



FACULTY OF PHARMACEUTICAL MEDICINE

OF THE ROYAL COLLEGES OF PHYSICIANS OF THE UNITED KINGDOM

Overview of the Certificate in Human Pharmacology

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Overview FPM Certificate in Human Pharmacology

1. SUMMARY

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the UK (FPM) has established the 'Certificate in Human Pharmacology' (CHP). The CHP is a part-time programme of courses and an examination intended for physicians and scientists in the pharmaceutical industry, universities and regulatory authorities, who have an interest in early clinical drug development. It is expected that trainees will take approximately 12 months to complete the CHP. This document outlines the objectives and content of the Certificate programme.

NB: The CHP is not an adequate qualification for physicians intending to serve as principal investigators; the Diploma in Human Pharmacology is the appropriate programme for such individuals.

2. OBJECTIVES

The purpose of the CHP programme is to enable students:

- to attain a comprehensive knowledge of Phase I studies, with particular emphasis on the design, conduct and analysis of 'First-in-Human' and other early exploratory studies of investigational medicinal products (IMPs) 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;
- to gain up-to-date knowledge of the scientific basis of drug action.

3. CURRICULUM

The Certificate curriculum comprises:

- two five-day CHP training courses with pre-course reading and completion of post-course assignments involving private study;
- an examination comprising two written papers.

3.1. Courses and private study

There are two CHP courses:

1. Advanced Course in Exploratory Development and Phase I Studies - 40 contact hours (five days);
2. Principles of Pharmacology – 40 contact hours (five days).

These courses 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 are expected to supplement their learning on the formal courses with private study, 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. It should be noted that the courses will be at an advanced level and are not appropriate for persons without a basic knowledge of Phase I or pharmacology.

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

3.2. Examinations

The Certificate examination, which is run on one day annually at the Royal College of Physicians, London*, is prepared and conducted by a subcommittee of the FPM Board of Examiners. It comprises two written papers, intended to test factual knowledge and ability to interpret data and apply knowledge to practical problems relating to any part of the syllabus. The papers are as follows:

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 short notes / bullet points in response to the questions, which may describe problem scenarios or contain data or text for interpretation.

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

4. ELIGIBILITY

Candidates eligible to enter the CHP programme are required to have a degree e.g. BSc in a relevant biological science, a BPharm or a medical degree. Applicants who do not have a basic knowledge of Phase I studies may be recommended to attend a basic course in Clinical Pharmacology prior to registering for the CHP.

5. APPLICATIONS

If you are interested in applying for the CHP, please request an application pack from the Faculty Office (fpm@fpm.org.uk).

6. FEES

The fee for the CHP programme is currently £4,100, which covers administration of the programme, teaching and materials associated with the CHP courses and the examination. The fee does not include travel or accommodation expenses or the Certificate document if successful.