CHAPTER IV RECOMMENDATION ON INSPECTIONS

RECOMMENDATIONS ON THE QUALIFICATIONS OF INSPECTORS VERIFYING COMPLIANCE IN CLINICAL TRIALS WITH THE PROVISIONS OF GOOD CLINICAL PRACTICE
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TABLE OF CONTENTS Page

1. Introduction

Article 15 of Directive 2001/20/EC[1] requires the Commission to draw up detailed guidelines on the qualification of inspectors to verify compliance of the clinical trial with the provisions of Good Clinical Practice. These detailed guidelines are implemented by Chapter 5 Directive 2005/28/EC[2].

Articles 21 and 22 of Directive 2005/28/EC provide details on the qualifications and training of inspectors for the verification of Good Clinical Practice.

The present document provides further recommendations on qualifications and training of Good Clinical Practice inspectors.

2. Scope

These recommendations are relevant to the qualifications for inspectors who conduct inspections of clinical trial to verify compliance with Good Clinical Practice

3.1 APPOINTMENT OF INSPECTORS

The inspectors should be officials of/or appointed by the Member States in accordance with national regulations and follow the provisions for the national competent authority.

All inspectors should be competent to carry out their assigned duties and should receive appropriate training.

3.2. PERSONAL QUALITIES

The personal skills of an inspector are important in helping to achieve the objectives of the inspections.

During an inspection, the inspector should facilitate the exchange of information. Inspectors need to remain objective during the inspection and in this context should answer questions or provide clarification but avoid entering into the role of a consultant.

4. EDUCATION AND TRAINING

4.1. Education

The level of education should allow good communication with all persons involved with the clinical trails.

The inspector should have demonstrated competence in clearly and fluently expressing concepts orally and in writing in their officially recognised language. In Member States where English is not the officially recognised language, the inspector should preferably also be able to read English.

The inspector should be familiar with basic medical terminology.

[1] OJ L 121, 1.5.2001 p.24
[2] OJ L 91, 9.4.2005, p.13

Where applicable and in some circumstances, the inspector may need to become familiar with the health care and regulatory systems of other countries.

To be able to act as lead inspector in inspections requested by the Committee for Human Medicinal Products and co-ordinated by European Medicines Agency (Agency) and to participate in the ongoing co-operation and harmonisation of procedures in the Community, the inspector should in addition be able to write and speak English.

4.2.Training

The inspectors should have undergone training to the extent necessary to ensure their competence and skills required for planning, carrying out and reporting inspections.

The training and experience should be documented individually and evaluated within the requirements of the applicable quality system of the competent authority/ inspectorate.

Based on the tasks assigned to the inspector, training is recommended to provide knowledge and understanding of:

- knowledge and understanding of Good Clinical Practice;
- knowledge of and training in working according to national and European guidelines for inspections;
- training in inspection technique, acquired by attending relevant course(s) and accompanying and being guided by qualified Good Clinical Practice inspectors, and participating as an observer when relevant during Good Manufacturing Practice and Good Laboratory Practice inspections;
- training in administration procedures required for managing an inspection, such as planning, organising, communicating or providing feed back to inspectees;
- knowledge and understanding of current technology, computer systems, information technology, data handling and archiving;
- requirements for laboratory facilities, analytical instrumentation, handling of samples and analyses, pharmacokinetics;
- training in evaluation of findings and reporting;
- the general principles of Quality Management Systems;
- review and design of clinical trials and processes, including protocol and Case Report Form design;
- the basic requirements for production e.g. labelling, storage and quality control, and distribution of investigational medicinal products;
- medical writing.

Prior to assuming responsibility for performing Good Clinical Practice inspections a new inspector should have gained experience by participation as team member in inspections led by experienced Good Clinical Practice inspectors. Preferably, the inspector should start with national Good Clinical Practice inspections as a member of a team and then deal progressively with more complex Good Clinical Practice inspections. Training is a prerequisite to be able to act as a team leader and/or reporting inspector in international inspections requested by the Committee for Human Medicinal Products and co-ordinated by Agency.

4.3. Management capabilities

The inspector should through suitable means demonstrate knowledge and capability of using the necessary management skills required in execution of an inspection, i.e. planning, announcing, conducting and reporting of an inspection.

4.4. Report writing

The inspector should document and demonstrate his/her capacity to write inspection reports according to national requirements as well as according to the EMEA system for inspections requested by the Committee for Human Medicinal Products.

4.5. Formation of inspection teams

It is up to the Member State to ensure that clinical trials are inspected in line with Directive 2001/20/EC and to that effect it may be necessary to form a team to ensure the presence of skills necessary for specific inspections.

5. MAINTENANCE OF COMPETENCE

According to Article 21(3) and (4) of Directive 2005/28/EC the competence should be maintained. This should be documented by the Member States competent authorities/inspectorate.

6. HARMONISATION IN THE COMMUNITY

In order to promote harmonisation in the Community in the interpretation of the Good Clinical Practice principles and compliance, the management of Good Clinical Practice inspections in the Member States facilitate training activities, including on the job training, at national and international levels.

Consultations with the staff of other Good Clinical Practice inspectorates and joint inspections or training visits are useful and should be encouraged.

Where possible, management should also facilitate the exchange of information and practical experience gained by inspectors in the fields of Good Laboratory Practice and Good Manufacturing Practice, especially in those parts that are closely related to Good Clinical Practice, e.g. laboratory facilities, computerised data recording and analyses and requirements in relation to medicinal products for investigational use.