



FACULTY OF PHARMACEUTICAL MEDICINE

OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM

Overview of the Diploma in Human Pharmacology

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1. Summary

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM) has established a 2-year training programme and qualification called the 'Diploma in Human Pharmacology' (DHP). The DHP is intended for medical doctors training to take on the responsibilities of a principal investigator (PI) for human pharmacology studies of investigational medicinal products (IMPs). This document outlines the objectives and content of the DHP.

2. Objectives

The overall purpose of the DHP programme is to enable trainees to attain and demonstrate competence to serve as a PI for human pharmacology studies of IMPs, in particular those involving the first administration to humans. Such studies include those conducted in healthy and patient volunteers, in which the primary end-points are tolerability, pharmacokinetics and evidence of drug effects on biomarkers of efficacy and safety. The training in practical aspects of working as a PI is underpinned by a knowledge of the scientific basis of drug action.

The FPM has no authority to make the DHP a prerequisite for serving as a PI and the qualification cannot be considered as formal evidence of 'fitness to practise'. However, the Diploma is now recognised by the Medicines and Healthcare products Regulatory Agency (MHRA) as the most appropriate qualification for accreditation of PIs in the pharmaceutical industry. Furthermore, it is hoped that high calibre doctors working in experimental medicine, translational medicine and clinical pharmacology in academia will wish to study for the DHP as it will provide them with particular skills and competencies of direct relevance to the conduct of their research in humans.

3. Curriculum

The curriculum comprises the following:

1. a minimum period of two years' supervised structured training in the workplace with evidence of attainment of defined Learning Objectives provided by a portfolio and quality assured assessments;
2. acquisition and maintenance of up-to-date clinical skills including satisfactory completion of an Advanced Life Support or equivalent course;
3. attendance at two five-day DHP training courses with pre-course reading and completion of post-course assignments involving private study and any other courses deemed necessary depending on the individual trainee's needs;
4. attendance at a one day (or two half-day) DHP training course on prevention and management of adverse reactions in Phase I studies;
5. a written examination at the end of the period of training.

Diplomates will be required to have completed all elements of the curriculum to a satisfactory standard.

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3.1. Supervised training in the workplace

Supervision of trainees will be performed by clinical pharmacologists with extensive experience of Phase I studies. These Educational Supervisors will be trained and accredited by the FPM, having fulfilled defined eligibility criteria. Assessments of trainee competence will be performed by the Supervisor and verified by a Senior Specialty Adviser (SSA) or the DHP Director of the FPM acting in the role of an external examiner / moderator.

The trainee is required to maintain a training record, with documented evidence of attainment of specified curriculum learning objectives, defined in terms of knowledge, skills, attitudes and behaviours.

The trainee is also required to produce a portfolio of work completed in the workplace over a minimum of two years. This portfolio should be reviewed and validated by the Educational Supervisor at least three times each year and by the SSA from the FPM at least once annually. At the end of the training period, the portfolio may also be reviewed by the DHP Advisory Subcommittee.

Details of the portfolio and associated documentation will be provided at a site visit at the time of enrolment.

3.2. Clinical skills

It is considered essential that trainees acquire and maintain a high level of clinical skills to manage resuscitation and other medical emergencies including treatment of arrhythmias, anaphylaxis and other allergic reactions. Diplomates will be required to have a recent certificate of satisfactory completion of training in Advanced Life Support or equivalent.

In addition to management of emergencies, it is considered important that investigators should be able to exercise sound clinical judgement. Therefore, trainees will be encouraged to have attachments / periods of secondment to a hospital in which they will be involved in acute medicine e.g. coronary care.

3.3. Courses and private study

Trainees will be required to complete three DHP courses as follows:

1. Advanced Course in Exploratory Development and Phase I Studies - 40 contact hours (five days) + assignments;
2. Principles of Pharmacology – 40 contact hours (five days) + assignments;
3. Prevention and Management of adverse reactions in Phase I Studies – 8 contact hours (1 day)

Residential courses 1 and 2 involve:

- preparatory reading using recommended texts, guidelines, directives and other documents from regulatory and scientific sources;
- active participation in case studies and workshops as well as tutorial-style lectures;
- completion of assignments as private study and submission for assessment within a specified time.

Trainees will also be required to show initiative by conducting their own searches of appropriate literature. Assignments will be assessed and must be of a satisfactory standard, which will be moderated by the FPM.

The content, material and delivery of the courses are quality assured by the FPM.

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The individual needs of trainees will be assessed at the time of registration and during their training. It is possible that trainees will be required to attend additional courses on specific aspects of the syllabus e.g. statistics or complete additional assignments.

3.4. Examination

The Diploma examination, which is run at the Royal College of Physicians, London*, is prepared and conducted by a subcommittee of the FPM Board of Examiners. It comprises four written papers. Papers on Day 1 are intended to test factual knowledge and ability to interpret data and apply knowledge to practical problems relating to any part of the syllabus. Papers on Day 2 are intended to test knowledge relating to clinical safety / medical care of subjects participating in Phase I/II studies including the ability to interpret safety data and manage adverse reactions. The papers are as follows:

Day 1

1. Multiple Choice Question paper in 'True/False' format. Each stem question has five completions. Candidates are required to indicate which are true and which false; any number may be true or false.
2. Short Answer Question paper in which candidates are required to write answers in the form of brief notes / bullet points. The questions may describe scenarios or contain data or text for interpretation.

Day 2

3. Multiple Choice Question paper in 'Best of Five' format. Each stem question has five completions. Candidates are required to select the single best completion.
4. A Short Answer Question paper in which candidates are required to write answers in the form of brief notes / bullet points or prose as specified in the questions, which may describe scenarios or contain data or text for interpretation.

Diplomates are required to pass all four parts of the examination. Please refer to FPM Examination Regulations and Appeal Procedures for further details.

*The FPM reserves the right to change the venue in the event of unforeseen circumstances.

4. Eligibility

4.1. Clinical Experience

Candidates eligible to enter the DHP programme must be fully registered as a medical practitioner in their country of employment and have attained Level 1 competencies or equivalent in clinical training. This will generally require considerable experience in acute care of patients. The FPM considers that adequate clinical experience involving acute care of patients is essential for principal investigators. However, it is recognised that occasionally, doctors wishing to study for the Diploma, including some who may already have been working in Phase I / human pharmacology for some time, may not have completed the required period of clinical training.

UK doctors who qualified before 2005 will normally require a minimum of three years' clinical training post-qualification. In exceptional circumstances, and at the discretion of an eligibility panel, those with less than three years clinical training post-qualification may be admitted to the programme.

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UK doctors who qualified after 2005 (under the Modernising Medical Careers programme) will require a minimum of four years' clinical training post-qualification. Doctors who have between three and four years clinical training post-qualification may, at the discretion of an eligibility panel, be admitted to the programme on the condition that they undertake a clinical attachment during the programme, the details of which will be specified by the panel. Applicants with less than three years' clinical training post qualification will not be admitted to the programme.

Doctors who have graduated and worked outside the UK will be required to demonstrate equivalent qualifications and experience.

4.2. Experience in Human Pharmacology

Ideally applicants will have gained some experience of conducting human pharmacology studies and will have a basic knowledge of the subject before enrolling in the programme but this is not a requirement for eligibility.

Candidates should normally be working within an organisation and at a site capable of providing supervision of human pharmacology workplace training in which all learning objectives can be met. In exceptional cases, it may be acceptable for trainees to be seconded to another site for part of their training if this is not available in the normal workplace. A formal assessment of the site will be made at a visit by the DHP Director from the FPM.

Doctors who have worked for some years in a suitable training environment and have already gained hands-on experience in the conduct of human pharmacology studies in an academic or commercial organisation may wish to gain retrospective recognition of time previously worked under supervision as an investigator. Trainees wishing to gain such retrospective recognition will be required to present a portfolio of work undertaken in the period being considered. The portfolio must provide evidence of appropriate experience and will be assessed by the FPM DHP Advisory Panel (see section on Portfolio above). The maximum permitted period of retrospective recognition of workplace training will be twelve (12) months, leaving a minimum of a further twelve (12) months of prospective workplace training for the Diploma.

5. Equal Opportunities

The Faculty of Pharmaceutical Medicine is committed to promoting equal opportunity and eliminating discrimination in all areas of its activity. Equal opportunities monitoring will be undertaken and information obtained may be analysed to assess compliance with the policy. Information will be held confidentially and used for monitoring purposes only. Any reports will be anonymised to ensure that individuals cannot be identified.

6. Fees

The fee for trainees enrolling on the DHP programme is currently £6,800, which covers administration of the programme, teaching and materials associated with the DHP courses and the examination. The fee does not include travel or accommodation expenses or the Diploma document if successful. If you wish to enrol for Pharmaceutical Medicine Specialty Training (PMST) at the same time as the DHP then you may be eligible for a reduction in fees.

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7. Summary of Enrolment Process

Prospective trainees may initiate the enrolment process by contacting the FPM office. The process of enrolling on the programme and actions required are summarised below.

STAGE 1 – Pre-enrolment

If you have contacted the FPM office expressing an interest in enrolling on the DHP training programme you will be sent the web link to the following documents:

- i. this summary of the enrolment process;
- ii. an Overview of the DHP;
- iii. a summary of the fees for entry to the 2-year programme;
- iv. a Curriculum Vitae template.

Action

- 1A Complete CV template and email to fpm@fpm.org.uk or post to the FPM office

STAGE 2 – Application to enrol, site assessment and provisional appointment of Educational Supervisor (ES)

Your CV will be reviewed and if it indicates that you should be eligible for the DHP, you will be sent the following documents:

- i. this summary of the enrolment process;
- ii. a DHP Programme Guide with information about the syllabus, curriculum and content of courses;
- iii. details of fees;
- iv. dates and other details of courses and examinations;
- v. Terms and Conditions;
- vi. Enrolment Application form;
- vii. a document for your prospective Educational Supervisor (ES) explaining the role and responsibilities of an ES;
- viii. ES application form;
- ix. Site Assessment form;
- x. Ethnicity Monitoring form.

Action

- 2A Complete the Enrolment Application form;
- 2B Arrange for the Site Assessment form to be completed by Medical Director, prospective ES or other senior medically qualified person;
- 2C Arrange for your prospective ES to complete the ES application form;

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- 2D Complete the Ethnicity monitoring form (optional);
- 2E Send the completed forms to the FPM with payment of first fee instalment;
- 2F Arrange a meeting on site for you, the FPM representative, and your prospective Educational Supervisor.
- NB: A senior manager should also be available for part of the time.
The purpose of the on-site meeting is:
- to enable the FPM representative to assess suitability of the site for training;
 - to discuss any arrangements required if the site is unable to deliver all aspects of the training;
 - to enable the FPM representative to meet the ES;
 - to discuss any other issues relating to your application;
 - to confirm commitment of the organisation.

STAGE 3 – Review by FPM and enrolment

Your application and related documents and the report of the FPM representative will be reviewed by the FPM DHP Advisory Panel. Any unresolved issues e.g. relating to your eligibility or suitability of your place of work for training, will be discussed and the FPM representative will then be in touch with you. Once any outstanding issues have been resolved satisfactorily your payment will be processed.

When the fee has been paid, you will receive:

- i. a letter from the FPM confirming your enrolment onto the DHP programme, including any particular conditions that apply and stating the date of entry from which the period of workplace training will be recognised;
- ii. A Training Record (on disk).