PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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RECOMMENDATION

QUALIFICATION AND TRAINING OF INSPECTORS IN THE FIELD OF HUMAN BLOOD, TISSUES AND CELLS

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TABLE OF CONTENTS

1. Document History 2
2. Introduction 2
3. Purpose 3
4. Scope 3
5. Education and Experience 3
6. Initial Training 3
7. Specialized Training 4
8. In-service Training, Qualification/Certification, Continuous Training 4
9. Revision History 5

1. DOCUMENT HISTORY

Adoption by PIC/S Committee	20 September 2006
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2. INTRODUCTION

2.1 The field of blood, tissues and cells is specialized, and in general inspections should be conducted by persons with appropriate qualification and sufficient training to understand the processes involved, and to identify circumstances which could result in products that endanger public health.

2.2 The general principles for personnel of a Pharmaceutical Inspectorate, stated in chapter 12.1 of the PIC/S document PI-002 (Recommendation on Quality System Requirements for Pharmaceutical Inspectorates) can be applied by analogy to inspections in the field of blood, tissues and cells. They are listed below (2.3 – 2.5).

2.3 *The (...) Inspectorate should possess the required personnel, expertise and other resources to perform inspections of manufacturers and/or wholesale distributors to determine their compliance with the principles and guidelines of current good practices and with the relevant legislation.*

2.4 *The staff responsible for inspections should have appropriate qualifications, training, experience and knowledge of the inspection process. They should have the ability to make professional judgements as to the conformance of the inspected party with the requirements of good practices and the relevant legislation and be able to apply an appropriate degree of risk assessment. They should have knowledge of current technology, including computerised systems and information technology*.

2.5 *The (...) Inspectorate should establish a documented system for recruiting and training its personnel and should carry out a regular review of the training received and the training needs for each member of staff. Individual training and qualification records should be maintained.*

3. PURPOSE

The purpose of this document is twofold. Firstly, it details the qualifications and experience that inspectors should have on being appointed and secondly the induction and ongoing training that should be given to the inspector by the Inspectorate.

4. SCOPE

4.1 This document applies to Inspectorates of competent authorities involved in inspections of blood, tissues and/or cells establishments.

4.2 At the time of issue, this document reflected the current state of the art. It is not intended to be a barrier to technical innovation or the pursuit of excellence.

5. EDUCATION AND EXPERIENCE

5.1. In general, the inspector should have the same level of qualification as the "responsible person" of the institution to be inspected or have the necessary education and experience to inspect such a site.

5.2. Analogous to the requirements of Directive 2002/98/EC[1] (art. 9, responsible person of a blood establishment) and Directive 2004/23/EC[2] (art. 17, responsible person of a tissue establishment) a blood, tissues or cells inspector shall possess a diploma, certificate or other evidence of formal qualification in the field of medical, biological or pharmaceutical sciences awarded on completion of a university course of study or a course recognized as equivalent.

5.3 The inspector shall have practical post-graduate experience in relevant areas of operations within a blood, tissues or cells establishment, or may have appropriate pharmaceutical industry or relevant healthcare experience or experience of working within a competent authority that inspects blood, tissues or cells establishments.

5.4 In certain circumstances experience can substitute for academic qualification.

5.5 In addition to a sound technical knowledge the inspector should possess good interpersonal skills. He/she should be a good communicator, be able to discuss and debate effectively, display a quick grasp of complicated issues, and act assertively while maintaining an appropriate level of tact and professional behaviour.

6. INITIAL TRAINING

6.1 In order to obtain a position as inspector within an Inspectorate the new employee will have demonstrated that he/she possesses the qualifications and experience necessary to perform the expected functions. However, it must be recognised the skills required to be an inspector are specialist and initial/induction training will be provided by the Inspectorate.

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[1] Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 (Official Journal of the European Union L33, 8.2.2003, p.30)

[2] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 (Official Journal of the European Union L102, 7.4.2004, p.48)

6.2 The initial/induction training should be designed to cover at least the following topics:

- Quality Management Systems (ISO, EN)
- GXP regulations (GMP, GDP, GCP; PIC/S, EU, WHO)
- National and relevant international legislation (incl. MRA's)
- Inspection techniques and procedures
- Licensing / authorisation systems
- Organisation of national/international regulatory authorities and inspectorates
- The necessary language skills to perform the required function at a national and international level.

7. SPECIALIZED TRAINING

7.1 As stated under 6.1 above inspectors will, in general, have a wide range of competency obtained through education qualification, previous work experience and/or by their complementary training programme. However, it is likely that the inspector will not have the same level of knowledge in all subjects relating to blood, tissues and cells. A procedure should be in place to perform a training needs analysis for new employees and current staff to ensure the inspector can perform inspections to the required standard.

7.2 The following list provides an outline of important subjects that the inspector may require training in (alphabetical order):

- Biotechnology
- Blood bank activities (collection, apheresis techniques, processing, testing, storage, distribution)
- Computer technology
- Haematology / Immunohaematology
- Haemovigilance
- Immunology
- Laboratory techniques / In vitro diagnostic tests (screening tests)
- Medical devices
- Microbiology (bacteriology, virology)
- Plasma fractionation process technology
- Risk Management
- Specific guidelines deemed necessary by the Inspectorate departments
- Statistics
- Structure of national blood / tissues / cells organisations
- Tissue (skin, bone, cartilage ...) and haematopoietic progenitor cells technologies
- Transfusion / Transplantation Medicine

8. IN-SERVICE TRAINING, QUALIFICATION/CERTIFICATION, CONTINUOUS TRAINING

8.1 The in service training program should include a certain number (to be defined by the Inspectorate) of witnessed inspections. The trainee inspector should observe a qualified inspector perform a number of inspections, then participate

in a number of inspections and then lead a number of inspections under the supervision of a qualified inspector.

8.2 The Inspectorate should have a system in place whereby in service/on the job training of inspectors can take place. A continuous/ongoing training program (to include re-training in the topics defined in 6.2) is also advised to ensure that inspectors are aware of changes (scientific and regulatory) in their fields of expertises and to ensure the continued professional development of inspectors.

8.3 All training should be performed as defined by the quality management system of the Inspectorate. Training should be documented and a documented assessment of training should be performed to qualify/certify the inspector to inspect certain facilities.

9. REVISION HISTORY

Date	Version number	Reasons for revision
17 April 2007	PI 026-2	Change in title (‘’Recommendation’’ instead of ‘’SOP’’) and in editor’s co-ordinates