



CERTIFICATION CRITERIA FOR THE

**PHARMACEUTICAL QUALITY MANAGEMENT
SYSTEMS (PQMS) FOUNDATION
TRAINING COURSE**

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INTRODUCTION

- 1.1 We, the International Register of Certificated Auditors (IRCA), have prepared these criteria to help you, the approved training organization, to achieve certification of a **Pharmaceutical Quality Management Systems (PQMS) Foundation** training course.
- 1.2 Before designing a PQMS Foundation training course to meet the requirements of this document you should consider the following:
- 1.2.1 **Aim of this course.** This course provides students (who have prior knowledge of or experience in pharmaceutical quality management – see 1.2.3) with an understanding of the management systems approach and the requirements of ICH Q10, and to provide a basis for students who wish to go on to complete other IRCA certified PQMS auditor training courses.
- 1.2.2 **Auditor certification.** Students who successfully complete this PQMS Foundation course will satisfy the part of the training requirement for initial certification as an IRCA Internal Auditor: to meet the full training requirement students must also successfully complete an IRCA PQMS Internal Auditor training course.
- 1.2.3 **Prior knowledge.** Before starting this course, you must inform students that they are advised to have the following prior knowledge before attending this course:
- Management systems**
- Plan-Do-Check-Act framework
 - The core elements of a management system and the interrelationship between management responsibility, policy, planning, implementation, measurement, review and continual improvement
- Pharmaceutical management**
- A basic knowledge of the requirements of the relevant GxP legislation and guidance for the discipline in which they operate e.g. Eudralex Volume 4 or 21 CFR (pertaining to cGMPs).
- 1.2.4 **Flexibility in course design.** These criteria specify the requirements for training courses including the knowledge and skills to be covered during the course. Your training course must be designed and delivered in accordance with these criteria, although you may exercise flexibility in the inclusion of additional material, and in the structure and selection of specific training methods used during the course. Many of the certification requirements common to the management and control of courses are detailed in IRCA/2000, *Requirements for Training Organization approval*. These requirements are in addition to the requirements of this document and are mandatory. It is essential, therefore, that you are familiar with the requirements of IRCA/2000.
- 1.2.5 **Training methods.** This course may be designed to be presented in a variety of ways:
- a) Classroom-based
 - b) Classroom-based as a series of part-time modules over a longer period.
 - c) Blended as a combination of self-study (i.e. e-learning course, correspondence course etc) and classroom-based learning.
 - d) Self study
- However it is designed, students must complete the whole course of study with your organization.

2. LEARNING OBJECTIVES

- 2.1 Learning objectives describe in outline what successful students will know and be able to do by the end of the course:
- 2.1.1 Explain the purpose and benefits of a pharmaceutical quality management system (see 3.1).
 - 2.1.2 Explain the specific pharmaceutical quality management related requirements of ICH Q10 (see 3.2).

3. ENABLING OBJECTIVES

In order for students to achieve the overall learning objectives, they will need to acquire and develop specific knowledge. These are specified below as “enabling objectives” and can be considered as steps to the achievement of learning objectives above.

- 3.1 **Explain the purpose and benefits of a pharmaceutical quality management system**
- 3.1.1 Explain the purpose and benefits of a pharmaceutical quality management system throughout the product lifecycle.
 - 3.1.2 Explain the purpose of ICH Q10 and its interrelationship with other ICH guidelines, with ISO 9001 and with relevant GxPs.
 - 3.1.3 Explain interrelationship between Management Responsibility; Continual Improvement of Process and Product; and Continual Improvement of the PQMS;
 - 3.1.4 Summarise relevant pharmaceutical legislation and sources of legislation.
 - 3.1.5 Explain the terminology defined in ICH Q10.
 - 3.1.6 Explain the difference between legal compliance and conformance with the guideline.
- 3.2 **Explain the specific pharmaceutical management related requirements of ICH Q10.**
- Management**
- 3.2.1 Describe **management responsibility** in ensuring an effective pharmaceutical quality management system.
 - 3.2.2 Describe what a **quality policy** should contain and how it should be maintained.
 - 3.2.3 Describe the role of **quality planning** in developing appropriate quality objectives and measures of performance.
 - 3.2.4 Describe the requirement for effective **resource allocation, communication and escalation** of product and system issues.
 - 3.2.5 Describe why the pharmaceutical quality system should extend to the control and review of any **outsourced activities, quality of purchased materials, and change in product ownership**.
 - 3.2.6 Describe management’s responsibility for periodic **review**.
- Continual Improvement – process and product quality**
- 3.2.7 Describe the **lifecycle stage goals**.
 - 3.2.8 Describe the four **PQMS elements** and give examples of application throughout the product lifecycle.
 - Process performance and product quality monitoring system;
 - Corrective action and preventive action (CAPA) system;
 - Change management system;
 - Management review of process performance and product quality.
- Continual Improvement - the PQMS**
- 3.2.9 Describe the **purpose of and inputs** to PQMS management review

- 3.2.10 Describe the **internal and external factors** that should be monitored and the potential impact on the PQMS.
- 3.2.11 Describe the typical **outcomes** of management review in terms of change and improvement.

4. TRAINING METHODS

- 4.1 Your course may be presented as a wholly classroom-based course; as a blended course (in other words part self-study and part classroom-based); as a series of separate modules, either as full-time or part-time study; or as self-study.
- 4.2 **Classroom-based training**
- 4.2.1 You must provide for students **an environment conducive to effective learning**. At the beginning of the course you must provide the students with a description of the learning objectives, course structure, format and programme, student responsibilities and the assessment processes and assessment criteria, and you must deal with any concerns or worries that students may have.
- 4.2.2 Your course must be based on the **learning cycle** (see guidance in Appendix 1) and include opportunities for students to:
- i. Experience new ideas and skills. (Note that tutor-led slide presentations as a sole method to help students learn new knowledge is not acceptable).
 - ii. Reflect on their learning and identify strengths and weaknesses. (Note that your course must include methods for monitoring and providing time for tutors and students to review tasks and activities and each student's achievement of the learning objectives).
 - iii. Address and improve on areas of weakness. (Note that your course must include provision for review and remedial work, and individual coaching, where necessary.)
- 4.2.3 Your course must include a **variety of learning methods** to suit the range of learning styles (see guidance in Appendix 1).
- 4.2.4 Your course must not rely on tutor presentations and tutor-led discussions to achieve **knowledge-based learning objectives**. We expect to see students learning these elements mostly through a process that requires them to complete a task or activities, often in teams, and to produce a defined output.
- 4.2.5 Timekeeping, planning and programme management are essential elements in the performance of an audit and, although we recognise that effective training is responsive to students' needs, deviations from the timetable must be managed so that all learning objectives are adequately covered and students are kept informed of significant changes to the programme.
- 4.2.6 You must submit **session plans** or tutor notes for each individual training session. Session plans must specify:
- learning objectives and duration for the session
 - nature of the activity and training method to be used
 - organizational arrangements, tutor and student briefing details
 - deliverables required from students for practical sessions
 - materials, exercises and equipment required to run the session
 - where training methods or use of exercises etc. are optional, this must be clearly indicated in session plans.

4.3 **Self-study courses**

- 4.3.1 Training methods selected should seek to involve and engage students throughout the duration of the course. Simply providing students with a set of reading materials will not be acceptable. Your self-study materials must be designed around a clearly structured learning process with:
- Theory.
 - Examples (scenarios, case studies etc).
 - Practice (activities, case studies, progress tests etc).
 - Feedback/self-assessment on activities and tests where relevant, to ensure students can self-assess their understanding and achievement of the learning objectives and identify any areas requiring further work.
- 4.3.2 Self-study course materials must be clearly presented and structured for ease of use, with appropriate navigational aids. You must make the following clear to students to help them manage their learning:
- The learning objectives for the overall self-study element of the course.
 - The learning objectives for each section within the course.
 - How the self-study element of the course links with the classroom component.
 - The structure and suggested or intended sequence of the materials.
 - Instructions for the students' use of the materials, including realistic timescales.
 - Examples of typical documents, reports, forms etc.
 - How, when and how often students may contact tutors for help, guidance and feedback.
 - Methods for students to assess their learning and to seek timely feedback and coaching from the tutor(s).
- 4.3.3 You must ensure that each student has timely access to a course tutor to answer questions and queries.

Note: as a guide, a response to communications from students within 24 hours would be acceptable.

5. COURSE CONTENT

- 5.1 At the beginning of the course presentation you must provide the students with a description of the learning objectives, course format and programme, student responsibilities and student evaluation processes and criteria.
- 5.2 You must ensure students secure a copy of ICH Q10 or you must provide them with a copy for self-study (if relevant) and for classroom-based elements of the course.
- 5.3 The course must cover all aspects defined in clause 2 learning objectives and amplified in clause 3 enabling objectives.
- 5.4 The course must cover the benefits of certification as an IRCA PQMS Auditor, including brief details of the IRCA PQMS auditor certification scheme, and provide students with details of how to contact IRCA and apply for certification. You must use IRCA/190 (or equivalents) for this purpose.

6. COURSE DURATION

6.1 Classroom-based learning

6.1.1 The total course must be at least 7 hours net, calculated as detailed in IRCA/2000.

6.2 Self Study learning

6.2.1 Elements of the courses that are delivered through self-study will allow students three times longer than classroom training.

6.2.2 Each student must complete self-study in no more than 90 days.

6.3 Translators

6.3.1 If the course is given through translators, the time must be increased as necessary to satisfy the learning objectives.

7. TUTORS & STUDENTS

7.1 Classroom-based learning

7.1.1 The number of students per course shall not exceed 20, or be less than 4.

7.1.2 The course shall be run with at least one designated tutor who shall satisfy the requirements for a tutor as stated in IRCA/2000. Additional resources or trainee tutors may be used for specific activities, however the designated tutor remains responsible for the entire presentation.

7.2 Self-study based learning

7.2.1 Tutors who provide educational support on self-study elements of blended learning must be competent to operate any media required.

7.3 Tutor competence - Tutors for this course must demonstrate competence in key attributes:

7.3.1 Competence in training; by satisfying the tutor or lead tutor requirements as appropriate (see IRCA/2000).

7.3.2 Competence in pharmaceutical quality management systems (ICH Q10); either through IRCA certification as an PQMS auditor or through the approved training provider's own assessment.

7.3.3 Competence to deliver training **and** student assessment on your specific course.

8. VARIATIONS

8.1 Requests for variations to any of these criteria, or in respect of any special circumstances, will be considered for approval on written submission by the approved training organization to IRCA. Any such request shall be made immediately upon the reason for the variation request becoming apparent.

8.2 We will consider the following when evaluating any request for variation:

8.2.1 Reasons for the requested variation.

8.2.2 Proposed modifications to the training.

8.2.3 The impact on the learning and assessment processes and how this will be managed.

9. STUDENT ASSESSMENT & EXAMINATION

9.1 **Successful completion:** in order to satisfactorily complete the course each student must:

9.1.1 Complete/attend all elements of the course.

10. COURSE PUBLICITY & ADVERTISING

- 10.1 Course advertising and promotional literature shall not state or imply that this course satisfies more than part of the training requirements for certification as an IRCA PQMS auditor.
- 10.2 Prior to the commencement of the course, you must inform potential students that IRCA recommends all students have the prior knowledge defined in clause 1.2.3.

APPENDIX 1: NOTES FOR GUIDANCE

1. Coverage of ICH Q10

This course is designed for students who have an existing knowledge of pharmaceutical quality issues and of the management system approach, but not of ICH Q10. This course will help these students apply their prior knowledge to understand the key pharmaceutical quality management related requirements of ICH Q10.

2. Meeting the learning and enabling objectives

We do not expect courses to be designed in the chronological order of the learning and enabling objectives in this document. We recognise that individual sessions within a training course can cover more than one learning or enabling objective at the same time.

3. Helping students learn new knowledge & skills

We promote the use of participative learning approaches because they are more efficient, in terms of speed and depth of comprehension, and more effective, in terms of long term retention of new knowledge. Therefore, you should employ practical tasks and activities to help students to understand new concepts and ideas. You should not rely on tutor-focused lecture/presentation to transfer new ideas and concepts.

We promote a variety of training methods in your course design. Different people learn in different ways so your sessions should follow the learning cycle and your course should include a variety of different learning activities to cater for all needs as far as possible. Honey and Mumford (*Learning Style Questionnaire*, Peter Honey Publications, ISBN 1 902899 07 5) provide one model for describing different learning styles that you may find useful as a basis.

Continuous assessment should have a clear link between: session plans (for tutors), clear task/activity instructions with defined and measurable outputs (for students and tutors), activity marking schemes / model answers (for tutors), model answers (for students), individual student continuous assessment record (for recording student performance).

4. Self-Study

We recommend that you consider the following documents when developing training based on information technology solutions:

BS 7988:2002 A Code of Practice for the use of information technology for the delivery of assessments

BS 8426:2003 A code of practice for e-support in e-learning systems