postgraduate diploma in drug evaluation and pharmaceutical sciences
INFORMATION BROCHURE 2010

POSTGRADUATE DIPLOMA IN DRUG EVALUATION AND PHARMACEUTICAL SCIENCES

The Graduate Diploma in Drug Evaluation and Pharmaceutical Sciences is a course designed to provide broad, vocationally relevant expertise related to drug development, evaluation and usage.

The course for the 2010 intake will commence teaching on Thursday 4th March 2010 and is available to graduates in medicine, pharmacy or science; others who can demonstrate relevant work experience in academia, government, industry or hospital medicine will be considered.

The course is structured in 3 major components:

1. Four units of teaching presentation
2. A unit of Practical Drug Evaluation (the "live-in")
3. An optional exposure to drug development and assessment.

"Today’s potent drugs, combined with the complex issues of their production and use has created a growing need for evaluation of their safety and efficacy. For such evaluation, wide ranging expertise is required in the areas of Chemistry, Pharmaceutics, Pharmacology and Toxicology, Clinical Medicine, Epidemiology and Legal and Ethical Considerations"

Prof Albert Frauman

1. Teaching Units
Areas of teaching will cover basic pharmacology, toxicology, pharmaceutical sciences, clinical trial design, statistics, epidemiology, current and possible future therapeutic practice, post-marketing surveillance and practical and policy aspects of international and Australian drug regulation. There are 5 units which are taken over 2 years (part-time) or one year (full-time).

In addition to face to face lectures, an outstanding feature of the course is its presentation of interactive video conferencing sessions. This approach has allowed for the provision of live lectures by nationally and internationally renowned faculty from Australia, the US Food and Drug Administration (FDA) and the World Health Organisation (WHO). Recordings of lectures will be available for those students unable to attend.

2. Practical Drug Evaluation
This intensive week-long unit will provide the student with supervised "hands-on" practical experience in the evaluation of sample material which will be in the format of that submitted by pharmaceutical companies for registration purposes. There will be group participation in the evaluation of these data.

3. Drug Development and Assessment (Optional Exposure)
The Austin Hospital is a major research and clinical institution and teaching hospital of the University of Melbourne. The Clinical Pharmacology and Therapeutics Unit at the Austin has a range of activities which encompass basic, clinical and regulatory sciences. In addition, the Clinical Pharmacology and Therapeutics Unit provide information and advice on therapeutic matters for all hospital clinical services. In the context of this active programme, all students have options to be exposed to a range of activities, in order to enrich their understanding of the drug development and evaluation process. This will include attendance at hospital therapeutic evaluation and surveillance committees, information about the University of Melbourne’s Drug Evaluation Unit and observation of the production of radiopharmaceuticals for tumour imaging, including synthesis, quality control, patient administration and scanning.

Information on this optional, non-examinable component of the course can be obtained from the Course Coordinators, Prof Albert Frauman or Dr Laurie Mashford.

Fees
The fee for local students starting in 2010 is $23,800
The fee for international students starting in 2010 is $38,700

Semester Dates
Semester I 4th March to 13th May 2010  Thursdays
(mid-semester break: 8th April)
Semester II 29th July to 7th October 2010  Thursdays
(mid-semester break: 9th September)
(Semester dates may change slightly due to availability of lecturers. Confirmed timetables will be sent out to all enrolled students.)
Course Description

YEAR 1

Semester I:
534802 Pharmacology and Toxicology
This unit aims to present the student with basic concepts of pharmacology, drug action, pharmacokinetics and toxicology in relationship to drug development.
Topics include:
- Receptors & Mechanisms of Drug Action
- Autonomic Nervous System (as a model of principles of drug action)
- Pharmacodynamics
- Routes of Drug Delivery & Absorption
- Pharmacokinetics
- Molecular Pharmacology
- Protection Against Chemical Damage
- Metabolism of Drugs
- Safety Evaluation of New Drugs - An Overview
- Safety Evaluation of New Drugs in Animals - Acute Toxicity
- Safety Evaluation of New Drugs - Mechanisms of Adverse Drug Reactions
- Safety Evaluation of New Drugs in Animals - Chronic Toxicity
- Safety Evaluation of New Drugs - Predictive Tests for Chemical Carcinogens
- Safety Evaluation of New Drugs - The Regulator’s Viewpoint and Requirements

Semester II:
543801 Pharmaceutics, Biotechnology and Statistics
This unit aims to examine chemistry and quality control issues.
Topics include:
- Dosage Forms
- Bioequivalence
- Parenteral Dosage Forms
- Parenteral Delivery Systems
- Determination of Chemical Purity
- Stability Studies
- Radiopharmacy
- Cytotoxic Drugs
- Drugs from Natural Sources
- Microbiology
- Monoclonal Antibodies
- Vaccines
- Clinical Trials
- Statistics
- DNA Technology
- Gene Therapy
- Pharmaceutical Chemistry - Regulatory Perspectives

YEAR 2

Semester I:
543802 Therapeutics and Epidemiology
This unit will explore the clinical pharmacology and clinical utility of drugs in various body systems.
Topics include:
- Cardiac Disorders
- Hyperlipidaemia
- Respiratory Disorders
- Gastrointestinal Disorders
- Neurological Disorders
- Endocrine Disorders
- Infective Diseases
- Oncological Disorders
- Haematological Disorders
- Clinical Immunology
- Rheumatology
- Women’s/Men’s Health Issues
- Alternative Medicines
- Epidemiology

Semester II:
543803 Drug Information, Regulation and Legal Issues
The objectives of this unit are to consider practical and policy issues in drug regulation.
Topics include:
- History of Drug Regulation
- Ethical Aspects of Regulation
- Legal and Practical Aspects in:
  - Australia
  - USA
  - European Union
  - Japan and other markets
- Harmonisation of Regulatory Requirements
- Economic Aspects of Therapeutic Drug Use: Australian and International Aspects
- Post-Marketing Surveillance: Australian and International Aspects; WHO
- The Role of Consumers in Drug Regulation and Use
- Rational Drug Use
  - Product Labelling
  - Consumer Product Information
  - Therapeutic Guidelines

543803 Drug Information, Regulation and Legal Issues
- A week-long subject of supervised evaluation of a pharmaceutical submission.

Assessment
If the course is taken over 2 years, each year’s work will be assessed by an assignment of 2,500 words and a multiple choice question examination.

With respect to the Practical Drug Evaluation, oral class presentation at the end of the week-long subject will be used.
For further information

Please contact:

Prof. Albert Frauman or Dr. Laurie Mashford
Drug Evaluation Unit
Department of Medicine
University of Melbourne
Austin Campus
Austin Health
Heidelberg VIC 3084
Phone: +61 3 9496 5486
Fax: +61 3 9459 3510
E-mail: njcash@unimelb.edu.au

For application procedures, or to submit an application, please contact:

School of Medicine
Faculty of Medicine, Dentistry and Health Sciences
The University of Melbourne VIC 3010
Phone: +61 3 8344 5998
Fax: +61 3 9347 7084

Applications must be submitted by 30th November 2009.
Late applications will be considered if places are available within the quota.

The course will be run subject to sufficient enrolments.

Administered by: School of Medicine,
Faculty of Medicine, Dentistry and Health Sciences,
University of Melbourne.

Coordinated by: Clinical Pharmacology and Therapeutics Unit,
Department of Medicine, Austin Hospital and the Department of Pharmacology, University of Melbourne

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