



THE UNIVERSITY OF
SYDNEY



Pharmaceutical & Medical Device Development

Postgraduate study:

Master's degree, Graduate Diploma and Graduate Certificate

PROFESSIONAL MEDICAL EDUCATION

Take the next step in your career



"Completing this course will hold you in good stead for employment within the pharmaceutical industry in Australia."

Karen Whitelock
Pharmacovigilance Head, AbbVie

Welcome from the Course Leader



I am delighted to introduce you to our postgraduate coursework degree in Pharmaceutical & Medical Device Development. We are offering a Graduate Certificate, Graduate Diploma and Master's degree to prepare you to develop drugs and devices and navigate the significant regulatory control process for these products. The coursework is designed to meet the requirements of those working or planning to work in the pharmaceutical and medical device areas.

This is an industry focused program, developed in partnership with leaders in the field – in academia, regulatory affairs, industry associations as well as a wide array of industry organisations. We have been overwhelmed by the

generosity of our contributors, who have been keen to address the urgent and unmet need to upskill the workforce in the areas covered by this program.

The coursework can be tailored to your requirements and is suitable for health, science and engineering graduates. 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. I look forward to working with you.

Paul M Young

A handwritten signature in black ink, appearing to read 'Paul M Young' in a cursive style.

PROFESSOR PAUL M YOUNG

Chair of Commercialisation
The University of Sydney
Faculty of Medicine and Health

Learn more online at:

[sydney.edu.au/medicine/study/postgraduate/
pharmaceutical-medical-device-
development.php](https://sydney.edu.au/medicine/study/postgraduate/pharmaceutical-medical-device-development.php)

About

Pharmaceutical & Medical Device Development: Graduate Certificate, Graduate Diploma, Master's degree

These courses provide education and guidance in the complex pharmaceutical and device regulatory sectors. They are flexible, with online delivery designed to support the learning of busy professionals. You will gain a thorough knowledge of the process of translating a new drug, formulation or medical device, from a laboratory setting to a final approved product. Building on this, you will develop the critical thinking needed to transform a new therapeutic drug or device into a commercially viable product. The program also offers a unique opportunity to learn from industry experts.

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.

Taught by leading minds in the field

The program is taught by industry professionals, regulatory body leaders, representatives of industry associations and academics. Our 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. Our educators come from a cross-section of organisations within the sector. These include dynamic start-up companies, small/medium enterprises, large pharma, regulatory body (TGA) and industry bodies such as the RACI, MTAA and ARCS.

Advisory Committee

Designed by the pharmaceutical and device sector for the pharmaceutical and device sector.

Our courses have been designed to make you work ready and effective. This has been achieved through an extensive consultation process and engagement with stakeholders in the field. Our Advisory Committee members are from numerous industry bodies, pharmaceutical companies and the Therapeutic Goods Administration. This dynamic committee has overseen the development of this program from its inception, to ensure that graduating students will meet the requirements and expectations of the field. The Committee, along with their industry-based colleagues, have made an ongoing commitment to the development and delivery of the program.

Admission requirements

The Graduate Certificate and Graduate Diploma require either a bachelor or postgraduate degree in a health or science-related discipline (including engineering), or a medical degree. The Master's requires you to have a bachelor degree in a health or science-related discipline (including engineering) with honours; or a bachelor plus a postgraduate degree in a health or science related discipline; or a bachelor's degree and a minimum of 12 months' relevant work experience; or a medical degree.



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



How will you study?

You can choose the degree that suits your needs: Graduate Certificate, Graduate Diploma or Master's and move between the degrees provided you meet the requirements in each case. The coursework is delivered online with an opportunity to work on a final scientific dossier in small groups. If you are working full-time, consider undertaking 1 or 2 units of study per semester.

Course Fees

Students are charged per unit of study and invoiced each semester.

Enquiries and how to apply

<http://sydney.edu.au/medicine/study/postgraduate/pharmaceutical-medical-device-development.php>

Compulsory units of study

Introduction to Clinical Epidemiology - CEPI5100

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

Pharm & 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 & 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 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.

Industrial Therapeutics (project) - PCOL5103

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

Medicines policy, economics and ethics - BETH5209

In this unit, you will explore and critique global and national policies and processes related to medicine, examining how research and development agendas are set, how medicines are assessed and evaluated, and how new technologies are translated into practice.

Trial design and methods - CLTR5001

In this unit of study you will focus on the strengths and weaknesses of different clinical study designs.

Elective units

Bioethics, law and society - BETH5104

Health indicators and health surveys - BSTA5003

Quality and safety in healthcare - CEPI5200

Diagnostic and screening tests - CEPI5312
Advanced trial design - CLTR5004

Business of health – HPOL5006

Economics and finance for health policy - HPOL5001

Introductory biostatistics - PUBH5018

Health and risk communication - PUBH5422

Introduction to systematic reviews – CEPI5315

Writing and reviewing medical papers – CEPI5215

Academic Leads:

Program Coordinators



Dr Hui Xin Ong (YY) | Program Coordinator

Hui Xin is a Lecturer in the Discipline of Pharmacology, Sydney Medical School and a research leader at the Woolcock Institute. She holds an honours degree in Pharmacy (B. Pharm) and a PhD in Pharmaceutical Sciences from the University of Sydney. She was a European Respiratory Society-European Lung Foundation Fellow and has worked with diverse experts from academia and industry partners leading to advancement and development of various state-of-the-art pharmaceutical formulations. Hui Xin is also currently the director of Ab-Initio Pharma, a formulation and GMP product manufacturing services.



Dr Rania Salama | Program Coordinator

Rania is a lecturer of Pharmaceutical Sciences in the discipline of Pharmacology, Sydney Medical School at The University of Sydney. She is also a Senior Research Scientist at the Woolcock institute of Medical Research. Rania 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. She has developed extensive expertise in curriculum design, academic programs evaluation and student centred online learning. Rania received her PhD from the Faculty of Pharmacy, The University of Sydney. She was the chief scientist leading industry linked projects for the development of inhalation formulations and optimisation of device design during her postdoctoral research role at The University of Sydney.

Academic Leads:

Program Advisors



Professor Paul Young | Program Advisor

Paul is Professor of Respiratory Technology in the Sydney Medical School at the University of Sydney. His team focusses on developing advanced drug delivery systems for treating a wide range of respiratory disorders ranging from asthma to tuberculosis. Paul has 20 years' experience in the Pharmaceutical Industry and comes from an industrial pharmaceutical background. He holds an honours degree in Chemistry (UWE, UK) and PhD in Pharmaceutical Sciences (University of Bath, UK). Paul has an interest in all areas of the pharmaceutical sector, in particular dosage form design, scalability and manufacturing logistics, clinical trials and end-product batch-to-batch and processing problem solving. He has authored 188 peer reviewed papers and has received several large grants.



Professor Daniela Traini | Program Advisor

Daniela is Professor in Respiratory Science in Sydney Medical School. She has extensive experience in both academic and industrial pharmaceuticals, and retains strong links with the pharmaceutical industry. She has published over 175 peer reviewed papers, holds 5 patents and has attracted more than \$12 million in competitive funding. Daniela's background is in both device and medicine engineering with a specific focus on respiratory research and development.

Advisory Committee: regulatory affairs



John Skerritt | Deputy Secretary | TGA

Professor Skerritt joined the Department of Health in 2012 and is Deputy Secretary for Health Products Regulation. The Health Products Regulation Group comprises the Therapeutic Goods Administration (TGA) and the Office of Drug Control (ODC). John is responsible for leading the design and implementation of broad-ranging reforms to the medicines and medical devices regulatory framework and developing a new regulatory framework for medicinal cannabis in Australia.

Professor Skerritt has extensive experience in regulation, research management, technology application and commercialisation. During the 1990s he held senior management positions in CSIRO and Cooperative Research Centres. He has significant experience on boards of international and national organisations and has more than 25 years of experience in negotiating and leading international technical and commercial collaborations. He is the author of 10 patents and almost 300 refereed scientific publications and is a Thomson-Reuters highly cited researcher.

John is an Adjunct Professor of The Universities of Sydney, Queensland and Canberra, has a PhD from the University of Sydney, and is a graduate of the Senior Executive Programs of London Business School and of the International Institute for Management Development (IMD) Business School in Switzerland. He was elected a Fellow of the Academy of Technological Sciences and Engineering and a Fellow of the Institute of Public Administration of Australia (Vic).

Advisory Committee:

Industry bodies



Shanny Dyer | CEO | ARCS Australia

Shanny is CEO of ARCS Australia Ltd and is an experienced senior executive, having held roles across industry, government and universities. She has expertise in public administration and policy development with strong corporate governance skills. 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. Shanny also has honorary positions as: Member of the R&D Taskforce; Panel member for NHMRC Development Grants; Panel member for ARCS Industrial Transformation Grants; Member of steering committee reviewing impact of University Research; Member of steering committee for the Australia and New Zealand Rheumatic Fever Vaccine development. Shanny is passionate about professional development and the healthcare sector.



Val Theisz | Director Regulatory Affairs | Medical Technology Association of Australia (MTAA)

Val is a Regulatory Affairs professional with over 15 years experience with medical devices, including life-sustaining, high risk active implantables. She has a master's degree in electrical engineering and holds Regulatory Affairs Certification credentials for EU and US regulations (RAC EU, RAC US) from the US-based Regulatory Affairs Professionals Society (RAPS). Val's experience within the field covers the entire product lifecycle: regulatory strategy; verification and validation (V&V); testing and compliance to international standards; clinical trials; submissions and pre-market approvals in established markets (CE Marking, FDA 510k and PMA, TGA registration, Health Canada licences); and post-market ongoing compliance. Her experience spans the major markets (EU, USA, Australia and Canada).

Val's specialties include: medical device design evaluation; QA systems auditor to ISO 13485; adverse events and recalls; regulatory information management including electronic document management systems (EDMS) and e-submissions. Val Theisz is the author of the book 'Medical Device Regulatory Practices: An International Perspective' available through CRC press.



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

David has more than 45 years experience in the therapeutic goods industry, having worked in manufacturing and QA roles at Sterling Pharmaceuticals, Lilly Industries and A.H. Robins. He spent over 20 years in the R&D company, Peptech Limited as QA and Regulatory manager and since 2008 has been a consultant. David serves and has served on voluntary committees involving therapeutic goods including membership/Chair of RACI Pharmaceutical Science Group (NSW) 1987-present and Associate member Pharmacopoeial Sub-committee of the Joint Interim Expert Advisory Committee on Standards 2005 – 2007.

Advisory Committee:

Industry



Alan Robertson | Chief Executive Officer | Alsonex

Alan was the CEO and MD of Pharmaxis Ltd for 14 years where he raised more than \$350 million in the US, Europe and Australia. In that role, he oversaw the development to marketing authorisation of a new inhaled dry powder treatment for cystic fibrosis (Bronchitol) and a bronchial challenge test for hyperactive airway disease (Aridol). He also built a drug discovery capability within Pharmaxis and participated in the creation of PXS4728 – now licensed to Boehringer Ingelheim for the treatment of NASH. He was the CEO of Promics Ltd (now part of Teva) and developed the first C5a receptor antagonist for patients with rheumatoid arthritis. While head of drug discovery at Kinacia, he invented KN-309, a PI3 kinase inhibitor (subsequently licensed to Astra Zeneca). He is a former member of the scientific advisory board of Xenome Limited, a former

Non-Executive Director of Patrys Limited and is a current non-executive director of Advent Ltd. As a Senior Scientist at Wellcome PLC, he developed the anti-migraine drug Zomig.



Roman Greifeneder | Executive Director | CathRx

Roman is Executive Director and Chief Operating Officer of CathRx. He has extensive experience in design and operations management, with a focus on new product development, technology development, technology transfer, manufacturing, engineering, and quality assurance.

Roman has over 20 years of experience in the medical device sector. Before joining CathRx, he served as Vice President of Operations for the international medical device company Ventracor Limited. His prior roles included Manufacturing/ Engineering Manager of ResMed Limited, and New Product Introduction Engineer at Telectronics Cardiac Pacing Systems.



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. Alan's 10 years in investment banking concentrated on the life sciences sector. He is a member of the board of Inteq Limited. He has experience in capital raisings, M&A and general corporate advisory. Alan was awarded the University Medal from the University of Sydney for his degree in Applied Science. He holds a PhD in Medicine and a Graduate Diploma in Applied Finance.



Nessa Banville | Medical Manager | Roche

Nessa Banville completed a PhD, focusing on COPD and Cystic Fibrosis from the Royal College of Surgeons, in Ireland. She continued her post-doc work at the Woolcock Institute of Medical Research in Sydney where she worked on ex-transplant lungs from patients with interstitial lung diseases, including IPF. Nessa joined the pharmaceutical industry in 2014 as a respiratory medical science liaison for GSK focusing on external engagement activities and recently moved to Roche Pharmaceuticals as a senior medical science liaison in the respiratory therapeutic area.



Ali Fathi | Founder | Trimph

Ali was instrumental in transitioning Trimph from a University research project to a tangible corporate entity. Ali developed Trimph's technology while undertaking his PhD at the University of Sydney. Ali is an alumnus of the NSW Government Medical Device Commercialisation Training Program from ATP Innovation. Ali's biochemical/medical and entrepreneurial aptitude provide both the technological and commercial expertise upon which the company is based.



Gary Phillips | Chief Executive Officer | Pharmaxis

Gary is Chief Executive Officer and Board Member of Pharmaxis, where he has worked since 2003. Pharmaxis is an Australian pharmaceutical research company with a portfolio that includes respiratory products (Bronchitol and Aridol) and a research pipeline focused on areas of high unmet clinical need. He has more than 30 years of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia, including roles as CEO of Ciba Geigy in Hungary, where he led the successful launch of a portfolio of new products. He worked as area manager for Novartis, and was then appointed Group Company Head and Chief Executive Officer of the Pharmaceutical Division of Novartis Australia. Gary holds a BPharm(Hons) and an MBA.



Dharmica Mistry | Chief Scientist | BCAL Diagnostics

Dharmica is the Chief Scientist at BCAL Diagnostics, a small Australian biotechnology company. She is the inventor of one of the company's founding patents and manages its scientific operations. Her interests include the detection and characterization of novel biomarkers for breast cancer detection. She holds a BSc (Hons) and a PhD and has filed an international patent related to her work.

In 2015, Dharmica was awarded the "Young Scientist Award" at the World Congress on Controversies in Breast Cancer and graduated with distinction from the NSW Health Medical Devices Commercialisation Training Program. In 2016 she was the recipient of the "NSW Young Woman of the Year" award and was among the six top young Australian executives in the Australian Financial Review's BOSS Magazine. In 2017, Dharmica won the "InStyle (Magazine) Women of Style Awards" in the category of Science.



Andrew Weekes | Medical Director | GSK

Andrew is Medical Director of GSK Australia. He is a pharmaceutical physician with over fifteen years' experience across international head office and national subsidiary roles. He has a strong track record as a collaborative and innovative member of executive teams and has lead large multifunctional departments within the Pharmaceutical sector. Andrew has a strong commercial acumen, he has consistently focused on generation, interpretation and communication of evidence to support patients and health care professionals. He has a significant interest in talent development and retention within the industry.



Karen Whitelock | Pharmacovigilance Head | AbbVie

Karen is a pharmacy graduate from the University of Sydney and is a registered pharmacist. After working in retail pharmacy for 10 years, she moved to Birmingham, Alabama where she trained hospital pharmacy technicians. Karen completed postgraduate studies in 1993, receiving a Fellowship from the Australian College of Pharmacy Practice. In 1994, she was appointed to Sydney's Concord Hospital as the inaugural HIV/AIDS Hospital Pharmacist and later as a clinical trials pharmacist.

Karen moved into the pharmaceutical industry in 2001, firstly to Omnicare Clinical Research, then worked in quality at Pfizer, before moving into pharmacovigilance leadership roles, at Sanofi, Novartis and now at AbbVie.



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.

Externally, playing a leading role among all the Regional Regulatory professionals in Asian Harmonization Working Party (AHWP), and was invited to provide regulatory training to local universities and industry organisations. Prof Wong is also very active in ASEAN, APEC, ISO and WHO projects.

Prof Wong developed the First Asia Regulatory Affairs Certificate course in 2007 with more than 1500 students in alumni. He is also the founder of Asia Regulatory Professional Associations (ARPA) since 2010 with more than 1600 members and Asia Good Regulatory Practice (GRP) Research Centre since 2011 with the support of more than 10 companies. He is the author of First Asia Regulatory Book in Asia (Handbook of Medical Device Regulatory Affairs in Asia) and the book was launched in May 2013 with the 2nd edition published in May 2018.



**George Lillis | Head of Regulatory Affairs
Australia & New Zealand |
Novartis**

George Lillis is the Head of Regulatory Affairs at Novartis Pharmaceuticals Australia. His responsibilities extend to New Zealand as well. He has over 20 years' experience in drug regulatory affairs, both locally and internationally, primarily working on the development of innovative medicines. George studied pharmacy at the University of Sydney where he also completed a PhD. He has a profound interest in developing graduates for careers within the healthcare industry and has supervised and sponsored undergraduate and postgraduate students from both Australian and overseas universities within Novartis. George's enthusiasm for mentoring students for roles within the industry goes back a decade. He has taught for almost 9 years and has co-written course material in advanced regulatory affairs for a number of institutions.



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, before focussing more recently on medical device development. Ben graduated from Brunel University, UK with a BSc (Hons) Industrial Design and has held technical and leadership roles with manufacturing companies, start-ups and design companies both in Australia and overseas. In his current role at IDE Group, he works with organisations ranging from university spinoffs, to large multinationals to develop and execute development strategies that help companies achieve their business objectives. Ben has a fervent belief that it takes a strong entrepreneurial spirit to navigate the treacherous path of medical device development and that paying equal attention to the commercial, technical, marketing and regulatory aspects of a project, leads to the greatest chance of success.



For more information

General Enrolment Enquiries | Basia Behnke
Education Support Officer, Professional Medical
Education

T +61 2 9036 6482

E basia.behnke@sydney.edu.au

www.sydney.edu.au/medicine/study/postgraduate/pharmaceutical-medical-device-development.php



THE UNIVERSITY OF
SYDNEY

CRICOS0026A