



CERTIFICATE OF GOOD CLINICAL PRACTICE

EXAMINATION REGULATIONS AND PROCEDURES

1. The Certificate of Good Clinical Practice is awarded by the Faculty on the recommendation of the Board of Examiners.
2. A Certificate examination is conducted at least once each calendar year by the Board of Examiners at a fixed time and place announced by the Faculty.
3. The Certificate candidate is required to sit a written exam, in which they are required to attain a pass in order to be recommended for award of the Certificate.

CERTIFICATE REGISTRATION

4. The Faculty will provide a Certificate Examination pack containing all necessary forms with the *Syllabus* and *Examination Regulations and Procedures* on request.
5. Candidates must complete the application form and submit it with a recent photograph for identity, along with payment, to the Faculty office by the announced closing date.
6. When attending the examination, candidates are required to provide photographic identity (passport, driving licence or ID from place of work) at registration.

ELIGIBILITY OF CANDIDATES

7. There are no specific eligibility criteria to register for the Certificate examination. It is open to all personnel involved in the conduct of clinical trials including research nurses, clinical research scientists and technicians as well as physicians.

SYLLABUS

8. The *Syllabus* for the Certificate Examination is presented in detail in Part 1 of this document.
9. From time to time, changes are introduced in GCP guidelines. Candidates should have up-to-date knowledge; recent changes may form the subject of

examination questions.

THE EXAMINATION

10. The place and time of the examination are available from the Faculty about 10 months before the examination and are advertised about 3 months before the closing date for registration.
11. The examination comprises a single *Multiple Choice Question* paper in 'True/False' format comprising 50 questions (stems) each with 5 completions (a total of 250 statements). The candidate is required to identify which statements are 'true' and which are 'false'. Any number may be true or false. Questions may be in the form of a simple statement or a problem or case scenario. The language of the question paper will be English. A total of 1 hour 30 minutes (90 minutes) is allowed for this paper.
12. The selection of questions for the examination paper is made by the GCP Examination Group of the Faculty's Board of Examiners. The GCP Examination Group ensures that the examination as a whole covers the syllabus appropriately. A candidate should expect questions during the examination on any section of the syllabus.
13. Candidates will not be allowed to leave the room within the first 15 minutes and candidates arriving late will not be admitted after this time. Any candidate wishing to leave and return to the examination room will be accompanied. Candidates are not permitted to leave during the last 10 minutes.
14. Mobile phones, calculators and other electronic devices may not be used during the examination and, if brought into the examination room, must be switched off and placed to the side of the room out of sight of all candidates.
15. Candidates are not allowed to copy questions or remove any items/papers relating to the examination from the examination room.

ASSESSMENT

16. The multiple-choice questions are marked by computer. Each correct response earns one mark; no response or an incorrect response receives zero marks.
17. The pass mark is set using a criterion-referenced procedure in which the pass mark is decided in advance by a panel. The panel will take into account the difficulty of each question and the standard expected of candidates. The pass mark is agreed by the Chair of the Board of Examiners prior to the date on which the examination is held. There is no limit to the number of candidates who can pass.
18. Candidates who have achieved the pass mark will pass the examination. Grades or Distinctions will not be awarded.

ADJUDICATION

19. As soon as possible after receipt of the marks, the GCP Examination Group and the Chair of the Board of Examiners meet to review the marks to ensure their integrity. No adjustment to marks or the pass mark will normally be made but if any such actions are taken, the reasons will be fully documented.

20. Candidates are identified by their candidate numbers only throughout the examination until after the adjudication.

COMMUNICATION OF RESULTS

21. The Faculty will advise all candidates of the outcome in writing.
22. A certificate will be provided as appropriate.
23. The Chair cannot enter into detailed discussion with a candidate but will try to be as constructive as possible in any correspondence.
24. An unsuccessful candidate may re-sit the Certificate Examination. A candidate that wishes to do so must re-apply and pay the appropriate examination fee.

FEES

25. The Faculty will maintain a schedule of fees, which will be included in the Certificate Examination pack with the conditions that apply clearly stated.

CONDUCT

26. The Faculty may refuse to register a person as a Certificate candidate and may withdraw such registration at any time if the candidate's behaviour is prejudicial before or during the examination by not complying with examination regulations or instructions.
27. The Faculty will investigate any suspected dishonesty or misconduct by a candidate in relation to the Certificate examination and, if appropriate, revoke the Certificate.
28. Any candidate who wishes account to be taken of exceptional circumstances or conditions present BEFORE the start of the examination that may affect his or her performance must refer to the Policy for Candidates with Special Requirements, details of which are available on the Faculty website or from the Faculty office. Such circumstances must be notified to the Chair of the Board of Examiners or the Education Administrator BEFORE SITTING the examination; such information passed to the Faculty after sitting the examination cannot be taken into account. This information will be kept confidential.
29. Any candidate who wishes account to be taken of exceptional conditions or circumstances arising AFTER THE START of the examination must make the invigilator / examiners aware of such circumstances AT THE TIME of the examination AND make representation in writing as described in the Appeals Procedure.
30. The Appeals Procedure should also be followed for any representations by candidates on the conduct of the Examination. Details are available on the Faculty website or from the Faculty office.

The Faculty of Pharmaceutical Medicine is committed to promoting equal opportunity and eliminating discrimination in all areas of its activity.