POSTGRADUATE DIPLOMA/MSc
IN
PHARMACEUTICAL MEDICINE

2018/2020
University of Dublin, Trinity College
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**Introduction**

This established course has been designed to improve the knowledge and skills of healthcare professionals in the area of pharmaceutical medicine. It provides comprehensive information to enable students acquire a proper understanding of each topic covered in the course. It looks at each topic from a European and international perspective and therefore is designed to cater for the needs of EU and non-EU students.

The course is aimed at the broad range of professionals working in the pharmaceutical healthcare area. The module content is in line with the current syllabus of the Faculty of Pharmaceutical Medicine (Royal College of Physicians of the United Kingdom) and the course has been accredited by IFAPP (International Federation of Associations of Pharmaceutical Physicians). In addition, Trinity was one of the partners in PharmaTrain (the EU funded Innovative Medicines Initiative) and the course content is compliant with the PharmaTrain syllabus.

**Aim**

The aim of the course is to provide suitably qualified healthcare professionals with specialist knowledge and skills in all aspects of pharmaceutical medicine to enable them extend their professional role within the pharmaceutical industry and healthcare system.

**Intended Participants**

Prospective students for the postgraduate diploma and MSc must hold a primary honours degree in either medicine or another relevant health or science subject. Candidates should have a minimum of 2 years’ practical experience in their area of qualification / pharmaceutical industry.

Candidates from within and outside the EU will be eligible for enrolment onto each course, providing their primary degree is from a recognised institution.
Course Structure

Postgraduate Diploma Programme

The course is a taught programme, run over 18 months for a total of 12 modules. Each module is typically for 3 days and consists of a combination of formal teaching sessions, workshops and interactive / practical sessions. Pre-module reading lists will be provided and will form part of the module teaching. Two of the modules will be undertaken by way of blended learning. Course materials will be circulated electronically and in paper format for the distance learning modules. In addition all registered students will have access to an interactive web-based learning facility. Students will be expected to interact with other class members and course co-ordinator via the e-learning platform.

Completion of each module is obligatory. Students are recommended to attend all of the taught modules, but must attend at least 10 of the 12 face-to-face modules.

Assessment will consist of personal assignments (continuous assessment) and written examinations. Continuous assessment assignments must be completed by the students for each module and submitted at designated time points. Students will be expected to submit assignments for all modules.

MSc. Programme

Students will complete the postgraduate diploma course modules, as outlined above. In addition, students will be assigned a research project (in primary research), which should be submitted as a dissertation (with the possibility of an oral examination) by the 31\textsuperscript{st} August of the second year, unless an extension is granted by the Faculty.
Course Content and Timetable

Year 1

Module 1: PM7011 - Introductory Programme: Principles of Discovery of Medicines and Development Planning (Sept 2018)

Module Overview:
The module introduces the aims and objectives of the course. It discusses the principles of pharmaceutical medicine. It describes the philosophy behind new drug development and how this impacts on the activity of a pharmaceutical company. It describes the various factors which have an impact on the life-cycle of a drug.

Module 2: PM7013 - Exploratory and Confirmatory Clinical Development (Term 1)*

Module Overview:
The aim of this module is to provide a comprehensive overview of the main types of studies used in clinical research and the legal, methodological and ethical issues involved in the undertaking of biomedical research (including Good Clinical Practice). It will detail the principles and practical application of statistics in clinical trials and the role and responsibilities of the statistician as part of the R & D team. It will outline the early studies in patients and describe the strategy behind drug development within the pharmaceutical industry and in particular the basis for assessing continuing viability of development projects.

Module 3: PM7014 - Clinical Trials (Term 1)*

Module Overview:
This module provides comprehensive information on the clinical development of new medicines. It describes the choice of clinical trial design and target populations, according to the proposed indication for use. It examines in detail the key issues involved in the conduct of a clinical trial and describes their statistical analysis and reporting. It describes the handling the safety data in clinical trials and how it impacts on drug development. It highlights the importance of evaluation in at-risk populations and explores the concept of benefit / risk assessment in clinical development. The aim of this module is to ensure comprehensive knowledge in the area of clinical development and how the clinical development programme interacts with the overall R & D programme.

* - these modules are run in parallel

March 2018
Module 4: PM7012 - Non-Clinical Testing, Pharmaceutical and Early Clinical Development (Term 2)

Module Overview:
The objective of this module is to develop a higher understanding of the types of pharmaceutical and non-clinical testing carried out on new drug substances and how these fit into the overall development programme. It discusses the principles of early pharmaceutical development of drug substance and how the choice of formulation is made with reference to the proposed indication for use. It provides background information on how potential candidates are tested for bioequivalence, stability, impurity and incompatibility in order to produce the final product specification. It describes in detail the different stages of non-clinical (pharmaco-toxicology testing) and how these findings are used to plan early exploratory development in man, as part of the overall R & D plan.

Module 5: PM7022 - Project Management in Medicines Development (Term 2)

Module Overview:
This module provides the student with the opportunity to develop competence in the logistical aspects of R & D (project management). It details how to define, plan, manage and verify the scope of the development of a medicine. It promotes in-depth knowledge of how to identify factors in failing clinical trials and discusses the concept of project rescue.

Module 6: PM7019 - Special Populations: Clinical Trial Practice and Regulation timing (Term 2)

Module Overview:
This module provides in-depth knowledge into the impact of the specific target population on the undertaking of clinical research. It details the importance of taking physiological profile, disease characteristics into account and provides practical examples of how to conduct clinical research in vulnerable populations. The aim of the module is to enable the student develop competence in the area of clinical research, appropriate to the target patient profile, particularly in vulnerable populations.
Year 2

Module 7: PM7020 - Medicines Regulation (Term 1)**

Module Overview:
This module, run in parallel with module 8, provides comprehensive information on the role of drug regulation before and during the authorisation of medicines. It details the current national and international regulatory requirements for the authorisation of medicines. It looks at the guidelines which are published to aid new drug development by the various regulatory agencies, and evaluates the importance of practical input from expert international organisations. The aim of the two modules is to enable the student gain competence in the handling of all regulatory lifecycle issues of a medicine both pre- peri- and post-authorisation in the various jurisdictions.

Module 8: PM7015 - Regulatory Affairs; Drug Safety & Pharmacovigilance (Term 1)**

Module Overview:
This module, run in parallel with module 7, provides comprehensive information on the role of drug regulation with a particular emphasis on the regulation of drug safety during and after the authorisation phase of drug development. It details the current national and international requirements for the regulatory aspects of the authorisation of medicines. It details the regulation and management of drug safety issues, both pre-and post-approval. The aim of the two modules is to enable the student gain competence in the handling of all regulatory lifecycle issues of a medicine both pre- peri- and post-authorisation in the various jurisdictions

**These modules will be undertaken by way of blended learning in parallel

Module 9: PM7017 - Drug Safety: Pharmacoepidemiology, Pharmacovigilance and Risk Management (Term 1) §

Module Overview:
This module provides comprehensive information on pharmacovigilance and the existing regulatory requirements for the pharmaceutical industry and regulatory authorities at EU and international level. It explains the principles of pharmacoepidemiology and how these are used to evaluate drug safety in practice. It discusses drug interactions and how they can be avoided; medication errors and their prevention +/- management and provides information on research methodology in pharmacovigilance. The aim of this module is to promote a higher understanding of the benefit/risk evaluation of drugs and the importance of safety monitoring throughout the lifecycle of a medicine.

March 2018
Module 10: PM7018 - Biologicals and Advanced Therapies (Term 1) §

Module Overview:
This module provides comprehensive information on medicines derived from biological sources, including those defined as advanced therapies. It details the legal, ethical, regulatory and practical issues relating to the development of such medicines and provides practical application of the regulatory provisions. The aim is to enable the student to be able to work as part of a team in the lifecycle management of a biological agent or advanced therapy.

§ - these modules may be run in parallel

Module 11: PM7021 - Health Economics / Pharmacoeconomics (Term 2) #

Module Overview:
The aim of this module is to provide a higher understanding of the importance of health economics in contemporary healthcare management. It will give a comprehensive overview of the principles of health economics, economic modelling, QALY’s and sensitivity analysis. It will provide practical examples of how economic principles are used to measure the cost-effectiveness of medicines and how this impacts on the pharmaceutical industry.

Module 12: PM7016 - Healthcare Marketplace; Economics of Healthcare (Term 2) #

Module content:
This module focuses on the lifecycle management of medicines. It describes the legal and ethical principles governing communication between the pharmaceutical industry and healthcare professionals and. It examines the provision of product information within the healthcare marketplace by a pharmaceutical company and the role of educational versus promotional activities relating to the use of medicines. It discusses the developing role of health technology assessment within the pharmaceutical arena. The aim of the module is to enable the student to be competent in the management of all aspects of the lifecycle management of a medicine.

# - these modules are run in parallel
Course Venue

The course will be held in the Trinity Centre for Health Sciences Building in St. James’s Hospital, Dublin 8. Enrolled students will be notified of the exact venue in advance of each module.

Course Materials

Comprehensive course materials will available on Blackboard for each module. In addition, students will be provided with pre-module reading before each of the taught modules. The students will be expected to review all material provided and to study the reading lists contained in the course materials. Personal assignments for each module must be completed by each student and returned within the designated time frame. Late assignments will be subject to penalties.

Students will be expected to provide their own computer and online access for the modules undertaken by distance learning.

Total Fees for 2018/2019*

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<tr>
<th></th>
<th>EU</th>
<th>Non-EU</th>
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<tr>
<td>Diploma fee</td>
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<tr>
<td>Year 1</td>
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*Fees shown include tuition fees, sports levy, USI levy and commencement fees
Course Faculty

Head of the Department

Prof Michael Barry is a physician in St James’s Hospital and senior lecturer and head of the Dept of Pharmacology and Therapeutics, Trinity College Dublin. He is also Director of the National Centre for Pharmacoeconomics (NCPE), which was established in Ireland in 1998. The aims of the NCPE are to promote expertise in Ireland for the advancement of the discipline of pharmacoeconomics through practice, research and education. Dr Barry’s research interests include investigation of anti-HIV drugs, pharmacoeconomic evaluation and development of cost-effective prescribing.

Course Director

Mary Teeling has overall responsibility for the postgraduate courses. She is a lecturer in Continuing Professional Development and Education in the School of Medicine, Trinity College and is also medical advisor to the National Medicines Information Centre. She has extensive experience in the area of pharmaceutical medicine and is a registered specialist pharmaceutical physician in Ireland. As former medical director of the Irish Medicines Board she served as the Irish delegate to the CPMP pharmacovigilance working party for 10 years. She was a member of the CPMP for 7 years and was its vice-chairman from 1998-2000. She is a former steering committee member of the International Conference on Harmonisation (ICH) and was actively involved in the CPMP Scientific Advice Group (Chairman 1999-2000) and Committee on Orphan Medicinal Products. She is Trinity College’s representative on the EU-funded IMI PharmaTrain initiative, which is currently working to harmonise postgraduate training in Pharmaceutical Medicine and Drug Development Sciences across Europe.

Course Co-ordinators

MaryJo MacAvin is responsible for the day-to-day running of the courses. She is also medical advisor to the National Medicines Information Centre. She trained in general practice in Scotland and worked as a general practitioner for five years. She subsequently worked for five years in child health in Scotland. On her return to Ireland, she spent 2 years working as a drug safety physician in Quintiles, the multinational contract research organization (CRO). She holds a MSc in Medical Education and recently completed a postgraduate diploma in statistics.

Mary Rafter is also responsible for day-to-day running of the courses. With a background as a pharmacist, she has spent a considerable portion of her career as a pharmaceutical assessor at the Health Products Regulatory Authority (HPRA, formerly Irish Medicines Board), and represented the board on various CPMP/CHMP/EMA committees as a pharmaceutical expert. This was interspersed with periods spent in the pharmaceutical industry, including as senior manager of a global regulatory affairs team at Pfizer Newbridge. She has worked as a consultant in the regulatory affairs arena and contributed to academic education programmes since obtaining her MSc in Pharmaceutical Medicine from Trinity College in 2010.
Course Executive Officer

Geraldine Crowther assists with the administration of the course. [E-mail : crowtheg@tcd.ie]

Faculty

In addition to the faculty members from the academic staff of the Dept of Pharmacology & Therapeutics, Trinity College, the course will include contributions from experts from the National Centres for Pharmacoeconomics and Medicines Information, the Health Product Regulatory Authority and external experts from the pharmaceutical industry. Modules will also include lectures from internationally known experts.

For Further Information

Contact the Course Co-ordinators (Mary-Jo MacAvin or Mary Rafter) at:

macavinm@tcd.ie or rafterm1@tcd.ie  
Phone: 00 353 1 4103731/8961568  
Fax: 00 353 1 4730596

or

http://www.medicine.tcd.ie/pharmacology_therapeutics/postgraduate/

Applications for this course should be made online via:

https://www.tcd.ie/study/apply/index.php

March 2018