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Guideline on training and qualifications of GMP inspectors

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Guideline on training and qualifications of GMP inspectors

1. Introduction

Taking into account its importance for the management of inspection services, this guideline establishes requirements concerning experience, training and qualifications of GMP inspectors.

Objectivity, professional integrity, competence in technical matters and inspection skills should be the main features of inspectors.

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 product in the light of requirements of Regulation (EU) No 536/2014) and in the way of conducting an inspection (inspection methodology).

The guideline provides information on minimal requirements. Member States may decide to add supplementary national requirements.

2. Scope

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 Union and the results shall be recognised by all the other Member States.

3. Background

3.1 General aspects:

Member States should appoint inspectors to inspect the manufacturing sites according to Directive 2001/83/EC, Regulation (EU) 2019/6 and Regulation (EU) No 536/2014. There should be sufficient resources at all levels to meet, effectively and efficiently, the EU requirements of verifying compliance with GMP of medicinal products.

The inspectors shall be officials of, or appointed by, the competent authorities of 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 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.

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.

There should be sufficient resource to ensure availability of competent inspectors to work according to contracts between EMA and the competent authority in the case of inspections requested by the CHMP or CVMP.

The training needs of inspectors should regularly be assessed within the requirements of the applicable quality system of the Competent Authority/Inspectorate and appropriate actions taken by the competent authority to maintain and improve inspection skills.

Information on the relevant experience, training and qualifications of the individual inspector must be documented and maintained by the competent authority. These records should be kept up-to-date.

3.2 Personal qualities:

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

During an inspection the inspector should help in creating an open atmosphere. 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.

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.

The inspector should have demonstrated competence in clearly and fluently expressing concepts and ideas orally and in writing in their officially recognised language.

4. Qualification and training

4.1 Qualification:

Inspectors should preferably have the same level of qualification as the "Qualified Person" as defined in Art. 48 of Directive 2001/83/EC, in Art. 97 of Regulation 2019/6 and therefore be eligible as a Qualified Person.

The inspector should have knowledge of the national legislation as well as systems, both at national and at Union level, for applications for marketing and control of medicinal products.

4.2 Training:

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.

The training and experience should be documented individually and evaluated within the requirements of the applicable quality system of the Competent Authority/ Inspectorate.

4.2.1 Basic training

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

- Union and national pharmaceutical legislation;
- Good Manufacturing Practice and Good Distribution Practice;
- Principles of quality assurance and quality management systems (ISO 9000:2000);
- Technical aspects of pharmaceutical and API manufacturing (e.g. pharmaceutical technology, process and ventilation engineering, validation, computerized systems, analytical instrumentation, microbiology);
- Organization and quality systems of the Competent Authority/Inspectorate and training in working according to relevant national and Union SOPs and procedures related to inspections;
- Marketing and manufacturing authorisation systems and their relationship;
- Interrelation of licensing, inspection, sampling and analysis;
- Knowledge of MRA and other relevant Union arrangements;
- Structure and principles of operation of commercial organizations;
- Inspection technique, acquired by attending relevant course(s) and or/by accompanying and/or guided by qualified GMP inspectors during inspection;
- Administration procedures required for managing an inspection, such as planning, organizing,

communicating or providing feedback to the inspectee;

- Evaluation of findings and reporting;
- Pharmaceutical Development, Quality Risk Management and Pharmaceutical Quality System (incl. ICH Q8, Q9, Q10 as implemented in the relevant EU guidelines);
- International organisations, their activities and documents (EDQM, ICH, PIC/S, WHO).

It is recognised that there are acceptable methods, other than those described in the Guide, which are capable of achieving the Quality Assurance principles of Good Manufacturing Practice. An inspector should be open and able to assess whether alternative methods and procedures meet these principles taking into account the principles of Quality Risk Management.

4.2.2 Further training

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 on the spot inspections carried out during their initial training.

Beside this and where needed, training courses in inspection techniques and communication, reporting, languages, legal matters and management should be organised by national inspectorates.

To be able to act as lead inspector in inspections requested by CHMP or CVMP and co-ordinated by EMA and to participate in the ongoing co-operation and harmonisation of procedures within EU, the inspector should also be able to write and speak in English.

For participating to activities as such as Joint Audit Programme, Joint Reassessment Programme, European Benchmarking, adequate training should be organized at EU or international level as appropriate.

4.2.3 Continuous training

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.

This could be achieved through their participation in courses, seminars, scientific meetings and conferences organized either by the national inspectorates or by national or international scientific organizations.

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.

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 Competent Authority/ Inspectorate.

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

4.3 Management capabilities:

The inspectors should through suitable means demonstrate their knowledge and capability of using the

necessary management skills required in the conduct of an inspection, i.e. planning, announcing, conducting and reporting an inspection.

4.4 Report writing:

The inspector's capacity to write inspection reports according to national and Union requirements should be demonstrated and documented.

5. Maintenance of competence

Inspectors should have their performance and qualifications periodically reviewed within the requirements of the applicable quality system of the Competent Authority/ Inspectorate. 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 periodically to ensure that:

Knowledge of GMP, quality systems standards and requirements is current;

Knowledge of inspection procedures and methods is current;

Knowledge of quality assurance activities within the requirements of the applicable quality system of the Competent Authority/ Inspectorate is current.

6. Harmonisation within EU

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 on the job training, at national and international levels.

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

The management 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.