The discovery, development and marketing of pharmaceuticals have become highly organised interdisciplinary team activities. Members of such teams need to be literate in all aspects of drug development ranging from procedures for identifying lead compounds through to the full development and testing, registration, and marketing of the product. The aim of the UNSW Postgraduate Studies Program in Drug Development is to enable people working in the field of developing, regulating and marketing pharmaceutical substances to obtain such literacy by providing core and elective materials in a mainly distance-learning format. Since interchange of ideas is an essential part of any educational activity, the course includes group discussions where students and tutors come together for telephone and/or Wimba tutorials and workshops on campus to develop practice skills, and generally to interchange ideas, and to build professional networks.

## Program Objectives

The aim of the Drug Development Programs is to provide scientific and other professional staff working within the pharmaceutical industry, government, academia, and relevant professions with a core knowledge of the scientific, legal, ethical, regulatory, and social issues relevant to the discovery, evaluation, registration, and promotion of medicines. The social goal of the programs is to improve the quality of health care by developing and promoting skills that hasten the development and supply of new therapeutic agents, and to assist in optimising the use of medicines and devices to maximise their benefits and minimise risk.

## Career Development

The Master of Medical Science in Drug Development is a valuable asset in recruitment and promotion within the pharmaceutical industry, medicine and government. The program is a vocational course, especially designed to enhance the capabilities of current or future staff whose vocation lies in the clinical, regulatory, scientific, informational, pharmacoeconomic, and managerial areas of the pharmaceutical industry, medicine or government.

All of these areas are interrelated. It is not possible to function to maximum potential in any of these areas without adequate knowledge of the others. The program thus includes core courses that provide a good working knowledge of the various areas mentioned, plus a selection of elective courses that enable students to gain depth in the areas of their particular interest. The Master of Medical Science in Drug Development, and to a lesser extent the Certificate and Diploma, will enable the student to fast-track, master and achieve, in a few years, a level of competency that would otherwise take decades.

The strengths of the program are the relevance of the material and the expertise that has been assembled to develop and deliver the program. This expertise rests with the combined strengths of the relevant departments of UNSW, working in close collaboration with experts in the pharmaceutical industry and Government regulatory authorities. A highly effective collaboration between academia, industry, the professions, and Government has been achieved in developing and teaching the course material.

## Program at a Glance

This is a full fee-paying postgraduate program designed for people working in, or wishing to work in, various Research and Development and Medical Departments of Pharmaceutical Companies.

— This is a distance-delivered program suitable for people in full-time employment and taken on a part-time basis

— There are two weekend schools (at UNSW) each semester

The Program is offered in three stages:

— Completion of Stage 1 leads to the Graduate Certificate in Drug Development (GradCertDrugDev). Minimum time required: two 14-week semesters (part time)

— Completion of Stages 1 and 2 leads to the Graduate Diploma in Drug Development (GradDipDrugDev). Minimum time required: four 14-week semesters (part time)

— Completion of Stages 1, 2 and 3 leads to Master of Medical Science in Drug Development (MMedSc). Minimum time required: six 14-week semesters (part time)

## Program Structure

There are eight core courses and currently nine elective courses. Award of the Graduate Certificate requires successful completion of the first four core courses. Award of the Graduate Diploma requires successful completion of all eight core courses. Award of the Master's degree requires successful completion of the eight core courses and four electives.

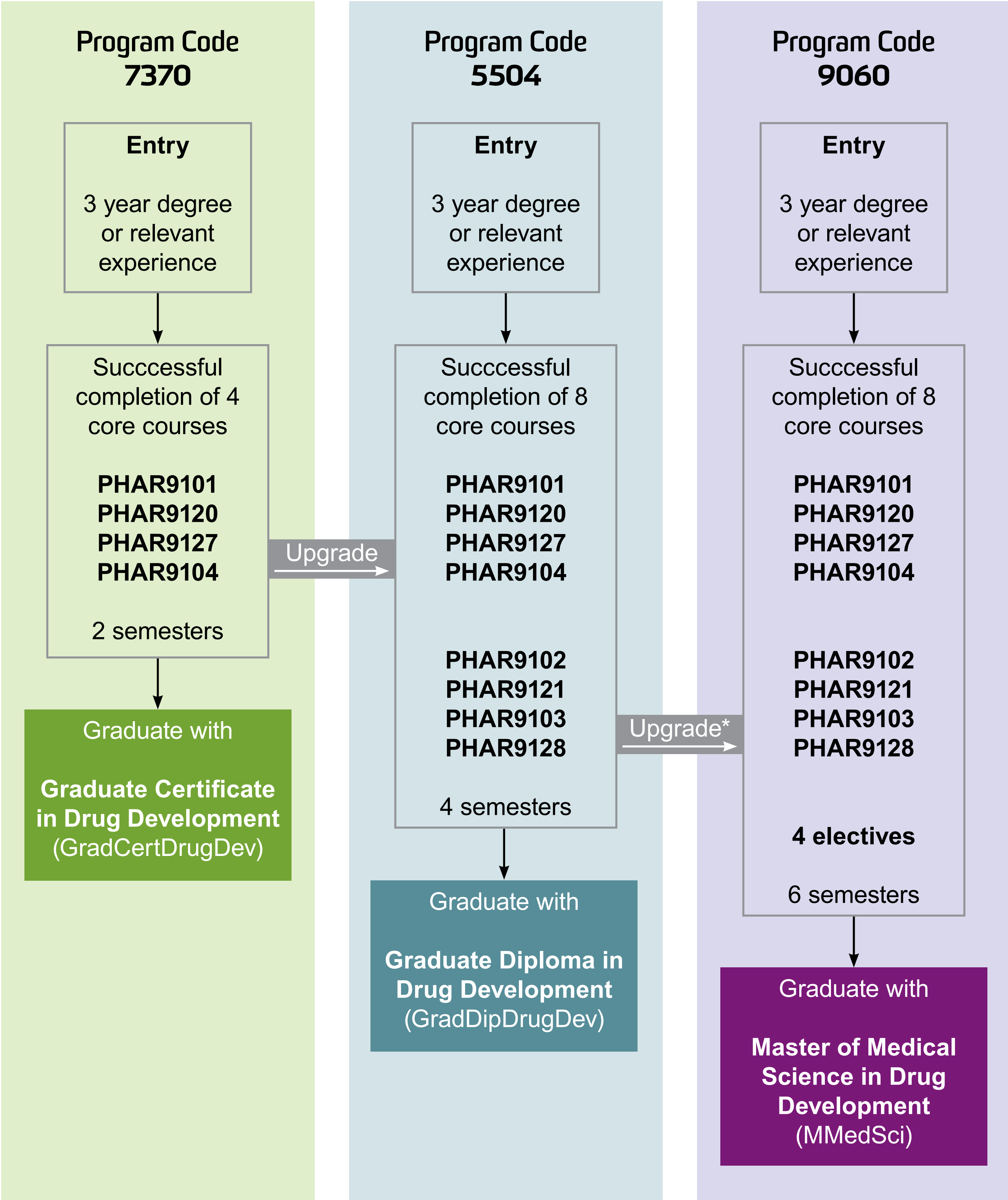
Students usually study 2 courses per semester.

## Entry Requirements

Generally, students should have a relevant degree. Those who do not have a degree but have relevant experience in the pharmaceutical industry may be admitted to the Graduate Certificate and, if successful, may apply to upgrade their candidature to the Graduate Diploma or Master's degree. Students with a three or four year, or higher degree are also required to enroll first in the Graduate Certificate or Graduate Diploma Program and, if successful in the core courses, may upgrade to the Masters degree. Note that progression from Diploma to the Masters is dependent on achieving an overall credit rating (65% or greater) over the full Diploma program.

## Time Frames

The minimum and maximum time frames for the three programs are:
— Graduate Certificate in Drug Development: 1 to 2 years (2 to 4 Semesters)
— Graduate Diploma in Drug Development: 2 to 4 years (4 to 8 Semesters)
— Master of Medical Science in Drug Development: 3 to 6 years (6 to 12 Semesters)




* Transfer of candidature from 5504 to 9060 requires an average grade of 65%

# Graduate Certificate In Drug Development (7370)

| Year | Course Code | Course Title |
|---|---|---|
| 1 | PHAR9101 | Principles of Drug Action |
| | PHAR9120 | Clinical Development of Medicines |
| | PHAR9127 | Efficacy and Safety of Medicines |
| | PHAR9104 | Law, Ethics and the Regulation of Medicines |

The Graduate Certificate in Drug Development comprises 4 core courses which provide, students with strong education training in the core skills relevant to an understanding of the early stages of drug development.

The courses within the program start with a general overview of the drug development process, with a focus on drug discovery, chemistry relevant to drug discovery and development issues, pharmacokinetics and codes of practices and standards, and regulation of medicines in Australia.

Significant attention is given to understanding the pharmacology and pharmacodynamic properties of drugs and how this also relates to pharmacokinetics.

This is explored further in drug safety assessments leading up to the first human clinical testing.

As the story of development of a drug, from discovery through to human testing progresses in the program, we deal with the important principles of clinical trial practice and management.

This includes protocol development, obtaining regulatory and ethical approval, planning trial recruitment, data management and data reporting.

An introduction to the Law as it pertains to the development of new drugs is provided. Emphasis is on Administrative Law as it applies to the review of regulatory decisions provided by the Therapeutic Goods Act.

The processes involved in the regulation of medicines, including prescription and non-prescription medicines, and medical devices within Australia are discussed in detail, along with the requirements of other international agencies.

### Starting Date

Semester 1: 4 March 2013
(Year 1 Orientation Weekend School 2-3 March 2013)
Semester 2: 29 July 2013

# Graduate Diploma In Drug Development (5504)

| Year | Course Code | Course Title |
|---|---|---|
| 1 | PHAR9101 | Principles of Drug Action |
| | PHAR9120 | Clinical Development of Medicines |
| | PHAR9127 | Efficacy and Safety of Medicines |
| | PHAR9104 | Law, Ethics and the Regulation of Medicines |
| 2 | PHAR9102 | Pharmaceutical Drug Development of Medicines |
| | PHAR9121 | Post-marketing Development of Medicines |
| | PHAR9103 | Biostatistics and Trial Design |
| | PHAR9128 | R & D in the Pharmaceutical Industry |

The Graduate Diploma in Drug Development builds upon the foundation of courses laid down in the first year of the program as outlined for the Graduate Certificate in Drug Development.


In the second year of the program, students examine issues related to the formulation of new medicines, with a strong focus on quality of product, examination of impurities and stability of the new medicine.

The program also includes methods of assessment and prevention of adverse events, reporting responsibilities and the use of safety information databases.

Protection of intellectual property relevant to the industry is examined.

Students conclude their program by examining the use of statistics in design of clinical trials and assessment of data. Factors driving the pharmaceutical industry and the importance of decision making throughout the drug development process are examined.

### Starting Date

Semester 1: 4 March 2013
(Year 1 Orientation Weekend School 2-3 March 2013)
Semester 2: 29 July 2013

# Masters Of Medical Sciences In Drug Development (9060)

| Year | Course Code | Course Title |
|---|---|---|
| 1 | PHAR9101 | Principles of Drug Action |
| | PHAR9120 | Clinical Development of Medicines |
| | PHAR9127 | Efficacy and Safety of Medicines |
| | PHAR9104 | Law, Ethics and the Regulation of Medicines |
| 2 | PHAR9102 | Pharmaceutical Drug Development of Medicines |
| | PHAR9121 | Post-marketing Development of Medicines |
| | PHAR9103 | Biostatistics and Trial Design |
| | PHAR9128 | R & D in the Pharmaceutical Industry |
| 3 | **Elective Courses** (select 4) | |
| | PHAR9107 | Therapeutics and the Molecular Basis of Disease 1 |
| | PHAR9118 | Therapeutics and the Molecular Basis of Disease 2 |
| | PHAR9111 | Advanced Pharmaceutical Development of Medicines |
| | PHAR9114 | Pharmacoeconomics |
| | PHAR9108 | Therapeutic Basis of Drug Use and Development 1 |
| | PHAR9109 | Therapeutic Basis of Drug Use and Development 2 |
| | PHAR9112 | Advanced Pharmacokinetics |
| | PHAR9113 | Advanced Regulatory Affairs |
| | PHAR9116 | Advanced Clinical Trials Management |

The Masters of Medical Science in Drug Development continues to build on the knowledge gained in the first two years of the Graduate Diploma program.

In the final year of the Masters program, students select four elective courses from those offered within the Drug Development suite. This gives students an opportunity to specialise in an area that is of particular interest to them, or where they have no experience and want to broaden their knowledge.

Students may select up to two elective MBA courses to a maximum of 12 UoC from the Australian Graduate School of Management (AGSM).

AGSM Elective course options are shown overleaf.

### Starting Date

Semester 1: 4 March 2013
(Year 1 Orientation Weekend School 2-3 March 2013)
Semester 2: 29 July 2013

## Electives available through AGSM

| Course Code | Course Title and Units of Coursework |
|---|---|
| MNGT6275 | Managing People & Organisations |
| MNGT6210 | Accounting & Financial Management |
| MNGT5251 | Marketing Management |
| MNGT6380 | Law for Practicing Managers |
| MNGT6321 | Corporate Finance |
| MNGT6302 | Economics in Management Practice |
| MNGT6372 | Managerial Skills |
| MNGT6371 | Managing Change |

# How to Apply

## Applications for Admission

Candidates will need to complete the appropriate UNSW application form and attach the requested documents. Application can be made by online application — instructions about applying online can be found at: http://apply.unsw.edu.au

All applications will be acknowledged and assessed for eligibility. Successful applicants will be sent an offer of admission with details of acceptance and enrolment procedures by mail.

Selection for admission to all graduate programs is based on the information supplied in your application.

Successful applicants will be notified by letter of the appropriate enrolment procedures, along with guidance to access the on-line learning system.

## New Student Application Procedures

Interested applicants should submit an application by **19 November 2012**.

Once you have been notified your application has been accepted then you must provide the following:

- Certified transcripts of your academic record including courses and grades
- Proof of completion of degree/diploma
- Proof of English language proficiency (where applicable)
- Certified English translation of documents (where applicable)
- Application fee
- A certified copy of your passport and current visa (where applicable)

Applications that do not provide necessary documentation are put on hold.

Successful applicants will be sent a full offer letter or conditional offer letter. A conditional offer is issued when an applicant has met the academic criteria for entry, but has not demonstrated that they meet the University's English language requirements.

Students receiving a full offer should accept their offer before the offer expiry date indicated in their letter.

The Program Administrator will contact you early 2013 with details about the Program and Orientation Weekend School.

# Fees for Courses

The fees* (2013) for local and international students in 2013 are set out in the tables:

### Local Tuition Fees:

| Program | A$ per 6 Unit Course | A$ per annum | Total Cost of Program (A$) |
|---|---|---|---|
| 7370: Graduate Certificate in Drug Development | 3,120 | 12,480 | 12,480 |
| 5504: Graduate Diploma in Drug Development | 3,120 | 12,480 | 24,960 |
| 9060: Masters of Medical Science in Drug Development | 3,120 | 12,480 | 37,440 |
| 5511: Graduate Diploma in Pharmaceutical Medicine | 3,120 | 12,480 | 24,960 |

### International Tuition Fees

| Program | A$ per 6 Unit Course | A$ per annum | Total Cost of Program (A$) |
|---|---|---|---|
| 7370: Graduate Certificate in Drug Development | 4,460 | 17,840 | 17,840 |
| 5504: Graduate Diploma in Drug Development | 4,460 | 17,840 | 35,680 |
| 9060: Masters of Medical Science in Drug Development | 4,460 | 17,840 | 53,520 |
| 5511: Graduate Diploma in Pharmaceutical Medicine | 4,460 | 17,840 | 35,680 |

** To be confirmed in late 2012*

### FEE-HELP Overview

FEE-HELP is an interest-free loans facility available to fee-paying postgraduate students undertaking coursework programs.

FEE-HELP enables eligible students to obtain a loan of up to $85,062 over a lifetime from the Commonwealth Government to pay all or part of their tuition fees. (*Student Activity Fees cannot be claimed from the ATO*).

FEE-HELP is available to commencing students who are either Australian Citizens or Australian Permanent Residents with a humanitarian visa, and continuing students who meet the requirements.

For advice about your eligibility for a FEE-HELP loan, please call the FEE-HELP enquiry line on 1800 020 108 or check on myUNSW.

# Course Selection in 2013

| Course Code | Course Name | Core/ Elective | Semester |
|---|---|---|---|
| PHAR9101 | Principles of Drug Action | Core | 1 |
| PHAR9120 | Clinical Development of Medicines | Core | 1 |
| PHAR9127 | Efficacy and Safety of Medicines | Core | 2 |
| PHAR9104 | Law, Ethics and the Regulation of Medicines | Core | 2 |
| PHAR9102 | Pharmaceutical Development of Medicines | Core | 1 |
| PHAR9121 | Post-marketing Development of Medicines | Core | 1 |
| PHAR9128 | R & D in the Pharmaceutical Industry | Core | 2 |
| PHAR9103 | Biostatistics and Trial Design | Core | 2 |
| PHAR9124* | Economic Drivers of the Pharmaceutical Industry and Medical Department Management | Core | 2 |
| PHAR9107 | Therapeutics and the Molecular Basis of Disease 1 | Elective | 1 |
| PHAR9118 | Therapeutics and the Molecular Basis of Disease 2 | Elective | 1 |
| PHAR9111 | Advanced Pharmaceutical Development of Medicines | Elective | 1 |
| PHAR9114 | Pharmacoeconomics | Elective | 1 |
| PHAR9108 | Therapeutic Basis of Drug Use and Development 1 | Elective | 2 |
| PHAR9109 | Therapeutic Basis of Drug Use and Development 2 | Elective | 2 |
| PHAR9112 | Advanced Pharmacokinetics | Elective | 2 |
| PHAR9113 | Advanced Regulatory Affairs | Elective | 2 |
| PHAR9116 | Advanced Clinical Trials Management | Elective | 2 |
| MNGT6275 | Managing People & Organisations | Elective | |
| MNGT6210 | Accounting & Financial Management | Elective | |
| MNGT5251 | Marketing Management | Elective | |
| MNGT6380 | Law for Practicing Managers | Elective | |
| MNGT6231 | Corporate Finance | Elective | |
| MNGT6302 | Economics in Management Practice | Elective | |
| MNGT6372 | Managerial Skills | Elective | |
| MNGT6371 | Managing Change | Elective | |

*Course only available to those enrolled in the Graduate Diploma of Pharmaceutical Medicine (5511)

# Course Descriptions

The University rates programs and subjects in terms of Units of Credit (UOC), where one UOC = 25 hours of work. In designing the program, we have used a system in which all courses are rated at 6 Units of Credit (i.e. about 150 hours of study). Thus, students who proceed at the maximum rate part-time, i.e. complete four courses in one year, can expect to do about 600 hours of study during the year. We have planned the program so that the average student should study for an average of 20 hours per week for each of the 28 weeks of our teaching year. These hours cover all aspects of the workload including reading set material, doing assignment work, preparing for tutorials and studying for examinations.

There are eight core courses for the Graduate Diploma in Pharmaceutical Medicine; four core courses for the Graduate Certificate in Drug Development; eight core courses for the Graduate Diploma in Drug Development; and eight core courses plus a range of electives (four to be completed) for the Masters of Medical Science in Drug Development. The courses for each program are indicated within the prospectus.

## PHAR9101 Principles of Drug Action

*Offered in Semester 1 (6 Units of Credit) This course is compulsory for programs 7370, 5504, 5511 and 9060.*

This course provides a general overview of the drug development process, and a focus on drug discovery, chemistry relevant to drug development and pharmacokinetics. The course introduces the subjects with an overview of the history of medicines, the various stages of development of a drug from discovery through to market, codes of practice and standards,and the regulation of medicines in Australia. The chapter on chemistry focuses on the importance of isomerism, acids, bases and salts, functionality in organic compounds, important chemical reactions, and characteristics of biological drugs. Various approaches to target identification and drug discovery are outlined, with historical examples provided.

The chapters on pharmacokinetics explore qualitative factors involved in determining pharmacokinetic properties: routes of administration of drugs, physicochemical properties, formulation, absorption, distribution, elimination(metabolism and excretion). Quantitative aspects of pharmacokinetics are also examined, dealing with important parameters used to express concentrations of drug in the body (bioavailability, volume of distribution, clearance, half-lives, etc.), and how dose optimisation can occur by evaluating these variables. The influence of non-drug factors (disease states, age, genetics, etc.) on pharmacokinetic and pharmacodynamic parameters, and hence on the dose-response relationship is also discussed.

## PHAR9120 Clinical Development of Medicines

*Offered in Semester 1 (6 Units of Credit) This course is compulsory for programs 7370, 5504, 5511 and 9060.*

This course provides an introduction to clinical project and clinical trial management, and interpreting the clinical literature. The course starts with a brief introduction to the regulatory requirements applicable for clinical development in Australia with reference to the relevant requirements of the US and European authorities. Clinical trials management reviews all stages involved in conducting a clinical trial. The stages covered include the initial project proposal; development of the protocol and other trial related documentation required to gain ethical and regulatory approval for a clinical trial; planning of all trial related materials required to commence the study; conduct of the trial during patient recruitment and treatment; data management and analysis of the data generated from the study; reporting of the data and finally "close-out" of the trial. Responsibilities of the sponsor in trial planning, approval, investigator selection, monitoring and auditing are discussed. The International Conference on Harmonisation (ICH) code of Good Clinical Practice (GCP) is emphasised throughout the course. The last chapter of the course will provide the essential knowledge, tools and practice to critically assess clinical research literature.

## PHAR9127 Efficacy and Safety of Medicines

*Offered in Semester 2 (6 Units of Credit) This course is compulsory for programs 7370, 5504, 5511 and 9060.*

This course forms a bridge between PHAR9101 (Principles of Drug Action) and PHAR9120 (Clinical Development of Medicines). The principles introduced in PHAR9101 are extended to include pharmacodynamics and a review of the major classes of pharmacological substances including those acting on the central and peripheral nervous systems and the major organ systems such as cardiovascular, pulmonary, renal, etc. Clinical uses and limitations of the drugs are summarised and examples given showing the application of pharmacodynamic and pharmacokinetic principles to clinical situations. Laboratory and clinical methods are reviewed. The focus is on the validation of analytical methodologies, and the role and limitations of animal models of disease, as a basis of understanding how drug efficacy and safety are assessed in the laboratory and in clinical settings. Systematic non-clinical safety assessment is then reviewed. This covers: (a) aims and definitions of safety assessment programs; (b) design and execution of toxicological studies; (c) special studies such as carcinogenicity, mutagenicity and reproductive studies; (d) toxicokinetics; (e) design and interpretation of toxicological studies; and (f) safety pharmacology. The course concludes with an introduction to Good Manufacturing Principles (GMP) and the preparation of drug supplies for use in early development testing.

## PHAR9104 Law, Ethics and the Regulation of Medicines

*Offered in Semester 2 (6 Units of Credit) This course is compulsory for programs 7370, 5504, 5511 and 9060.*

This course provides a general overview of ethical issues and laws relevant to the development and marketing of medicines. It includes the following topics: An Introduction to the Law and Administrative Law as it applies to the review of regulatory decisions provided by the Therapeutic Goods Act 1989 (Cth); and judicial review of other decisions.

Regulation of Medicines discusses regulatory principles regarding the use of developmental therapeutic products (medicines and medical devices) in human subjects and the risk/ benefit considerations that are made by regulatory authorities worldwide when they consider whether a new product should be registered. Medicines can be further classified into prescription medicines and non-prescription medicines (including over-the-counter and complementary medicines). The organisation of the regulatory processes in Australia: the Therapeutic Goods Administration and advisory bodies are covered. Also dealt with are: preparation and submission of an application for approval to market a medicine or medical device and the relevant appeal processes; integration of regulatory affairs into the pre- and post-marketing planning and review of product development strategies; input from international bodies and national agencies. Regulatory access to unapproved medicines is discussed, including clinical trials and the Special Access Scheme in Australia. The course concludes with a description of the processes involved in registration of a medical device and the conformity requirements within Australia.

## PHAR9102 Pharmaceutical Development of Medicines

*Offered in Semester 1 (6 Units of Credit) This course is compulsory for programs 5504, 5511 and 9060.*

The course begins with an introduction to dosage forms and discusses the selection of a particular dosage form in a given case. The design, development and manufacture of a dosage form is described using tablets as an example. The relevance of the properties of active ingredients to product development is discussed. The chapter on product quality outlines concepts of quality, quality assurance and quality control, discusses the significance of pharmacopoeial monographs, and provides a rationale for the various in vitro tests of quality for raw materials and finished products. Particular attention is given to methods of testing for impurity content, the significance of different types of impurity, disintegration and dissolution testing, and the design and interpretation of stability studies. Concepts of sterility and sterilisation are introduced together with the means of achieving control. The fundamental relationship between ongoing quality and Good Manufacturing Practice is discussed, together with examples of validation of later changes or variations to formulation and manufacturing aspects. The design, conduct and reporting of bioavailability and bioequivalence studies is described along with formulation strategies for drugs which have limited bioavailability. There is an introduction to biological medicines, which outlines their characteristics, quality control and potential for contamination by infectious agents. The particular problems associated with formulation of protein pharmaceuticals are considered, together with their stability and compatibility.

## PHAR9121 Post-Marketing Development of Medicines

*Offered in Semester 1 (6 Units of Credit) This course is compulsory for programs 5504, 5511 and 9060.*

This course consists of two parts that focus on the use of medicines in the post-marketing period.

Part 1 discusses concepts and issues associated with the safety of medicines in the post-marketing period. This area has been gaining widespread prominence recently. There have been numerous recent examples of registered medicines causing unanticipated harm, leading to product withdrawal, legal action and tarnishing the reputations of both the pharmaceutical industry and drug regulators. Objectives include, recognition of the interaction between Consumers (e.g., health care professionals, patients), Pharmaceutical Companies and Regulatory Authorities; development of a vocabulary and understanding of concepts related to adverse drug reactions, safety data collection, risk management and regulatory requirements; and identification of similarities and differences in international regulatory requirements related to drug safety.

Part 2 of the course addresses Pharmaceutical Information. It discusses the information resources and information services required to bring together and utilise all the information about a drug product which has been generated during its development and marketing. It provides an introduction to and an understanding of the restrictions under which pharmaceutical companies operate in terms of the provision of information, promotion and advertising. Core to this will be an understanding of the requirements of the Product Information and Consumer Medicine Information documents.

## PHAR9128 R&D in the Pharmaceutical Industry

*Offered in Semester 2 (6 Units of Credit) This course is compulsory for programs 5504 and 9060.*

The aim of PHAR9128 is to provide insight into the integration of the various processes involved in the development of new drugs, starting with some lead compounds and progressing through a series of Go / No-Go decisions until a small number of candidate drugs remain that seem worth progressing to market. The decisions that determine Go or No-Go in drug development are a complex mixture of scientific, legal, cultural, budgetary, and commercial factors.

Enormous investments are made in drug development and strategies are important to protect and capitalise on that investment. There are, however, limits to that protection which allow for early market entry of generic medicines.

Patent law is an enormously technical and complex subject. It is a mixture of ‘state of the art’ science and innovation in technological fields such as structural chemistry, analytical chemistry, formulation chemistry, molecular biology, and gene technology combined with a body of legal principles developed over many years of litigation and legislation to define and set the limits of a claimed invention. Its purpose is to provide certainty to the owner of a patent during the ‘monopoly period’ to allow the patentee sufficient time to recoup its initial investment and at the same time to provide certainty to competitors to know precisely the limits around a particular invention and hence when they are permitted to enter the market with competitor products.

## PHAR9103 Biostatistics and Trial Design

*Offered in Semester 2 (6 Units of Credit) This course is compulsory for programs 5504, 5511 and 9060.*

Biostatistics in Drug Development, Critical Appraisal and Design of Clinical Trials will provide an introduction to epidemiology studies and the different types of clinical trial designs. The course will provide students with an understanding of the importance of clinical trial design in development of a new drug candidate, and the use of appropriate statistical analysis to assist in decision making as a product advances towards the market. Students will become familiar with various statistical tests, including distributions, confidence intervals, hypothesis testing, analysis of dependent and independent variables, regressions, dose responses and sample sizes, with examples of how they are used in different trial settings, to assist in both trial design and data analysis.

Critical appraisal of published literature is examined. This is a skill needed across all aspects of medicine and device development and marketing, and is heavily dependent on statistical principles and knowledge.

## PHAR9124 Economic Drivers of the Pharmaceutical Industry & Medical Department Management

*Offered in Semester 2 (6 Units of Credit) This course is compulsory and only available for Program 5511.*

This course provides an overview of the economic and financial background against which medical department decisions or recommendations are made about introducing and marketing new pharmaceutical products. This includes general issues of healthcare economics as they relate to the pharmaceutical industry including measures of health care, governmental policy, approval and appeals processes, and third-party reimbursement. Also included is an orientation on return on capital, fixed assets, budgeting, and profitability, marketing structure and competition. Basic principles of pharmacoeconomic studies are addressed, including health economic principles and practices, quality of life measures, and the application and validity of the methodology used to assess cost/ benefit ratios of healthcare options.

This course also focuses on organisation, staffing and function of the medical department within a pharmaceutical company. It explores the management skills required to run an effective medical department namely: inter-personal skills, human resource (HR) management, project management, and crisis management. The role and responsibilities of the pharmaceutical physician in each of these areas is discussed and is the theme of the weekend workshop for this course. Students spend at least one full day working with their mentor in a medical department gaining background and experience in the skills referred to above.

## PHAR9107 Therapeutics and the Molecular Basis of Disease 1

*Offered in Semester 1 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

This course provides a basis for understanding the mechanisms involved in the disordered physiology that underlies common disease states. The objective is to provide an understanding of those disorders that are amenable to correction or amelioration with drug therapy. It thus provides a rationale for drug design and utilisation. The course consists of four main sections. Section 1 deals with cellular injury and death and covers causes of cell injury, general mechanisms of cell injury and necrosis, apoptosis, stress proteins and cell injury, sub cellular alterations in cell injury, intracellular accumulations, pathological calcification, hyaline change, cellular ageing. Section 2 deals with inflammation and repair and covers acute inflammation, chemical mediators of inflammation, chronic inflammation, morphological patterns in acute and chronic inflammation, systemic effects of inflammation, and wound healing. Section 3 covers immunology and diseases of immunity and includes a review of normal immune system mechanisms (cells of the immune system, cytokines, histocompatibility antigens, and hypersensitivity reactions); mechanisms of autoimmune diseases, immunologic deficiency syndromes, and other actual or suspected immune system diseases (e.g. amyloidosis). Section 4 covers oedema, hyperaemia and congestion, haemorrhage, haemostasis and thrombosis, embolism, and shock.

## PHAR9118 Therapeutics and the Molecular Basis of Disease 2

*Offered in Semester 1 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

Material in this course is complementary to PHAR9107 and aims to provide a basis for understanding the mechanisms involved in the disordered physiology that underlies common disease states. The object is to provide an understanding of those disorders that are amenable to correction or amelioration with drug therapy. It thus provides a rationale for drug design and utilisation. The course consists of four main sections. Section 1 deals with cellular growth and differentiation including control of cell growth, extra cellular matrix and cell-matrix interactions, and cellular adaptations of growth and differentiation. Section 2 deals with neoplasia and includes definitions and nomenclature, characteristics of benign and malignant neoplasms, epidemiology, molecular basis of cancer, biology of tumour growth, carcinogenic agents and their cellular interactions, host defence mechanisms, and clinical features of tumours. Section 3 covers genetic disorders and includes a brief section on the 'new genetics', mutations, Mendelian disorders, disorders with multifactorial inheritance, normal karyotype cytogenetic disorders, single-gene disorders with non-classic inheritance, and molecular diagnosis. Aspects of molecular biology relevant to the preceding topics (e.g. gene therapy) are also discussed. Finally Section 4 deals with infection and includes a brief introduction to microbiology, general principles of microbial pathogenesis, discussion of selected human infectious diseases and introduces the concept of anti-infective therapeutics.

## PHAR9108 Therapeutic Basis of Drug Use and Development 1

*Offered in Semester 2 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

This course aims to provide an understanding of the major medical problems and current treatments that need to be understood in developing new therapeutic agents and optimising their use. Emphasis will be on highlighting the strengths and weaknesses of present therapies and identification of current research aimed at developing new therapeutic agents.

The course provides an integrated description of relevant physiology, pathophysiology, disease state manifestations and clinical pharmacology with respect to the following disease states: (a) infectious disease: bacterial, fungal, viral and parasitic infections; (b) cardiovascular disorders: cardiac arrhythmia, ischaemic heart disease, heart failure, hypertension, vascular disorders; (c) respiratory tract disorders: upper respiratory tract disorders, asthma, chronic obstructive pulmonary disease, acute bronchitis, bronchiectasis, cystic fibrosis, pneumonia; (d) renal tract disorders: renal failure, disorders of renal tubule function, obstructive uropathies, myoneurogenic disorders, incontinence, neoplasms; (e) diabetes: Type I and Type II.

## PHAR9109 Therapeutic Basis of Drug Use and Development 2

*Offered in Semester 2 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

This course aims to provide an understanding of the major medical problems and treatments that need to be understood in developing new therapeutic agents and optimising their use. Emphasis will be on highlighting the strengths and weaknesses of present therapies and identification of current research aimed at developing new therapeutic agents.

The course provides an integrated description of relevant physiology, pathophysiology, disease state manifestations and clinical pharmacology with respect to the following disease states: (a) gastrointestinal disorders: oesophageal disorders, gastritis, peptic ulcer, diarrhoea and constipation, gastroenteritis, malabsorption syndromes, chronic inflammation of the bowel, gastrointestinal neoplasms; (b) hepatic and biliary disorders: jaundice, ascites, fibrosis, cirrhosis, hepatitis, neoplasms; (c) Endocrinological disorders: Osteoporosis, thyroid diseases (hypothyroidism and hyperthyroidism); (d) Haematology disorders: acute and chronic leukaemias, plasma cell disorders, polycythaemia, lymphomas; (e) Rheumatology disorders: rheumatoid arthritis, systemic lupus erythematosis, polymyalgia; (f) Oncology: Myelomas, principles of cancer treatment, pharmacokinetics and pharmacogenetics; (g) Neurological disorders: Alzheimer’s Disease, Parkinson’s Disease, Epilepsy; (h) Psychiatric disorders: Schizophrenia, Depression, Bipolar disorders.

## PHAR9111 Advanced Pharmaceutical Development of Medicines

*Offered in Semester 1 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

This course extends the principles covered in Pharmaceutical Development of Medicines (PHAR9102) and includes detailed review of the formulation and *in vitro* / *in vivo* assessment of oral controlled-release products and novel dosage forms such as transdermal therapeutic systems and osmotic pumps. There is an extensive chapter on the formulation and testing of inhaled medicines, including metered dose inhalers, dry powder inhalers and nebulisers and a chapter describing disperse formulations; the latter group includes emulsions, suspensions, ointments and creams.

Regulatory aspects of the quality and bioavailability of all of these products are discussed. The section on biological medicines expands on material delivered in PHAR9102, providing a detailed discussion of issues and considerations in the development of a range of biological medicines including those derived from natural and recombinant DNA sources and cellular and tissue therapies. Issues covered include appropriate sourcing of biological starting materials, choice of cell lines for the expression of recombinant products, handling of infectious and potentially infectious biological materials, product characterisation, and storage and regulatory issues.

## PHAR9112 Advanced Pharmacokinetics

*Offered in Semester 2 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

This course greatly extends the introduction to pharmacokinetics given in the core module Principles of Drug Action, with particular emphasis being given to new aspects of pharmacokinetics. Topics covered include methods used in drug development to investigate the pharmacokinetic characteristics of new chemical entities in the non-clinical and clinical phase. The role of pharmacokinetics in drug selection is highlighted and emphasis is placed on critical appraisal of the pharmacokinetic literature. Other topics include investigating drug interactions and population pharmacokinetics as a tool to inform drug development about the clinical utility of medicines. Students electing to take this unit will also have a chance to pursue a short assignment in an area of interest to their work place, related to the area of pharmacokinetics and pharmacodynamics.

## PHAR9113 Advanced Regulatory Affairs

*Offered in Semester 2 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

This course extends the core course PHAR9104, by providing a comprehensive examination of the role of the international regulatory agencies such as those of the European Union and the United States and their influence on the Australian regulatory processes. The major emphasis of the course will be on case studies and critical appraisal. Students review registration dossiers, write evaluation reports and prepare responses for pre-committee (ACPM) meetings. The focus is on providing students with working examples to give experience in preparing regulatory submissions, finding appropriate guidelines, and ensuring an understanding of the regulatory processes involved. Scenario based problems are used to provide examples of decision making both within the regulatory agencies, and those required by sponsors.

## PHAR9114 Pharmacoeconomics

*Offered in Semester 1 (6 Units of Credit)*
*This course is elective and only available for Program 9060.*

As limits are placed on health care budgets, the relative value of competing uses of scarce resources is becoming a significant part of decision making. Pharmacoeconomics assists the decision-maker by determining the comparative value of a product, and whether this value is worth the loss of benefits that could have been obtained by using the money in a different way. In the Australian environment, pharmacoeconomic analyses are considered by the Pharmaceutical Benefits Advisory Committee which advises the Minister on whether the product should be reimbursed under the Pharmaceutical Benefits Scheme (PBS). They are also used in hospital formulary submissions within the public hospital setting, and in support material and publications for doctors. Pharmacoeconomic models can help to assess the potential value of a product and they can also identify threshold levels of efficacy that must be met for the product to be commercially viable.

This course focuses on the principles of pharmacoeconomics, the process of obtaining reimbursement of a product on the PBS, and issues in applying pharmacoeconomic theory to the real world. The course also covers economic concepts, efficiency, equity and ethics of decision making in the health care field and provides an overview of pharmacoeconomics internationally. Specific areas include the different types of economic analysis, sources of data, randomised trials versus naturalistic or pragmatic trials, quality of life and assessment of utility, and league tables. This is of benefit to those wishing to work in the area of pharmacoeconomics or broaden their knowledge base in this important area.

## PHAR9116 Advanced Clinical Trials Management

*Offered in Semester 2 (6 Units of Credit) This course is elective and only available for Program 9060.*

The focus of the advanced course is to learn how to manage a clinical trial by using a specific example of a study in a selected therapeutic area. The course builds on knowledge gained, in particular, from PHAR9120 including the critical appraisal skills that have been emphasised as a key competency for any individual involved in the development and regulation of medicines and devices. It is not the intention that the course is a 'project management' course per se. The aim, rather, is to provide students with a good, practical understanding of clinical research and trials.

The course covers how to plan a clinical trial to meet designated timelines and within budgetary constraints; how to further understanding of the putative mechanisms of action of the therapeutic agent being investigated, and of the clinical area and the endpoints that are important for studies in that area. An important component of the course involves critical appraisal of a study in the selected therapeutic area and writing the synopsis for the study report. Preparation of a consent form for submission to a Human Research Ethics Committee (HREC), pages for a Case Record Form (CRF) and a study budget are exercises undertaken in the course. The weekend school provides interactive practical examples and reviews of the assignment work.

# Course Dates

## Key Dates 2013

| Semester 1 2013 (T1): 4 March to 22 June 2013 | |
|---|---|
| Orientation Weekend School (Yr 1 only 7370, 5504, 5511, 9060): | 2 & 3 March |
| Semester 1 (T1) begins: | 4 March |
| Mid-Semester break: | 29 March - 7 April |
| Weekend School in Sydney: (not year 1 students) | 13 & 14 April |
| Weekend School in Sydney: | 18 & 19 May |
| Last day of Semester 1 Teaching Period: | 7 June |
| Examinations: | 15 & 22 June |

| Semester 2 2013 (T2): 29 July to 16 November 2013 | |
|---|---|
| Semester 2 (T2) begins: | 29 July |
| Weekend School in Sydney: | 24 & 25 August |
| Mid-Semester break: | 28 September - 7 October |
| Weekend School in Sydney: | 12 & 13 October |
| Last day of Semester 2 Teaching Period: | 1 November |
| Examinations: | 9 & 16 November |

Results for Semester 1 are available mid-July and for Semester 2 are available late-November.

## Courses by Semester

| Semester 1 |
| --- |
| Year 1 (7370, 5504, 9060, 5511) |
| — PHAR9101 Principles of Drug Action |
| — PHAR9120 Clinical Development of Medicines |
| Year 2 (5504, 9060, 5511) |
| — PHAR9102 Pharmaceutical Development of Medicines |
| — PHAR9121 Post-marketing Development of Medicines |
| Year 3 (9060) |
| — PHAR9107 Therapeutics and Molecular Basis of Disease 1 |
| — PHAR9118 Therapeutics and Molecular Basis of Disease 2 |
| — PHAR9114 Pharmacoeconomics |
| — PHAR9111 Advanced Pharmaceutical Development of Medicines |

| Semester 2 |
| --- |
| Year 1 (7370, 5504, 9060, 5511) |
| — PHAR9127 Efficacy and Safety of Medicines |
| — PHAR9104 Law, Ethics and Regulation of Medicines |
| Year 2 (5504, 9060, 5511) |
| — PHAR9103 Biostatistics and Clinical Trial Design |
| — PHAR9128 R&D in the Pharmaceutical Industry |
| — PHAR9124 Economic Drivers and Medical Department Management in the Pharmaceutical Industry (Program 5511 only) |
| Year 3 (9060) |
| — PHAR9108 Therapeutic Basis of Drug Use and Development 1 |
| — PHAR9109 Therapeutic Basis of Drug Use and Development 2 |
| — PHAR9112 Advanced Pharmacokinetics |
| — PHAR9113 Advanced Regulatory Affairs |
| — PHAR9116 Advanced Clinical Trials Management |

# Information For Enrolled Students

## Student Cards

Student cards are issued upon enrolment and are valid for 3 years. This card is used to borrow books from the University library and is used as proof of identification on campus as well as identification for University examinations. Student cards can be obtained from FM Assist (level 2, Mathews Building, UNSW). See FM Assist website for more information on security, parking on campus, lost property, maps and student cards:

http://www.facilities.unsw.edu.au/fm-assist

## Email

All enrolled students are allocated a student email account. Important information about fees, enrolment and results is sent to student email accounts. Details about accessing and activating your account are provided upon enrolment.

It is important to arrange for your student account to be forwarded to an alternate account if you do not check your student email account regularly. To forward your email see:

https://www.it.unsw.edu.au

## Results

Final results for courses are emailed to student email addresses in mid-July for Semester 1 and late November for semester 2. Results can also be viewed online by logging into myUNSW and selecting "View Results" under "My Student Profile".

## Leave of Absence

If you intend to take leave for one or two semesters, you must complete the Program Enrolment Variation Form before the census date for each semester. The form should be returned to the Program Administrator for School approval. Your Program Administrator will check that you have been withdrawn from all enrolments. The form will then be forwarded to Student services for processing.

NB: If you do not enrol and do not officially request leave from your studies then your enrolment will lapse at the census date and you will not be able to enrol in the following semester.

## Withdrawal from Courses

The last date to discontinue a course without academic or financial penalty is the census date in each semester.

You may still discontinue courses after the census date and until the Withdrawal without Failure date without academic penalty. However, you are still liable for fees for the course. If your request for withdrawal from one or more courses is the result of exceptional circumstances you may be eligible to apply for reimbursement of charges for the course. In addition, if exceptional circumstances prevent you from completing a course, and the Withdrawal without Failure date has passed then you may choose to apply for late withdrawal from a course. In both cases you must demonstrate that you were prevented from completing a course by circumstances beyond your control, which extended over a significant period of time.

## Special Consideration

On some occasions sickness, misadventure or other circumstance out of your control may prevent you from completing a course requirement, and attending or submitting assessable work for a course. The University has procedures that allow you to apply for consideration for the affected assessments. Depending on the circumstances, the University may take action to allow you to overcome the disadvantage; e.g. Give you additional assessment or extend a deadline.

You should note that merely submitting a request for Special Consideration does not automatically mean you will be granted leave, nor that you will be awarded an amended result.

More information is available at the following website:

https://my.unsw.edu.au/student/atoz/SpecialConsideration.html

## Return of Study Material upon Discontinuation

Students who discontinue a course before payment of fees for that course are required to return all study materials within 14 days, at their own expense. A fee may be applied for costs of course materials should students discontinue early or if student enrols late and additional materials need to be produced. Where payment of fees is outstanding, course results for completed courses may be withheld.

## Blackboard

Blackboard is the UNSW web-based learning and teaching tool that is used for all courses in Pharmaceutical Medicine and Drug Development. Information about web-based teaching and login to the courses is available at:

http://lms-blackboard.telt.unsw.edu.au

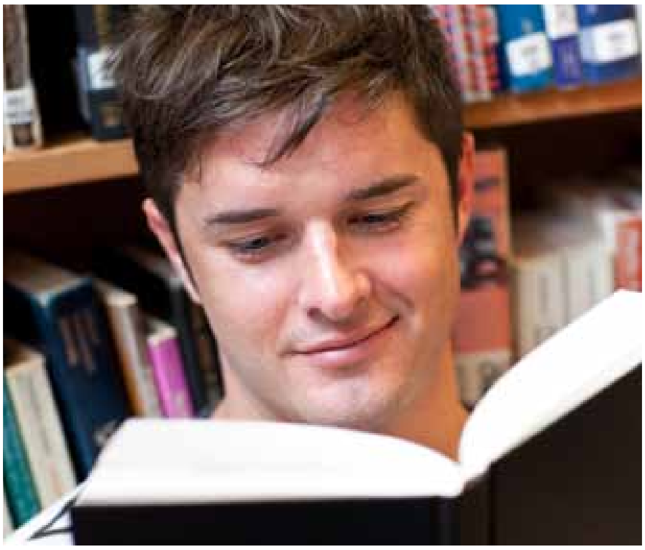
## IT Requirements

Our courses have online components which have been developed and are taught on the assumption that all students meet the “IT requirements for UNSW Students Policy” which is viewable at:

http://www.its.unsw.edu.au/policies/policies_home.html

Students have access to many UNSW network services including student email account, and library services. To gain access you need to obtain your zPass from the IT Service Desk.

To contact the Service Desk visit: https://www.it.unsw.edu.au, telephone (61 2) 9385 1333 or email: itservicecentre@unsw.edu.au



# Key Contacts Within UNSW

| Department | Contact Details | Overview |
|---|---|---|
| UNSW website | http://www.unsw.edu.au | Gateway to university departments, schools, activities and news. A good place to start a university wide search |
| Drug Development Website | http://drugdev.med.unsw.edu.au | Pharmaceutical Medicine and Drug Development website with links to Program Handbook, program and course timetables, and general information related to the program. |
| NSW Student Central | Lower Ground Floor<br>Chancellery Building<br>Tel: 02 9385 8500<br>http://my.unsw.edu.au<br>Email: studentcentral@unsw.edu.au | Student enquiries—provides referral and advice on administrative procedures and policies for students enrolled in coursework degrees. |
| myUNSW | http://my.unsw.edu.au | Access enrolment information, check results, change personal contact details, pay fees, obtain copy of academic record and view information about UNSW procedures and deadlines. |
| FMAssist | Level 2, Mathews Building<br>Tel: 9385 5111 or 9385 5800<br>http://www.facilities.unsw.edu.au/fm-assist | Obtaining student ID cards |
| Fees/Payment | Chancellery Building, LG Floor<br>Tel: 02 9385 3119<br>Email: csandfees@unsw.edu.au<br>https://my.unsw.edu.au/student/fees/FeesMainPage.html | Queries regarding fee payment |
| Commonwealth Supported Places | Chancellery Building, LG Floor<br>Email: csandfees@unsw.edu.au<br>https://my.unsw.edu.au/student/fees/CSP.html | Queries regarding Commonwealth Supported Places |
| IT Service Centre | Tel: 02 9385 1333<br>UNSW Library<br>Email: itservicecentre@unsw.edu.au<br>http://www.it.unsw.edu.au | Information about accessing student email, updating changes and forwarding email, UniPass and zPass queries, UniWeb, Software and technical assistance with Blackboard |
| Blackboard | http://lms-blackboard.telt.unsw.edu.au | Information about web-based teaching and log-in to web-based courses |
| The Learning Centre | http://www.lc.unsw.edu.au | Offers support services & workshops in regards to developing academic skills e.g. writing, presentations, computer skills, plagiarism, referencing. |

# Prospective International Students

Both, the Graduate Diploma of Pharmaceutical Medicine and all Drug Development programs are offered by distance education and on a part-time basis. For this reason neither program qualifies for CRICOS registration and so cannot be offered to international students who come to Australia to study on a student visa.

The National code of Practice, which was established as part of the Education Services for Overseas Students (ESOS) Act 2000 states in paragraph 13.1 that, distance education and part-time courses are not to be registered on CRICOS. This does not prohibit the course being offered to international students, however, they must be overseas when doing the program or be in Australia on another type of visa (e.g. long stay business visa). The students need to ensure they are not breaching any restrictions/conditions of that particular visa. A student who wants to come to Australia for the sole purpose of studying the program is not able to obtain a visa to do so and the only option available to students is to study from overseas.

The University of New South Wales also requires that international students demonstrate proficiency in spoken and written English.

Overseas students need to fulfill all requirements to complete courses including attendance at weekend schools.

## Contact Details:

Pharmaceutical Medicine & Drug Development
Wallace Wurth Medical Building
School of Medical Sciences
The University of New South Wales
Sydney NSW 2052 Australia
Tel: +61 2 9385 2557
Fax: +61 2 9313 8629
Email: drugdev@unsw.edu.au

CRICOS Provider No. 00098G