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Pharmaceutical and Medical Device Development

Professional Medical Education

Welcome from course directors

We are delighted to introduce you to our postgraduate coursework degree in Pharmaceutical and Medical Device Development.



Dr Rania Salama, Program Director; Dr Hui Ong (YY), Program Director; Professor Daniela Traini, Program Advisor; Professor Paul M Young, Program Advisor

The University of Sydney postgraduate coursework in Pharmaceutical and Medical Device Development will guide you in the development and regulation of drugs and devices. It is suitable for those already working, or planning to work, in the pharmaceutical and medical device areas. Flexible study options are available which include short, focussed professional certificates and detailed master programs.

Our program has been designed with a strong grounding in industry, developed in partnership with leaders in the field – in academia, regulatory affairs and industry associations and industry partners. Industry leaders have generously given their time and expertise to this course, and have been engaged in the design and content

development. They are committed to ensuring that we upskill the workforce to address the current unmet need in this rapidly growing field.

The coursework can be tailored to your requirements and is suitable for health, science and engineering graduates, as well as those already working in pharmaceutical or medical devices industries. The higher degrees offer the opportunity to develop your skills in areas such as research, health economics, Pharma R&D and regulation.

Please feel free to approach us if you have any questions about the degrees. We're happy to help you design a study plan that meets your goals.

Study Pharmaceutical and Medical Device Development

Pursue new opportunities and upskill with a postgraduate qualification

Learn how to successfully manage the progress of pharmaceuticals and medical devices through crucial regulatory processes. Bring your own experience and learn from the wealth of our experts in this unique program.

These courses are for graduates from a health, medical, engineering or science-related discipline who currently work, or plan to work, in the pharmaceutical, medical device or regulatory industries.

Sought after by industry

The program has been carefully designed to ensure the knowledge and skills you gain meet current industry needs and can be readily integrated into your day-to-day work. You will develop expertise in modern drug development practices worldwide, from concept to registration and beyond. The advanced option provides the opportunity for an industry placement or research project of your choice, providing you with valuable industry experience and connections.

Adapt the course to your needs

Whether you are an experienced industry professional or hoping to enter the industry, you can curate the degree to suit your current needs and career goals.

If you are interested in R&D or medical affairs, you can study units that enhance your expertise of the translation of a drug or device from the lab setting to a final approved product. You can also undertake electives in units in biostatistics, health surveys and trial design and methods.

If you want to bring a new pharmaceutical product or a novel medical device into the market, you can complete units in commercialisation to develop your understanding of the business skills essential to bring products to market in the medical devices and pharmaceutical sectors, and you can complement your studies with electives in the business of health, as well as economics and finance.





Taught by leading minds in the field

The program is taught and developed by industry professionals, regulatory body leaders, representatives of industry associations as well as academics. Our expert multidisciplinary team covers the breadth

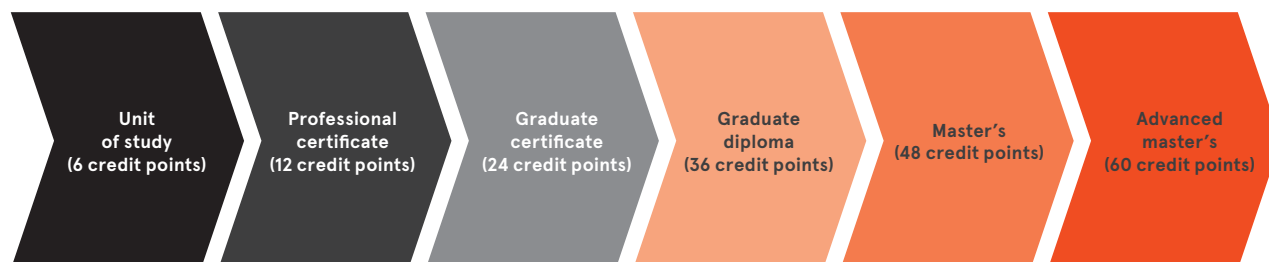
of career paths and expertise required for the development, registration and provision of medicines and medical devices in Australia and internationally.

Flexible study options

Our units are delivered online, giving you the flexibility to study while still working.

You can complete the degree at your own pace, provided you finish within the University's requirements (up to 10 years for a master's degree).

The study options available are shown in the arrow below, and you can move between these options provided you meet the requirements of each degree.



Where can this program take you?

Our graduates work in a range of roles within the pharmaceutical and medical devices industries

This industry-focused course will prepare you for a multitude of careers within the diverse and wide-ranging pharmaceutical and medical device development industries. Our graduates have worked, transitioned and developed careers in a variety of jobs in both the medical devices and pharmaceutical industries.

With units that span the journey of product development – from the initial R&D stage to the end-consumer – you can explore the many and diverse careers on offer to you in the pharmaceutical and medical device industries as well as the regulatory sector.

Pursue a career in:

- Clinical research
- Medical affairs
- Quality Control and Quality Assurance (QC & QA)
- Regulatory affairs
- Research and development (R&D)
- Product manufacturing
- Pharmacovigilance
- Pharmacoeconomics

Hear from our students

“There were elements of the program which directly benefitted my current role, and it has provided context and ideas to improve some of my clinical compliance work. I’ve enjoyed gaining a broader and deeper understanding of industry, academia and medical policy, along with the ethical and scientific challenges and opportunities.”

Simon Lewi,
Senior Director Clinical Safety & Compliance, ResMed

“The program has guided my career into an exciting direction and has been relevant to my current role. I started out with the intention of entering regulatory affairs, but through my studies I became intrigued by clinical research, and now I’m working with a wonderful team to help manage and monitor various clinical trials across Australia.”

John Nesvaderani,
Clinical Trials Assistant, Bayer

What will you study?

Designed by expert industry professionals, our units of study help you navigate and manoeuvre the complex pharmaceutical and device regulatory sectors.

As you study, you will gain the required knowledge and critical thinking skills about the process of translating a new drug, formulation or medical device from a laboratory setting to the final approved commercially viable product.

Master's students complete two compulsory units of study, four stream-specific units of study, and two stream-specific or elective units of study.

Graduate diploma students complete one compulsory unit, four stream-specific units and one elective and graduate certificate students can choose from stream-specific units.

Compulsory units of study

Introduction to Clinical Epidemiology (CEP5100)

In this unit, you will be introduced to the concept of clinical epidemiology and develop core skills at an introductory level.

Pharm and medical device development (PCOL5104)

In this capstone unit (master's only), you will develop the critical thinking needed to transform a new therapeutic drug or device into a commercially-viable product.

Stream-specific units of study

Drugs and devices: R&D to registration (PCOL5101)

This unit will provide you with a strong foundation in the process of translating a new drug, formulation and/or delivery device from a laboratory to setting to a final approved product.

Modern therapeutics and medical devices (PCOL5102)

This unit will develop your understanding and knowledge in state-of-the-art therapeutic technologies.

Therapeutics and device innovations (project) (PCOL5103)

You will work on a project identifying, evaluating and solving complex technical problems.

Commercialising MedTech and Pharma (PCOL5105)

This unit provides key business skills and related knowledge essential for the commercialisation of products in the medical device and pharmaceuticals sectors.

Regulations of Complementary Medicines (PHAR7815)

This unit provides a detailed overview of the regulatory framework, policies, ethical implications and processes involved in the production of complementary medicines and devices.

Electives

Advanced trial design (CLTR5004)

Bioethics, law and society (BETH5104)

Business of health (HPOL5006)

Diagnostic and screening tests (CEPI5312)

Economics and finance for health policy (HPOL5001)

Health and risk communication (PUBH5422)

Health indicators and health surveys (BSTA5003)

Introductory biostatistics (PUBH5018)

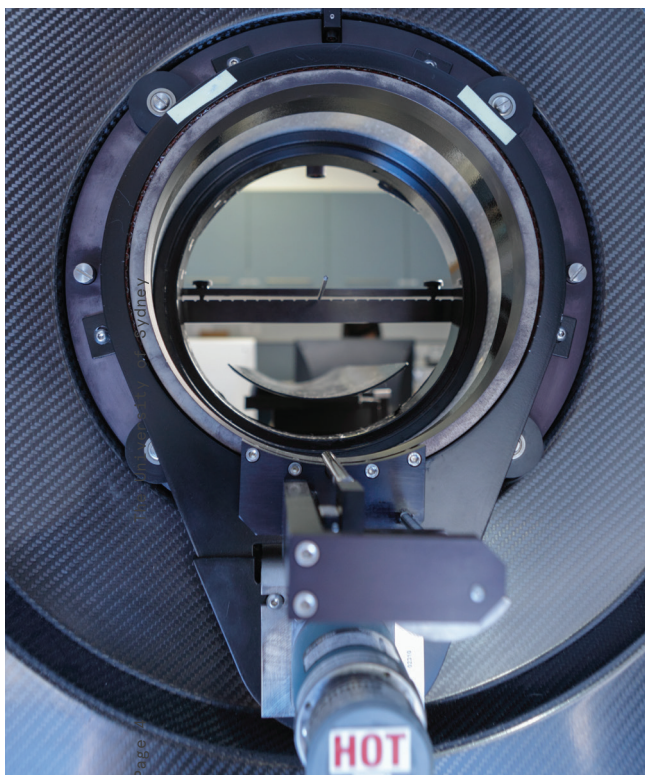
Introduction to systematic reviews (CEPI5315)

Medicines policy, economics and ethics (BETH5209)

Quality and safety in healthcare (CEPI5200)

Trial design and methods (CLTR5001)

Writing and reviewing medical papers (CEPI5215)



Our people

Key contributors to our program

Academic Leads



Dr Hui Xin Ong (YY), Program Director

Dr Ong is a Lecturer in the discipline of Pharmacology at Sydney Medical School, and a research leader at the Woolcock Institute of Medical Research. She has worked with diverse experts from academia and industry partners, and is the current director of Ab-Initio Pharma, a formulation and GMP product manufactory service.



Dr Rania Salama, Program Director

Dr Salama is a pharmacist with over 20 years of higher education experience in the fields of drug development, novel formulation design, industrial pharmacy, pharmacokinetics and clinical trials. In her postdoctoral role at the University she was the chief scientist leading industry-linked projects for the development of inhalation formulations and optimisation of device design.



Professor Paul Young, Program Advisor

Professor Young is a Professor of Respiratory Technology and pharmacologist at Sydney Medical School, where his team focusses on developing advanced drug delivery systems for treating a wide range of respiratory disorders. Paul has 20 years' experience in the pharmaceutical industry.



Professor Daniela Traini, Program Advisor

Professor Traini is a Professor in Respiratory Science at Sydney Medical School, and has extensive experience in both academic and industrial pharmaceuticals, retaining strong links with the industry. Her background is in both device and medicine engineering, with a specific focus on respiratory research and development.

Advisory committee

Our expert advisory committee has contributed and sculpted the program to ensure our graduates can respond to changing industry needs.



Adjunct Professor John Skerritt, Deputy Secretary Therapeutic Goods Administration

Professor Skerritt joined the Department of Health in 2012, and is responsible for leading the design and implementation of broad-ranging reforms to the medicines and medical devices regulatory framework and developing new regulatory framework for medicinal cannabis in Australia.



Roman Griefeneder, Executive Director, Khelix (CathRx)

Roman is the Executive Director and COO of Khelix (CathRx) with over 20 years of experience in the medical devices sector. He has extensive experience in design and operations management, with a focus on new product development, technology transfer, manufacturing, engineering and quality assurance.



Nessa Banville, Medical Manager, Roche

Nessa joined the pharmaceutical industry in 2014 as a respiratory medical science liaison for GSK following research into respiratory diseases. Her role at GSK focused on external engagement activities and she recently moved to Roche Pharmaceuticals as a senior medical science liaison in the respiratory therapeutic area.



Gary Phillips, CEO Pharmaxis

Gary has been with Pharmaxis since 2003 and has over 30 years of operation management experience in the pharmaceutical and healthcare industries worldwide. Pharmaxis' portfolio includes respiratory products and a research pipeline that focuses on areas of unmet clinical needs.



Dharmica Mistry, Chief Scientist, BCAL Diagnostics

Dharmica is the inventor of one of BCAL's founding patents and manages its scientific operations. Her interests include the detection and characterisation of novel biomarkers for breast cancer detection, and has filed an international patent related to her work in breast cancer detection.

**Karen Whitelock,
Pharmacovigilance Health, AbbVie**

Karen first moved into the pharmaceutical industry in 2001, following a career in both retail and hospital pharmacy. She has worked in quality at Pfizer, and has since moved into pharmacovigilance leadership roles at Sanofi, Novartis and now at Abbvie.

**George Lillis, Head of Regulatory Affairs
(Australia and New Zealand), Novartis**

George has over 20 years' experience in drug regulatory affairs, both locally and internationally, primarily working on the development of innovative medicines. He has a profound interest in developing graduates for careers within the healthcare industry and has supervised and sponsored students within Novartis.

**Ben Cullen, Design &
Entrepreneurship Leader, IDE Group**

Ben has 20 years of product development experience in industries such as industrial equipment, telecoms and personal computing, and currently focuses on medical device development. He works with organisations ranging from university spinoffs, to large multinationals to develop and execute development strategies that help companies achieve their business objectives.

Shanny Dyer, CEO, ARCS Australia

Shanny is an experienced senior executive, having held roles across industry, government and universities. Over the last ten years Shanny has been involved in many biotech developments and still holds directorships with Wavefront Biometric Technologies Pty Ltd, Seagull Technology Pty Ltd and Bionic Vision Australia Pty Ltd.



Ali Fathi, Founder, Trimph

Ali developed Trimph's technology while undertaking his PhD at the University of Sydney, and was instrumental to transitioning it from a University project into a tangible corporate entity. Ali's biochemical, medical and entrepreneurial aptitude provide both the technological and commercial expertise upon which the company is based.

**Val Theisz, Director Regulator Affairs,
Medical Technology Association of Australia (MTAA)**

Val is a Regulatory Affairs professional with over 15 years' experience with medical. Val's experience within the field covers the entire product lifecycle across the major global markets – including experience in regulatory strategy; verification and validation; testing and compliance to international standards; clinical trials; submissions and pre-market approvals in established markets and post-market ongoing compliance.

William Glover, NPI Project Manager, Phebra

William completed his PhD in Pharmacy at the University of Sydney. He has worked in drug formulation at Nanomaterials Technology and as a medical scientist at GSK. He has been a quality control manager for various companies including Phebra and GSK.

Jack Wong, Head of Regulatory Affairs, Baxter Healthcare (Asia)

Jack has over 20 years of Regulatory, Clinical Trial and Pharmacovigilance experience in Asia with good knowledge in the field of Medical Devices, Pharmaceuticals, Nutritional, Consumer Healthcare and Biological products.

David Edmonds, Principal, CMC Regulatory & Royal Australian Chemical Institute (RACI)

With over 45 years of experience in the therapeutic goods industry, David has worked in manufacturing and QA roles at Sterling Pharmaceuticals, Lilly Industries and A. H. Robins and has spent over 20 years in the R&D company, Peptech Ltd. As QA and Regulatory manager.

Alan Robertson, CEO Alsonex

Alan was the CEO and MD of Pharmaxis LTD for 14 years, where he over the development to marketing authorisation of a new inhaled dry powder treatment for cystic fibrosis and a bronchial challenge test for hyperactive airway disease. He also built a drug discovery capability within Pharmaxis, and raised more than \$350 million in the US, Europe and Australia.

Alan Taylor, Executive Chairman, Clarity Pharmaceuticals

Alan is Executive Chairman of Clarity Pharmaceuticals, a radiopharmaceutical company focused on the development of new treatments for cancer and other serious diseases. He has previously worked as a scientist, investment banker, entrepreneur and investor. He is a member of the board of Inteq Limited.

Andrew Weekes, Medical Director, GSK

Andrew is a pharmaceutical physician with over fifteen years' experience across international head offices and national subsidiary role and strong track record as a collaborative and innovative member of executive teams.



Admissions

This program is offered through two pathways – the Master of Medicine for medical graduates, and the Master of Science in Medicine for health or science-related graduates.

To be eligible for the graduate certificate and graduate diploma you require either of the following:

- a bachelor or postgraduate degree in health or science-related discipline (including engineering)
- a medical degree.

The master's requires you have one of the following:

- a bachelor's degree in a health or science-related discipline (including engineering) with honours
- a bachelor's degree and a minimum 12 months' relevant work experience
- a medical degree.

The advanced option provides an opportunity to undertake research or an industry placement and is only available to students who have completed the requirements for the master's and have achieved an average mark of at least 75 percent in 24 credit points of compulsory and/or stream-specific units of study.

Course fees

The course you have chosen and your citizenship and residency status influence your tuition fees, student contribution and the loan schemes available to you. **You do not have to pay for your entire course upfront,** students are charged per unit of study and invoiced each semester.

How to apply

Applications are completed online.

Visit sydney.edu.au/courses and search for your desired program to apply.

sydney.edu.au

The University of Sydney

Learn more

Visit sydney.edu.au/medicine-health/professional-medical-education or email
pgmed-support@sydney.edu.au

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