DECISION

No. 6/09.03.2007

on approval of Guideline on training and qualifications of GMP inspectors

The Scientific Council of the National Medicines Agency,
set up based on Minister of Public Health Order No. 485/09.05.2005, modified and completed through Minister of Health Orders No. 159/22.02.2006, No. 1599/12.12.2006 and No. 395/27.02.2007, reunited on summons of the National Medicines Agency President in the ordinary meeting of 09.03.2007, in accord with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, agrees on the following

DECISION

Article 1. – The Guideline on training and qualifications of GMP inspectors, according to the Annex, which is integral part of this decision, is approved.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

GUIDELINE
on training and qualification of GMP inspectors

CHAPTER I
Introduction

Art. 1. - (1) This Guideline is a translation into Romanian and an adaptation of the Guideline EMEA/INS/GMP/313525/2006 on training and qualification of Good Manufacturing Practice (GMP) inspectors, issued by the European Medicines Agency (EMEA).

(2) Taking into account the special importance of management of inspection activities, this Guideline establishes several requests concerning the experience, training and qualification of the GMP inspectors.

(3) Objectivity, professional integrity and competence in technical matters and inspection skills should be the main qualities of inspectors.

(4) Inspectors should be very well trained in all the relevant topics concerning Quality Assurance management, manufacturing processes, control and distribution of medicinal products (including investigational medicinal products in the light of requirements of minister of public health Order No. 904/2006) and in the way of conducting an inspection (inspection methodology).

(5) The guideline provides information on minimal requirements concerning the training and qualifications of the GMP inspectors and it is conceived as an additional feature to the requirements of the national legislation.

CHAPTER II
Scope

Art. 2. - This guideline applies to the training and qualifications required for an inspector who shall conduct an inspection to verify compliance with GMP for the competent authority of the Member State concerned. Inspections are carried out on behalf of the European Union (EU). The results shall be recognised by all the other Member States (MS).

CHAPTER III
General provisions

III.1 General aspects

Art. 3. - (1) The NMA should name inspectors for the inspection of the manufacturing sites according to Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product. There must be sufficient resources at all levels in order to effectively and efficiently meet the requirements of GMP compliance for medicinal products.

(2) The inspectors shall be appointed by the NMA in accordance with the provisions issued by the NMA.

(3) All inspectors should be competent to carry out their assigned duties and receive appropriate training. When needed, teams of inspectors may be nominated

comprising inspectors with appropriate qualifications and experience to collectively fulfil the requirements necessary for conducting the inspection.

(4) The inspectors should be made aware of and maintain confidentiality whenever they gain access to confidential information as a result of GMP inspections according to applicable national laws, European requirements or international agreements.

Art. 4. - (1) There should be sufficient resource to ensure availability of competent inspectors to work according to contracts between EMEA and the NMA in the case of inspections requested by the Committee for Human Medicinal Products.

(2) The training needs of inspectors should regularly be assessed within the requirements of the applicable quality system of the NMA/PID and appropriate actions taken by the NMA in order to maintain and improve inspection skills.

(3) Information on the relevant experience, training and qualifications of each inspector must be documented and maintained by the NMA. These records should be kept up-to-date.

III.2 Personal qualities

Art. 5. - (1) The personal skills of an inspector are important in helping to achieve the objectives of inspections.

(2) During an inspection the inspector should help in creating an open atmosphere. Inspectors need to remain objective during the inspections and in this context should answer questions or provide clarification but avoid entering into the role of a consultant.

(3) The inspector should have a high level of personal integrity, maturity, be open-minded, understanding of complexity, possess sound judgement, assertiveness, analytical skills and tenacity and have the ability to perceive situations in a realistic way.

(4) The inspector should have demonstrated competence in clearly and fluently expressing concepts and ideas orally and in writing in Romanian.

CHAPTER IV
Qualification and training

IV.1 Qualification

Art. 6. - (1) The inspector should have knowledge of the national legislation as well as systems, both at national and at Community level, for applications for marketing and control of medicinal products.

(2) In order to conduct inspections requested by the CHMP and coordinated by the EMEA and in order to participate to the cooperation and harmonization of procedures within the EU, the inspector should also be capable of speaking and writing in English.

IV.2 Training

Art. 7. - (1) The inspectors should have undergone training to the extent necessary to ensure their competence in the skills required for planning, carrying out and reporting inspections.

(2) The training and experience should be documented individually and evaluated within the requirements of the applicable quality system of the NMA.

IV.2.1 Basic training

Art. 8. - (1) It is preferable that the inspector and the „Qualified Person" possess the same qualification level the way it is shown in Art. 757 from Law No. 95/2006 and there be eligible for a Qualified Person.

(2) Moreover, in order to be appointed as GMP inspectors, the candidates should demonstrate their knowledge of the relevant matters in the pharmaceutical field, including:

a) European GMP;
b) community and national pharmaceutical legislation;
c) organisation of the NMA;
d) structure and operating principles of trade organisations;
e) marketing and manufacturing authorisation systems and their relationship;
f) microbiology, process and ventilation engineering, analytic equipments, computerised systems, validation of the processes;
g) interrelation of inspection, sampling and analysis of evidence, certification;
h) distribution of medicinal products;
i) pharmaceutical technology;
j) audit techniques;
k) communication abilities, orally and in writing;
l) general principles of quality management systems (ISO 9000:2000, etc);
m) knowledge of NMA/PID quality systems;
n) knowledge and training during the conduct of the activity according to national and EMEA inspection procedures;
o) knowledge of the Mutual Recognition Agreement and the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products
p) training in inspection technique acquired through participation to adequate courses and/or by accompanying and/or through guidance by several GMP inspectors qualified during inspections;
q) training in administrative procedures needed in the management of an inspection, such as planification, organisation, communication or providing feed-back to the inspected persons;
r) training and assessment of observations and reporting.

IV.2.2 Workplace training

Art. 9. - (1) After recruitment and in addition to their basic training, new inspectors should be trained by senior inspectors. The theory of inspection should be explained and the practice should be shown in the field, so that concrete examples of the meaning and of the goals of inspections are given and can be discussed. New inspectors should participate, but only as observers, in inspections carried out during their initial training.

(2) In addition to this and where needed, training courses in inspection techniques and communication, reporting, languages, legal matters and management should be organised by national inspectorates.

IV.2.3 Continuous training

Art. 10. - (1) Considering the rapid implementation of new manufacturing technologies, the ever more frequent utilization of automatic and computerized systems both in production and quality control of medicinal products, inspectors should also receive continuous training.

(2) This could be achieved through their participation in courses, seminars, scientific meetings and conferences organised either by the national inspectorates or by national or international scientific organisations.

(3) When appropriate, joint inspections or training visits with other inspectors of the same Member State or of other Member States may be a useful training method.

(4) Prior to assuming responsibility for performing GMP inspections the new inspector should have gained experience by participation as team member in inspections led by senior inspectors. Preferably, the inspector should start with national GMP inspections as a member of a team and then deal progressively with more complex GMP inspections to be able to act as a team leader and/or reporting inspector in international inspections. This should be recorded within the requirements of the applicable quality system of the NMA/PID.

(5) Ten days of training (e.g. courses, symposia, conferences, etc.) per year should be considered as a reasonable average.

IV.2.4 Management capabilities

Art. 11. - The inspectors should through suitable means demonstrate their knowledge and capability of using the necessary management skills required in the conduct of an inspection (planning, announcing, conducting and reporting an inspection.)

IV.2.5 Report writing

Art. 12. - The inspector's capacity to write inspection reports according to national and EMEA requirements for the inspection requested by the CHMP should be demonstrated and documented.

CHAPTER V
Maintenance of competence

Art. 13. - Inspectors should have their performance and qualifications periodically reviewed within the requirements of the applicable quality system of the NMA/PID. Their competence should be maintained and updated by practical experience and by participating in courses, seminars, scientific meetings, conferences and through review of relevant publications. This should be documented and its effectiveness assessed in order to ensure that:

a) Knowledge of GMP, quality systems standards and requirements is current;
b) Knowledge of inspection procedures and methods is current;
c) Knowledge of quality assurance activities within the requirements of the applicable quality system of the ANM/DIF is current.

CHAPTER VI
Harmonisation within EU

Art. 14. - (1) In order to promote international harmonisation in the interpretation of the principles of GMP and compliance, the Inspectorate's management should facilitate training activities, including workplace training, at national and international levels.

(2) Consultations with the staff of other GMP inspectorates and joint inspections or training visits is useful in this context and should be encouraged.

(3) The management of the NMA should also facilitate the exchange of information and practical experience gained by inspectors in the field of GMP, with inspectorates in other disciplines especially in those areas that are closely related (e.g. laboratory facilities, computerised data recording and analyses and requirements in relation to medicinal products for investigational use).