EU GDP

2013/C 343/01

Guidelines on Good Distribution Practice of Medicinal Products for Human Use

November 5, 2013

KEY2COMPLIANCE®
Compliance Training Network

1205en
141105

customs areas, such as in free zones or in free warehouses. All obligations related to wholesale distribution activities (such as exporting, holding or supplying) also apply to these distributors. Relevant sections of these guidelines should also be adhered to by other actors involved in the distribution of medicinal products.

Other actors such as brokers may also play a role in the distribution channel for medicinal products. According to Article 85(b), persons brokering medicinal products must be subject to certain provisions applicable to wholesale distributors, as well as specific provisions on brokering.

Chapter 1 - Quality management

1.1. Principle

Wholesale distributors must maintain a quality system setting out responsibilities, processes and risk management principles in relation to their activities (2). All distribution activities should be clearly defined and systematically reviewed. All critical steps of distribution processes and significant changes should be justified and where relevant validated. The quality system is the responsibility of the organisation's management and requires their leadership and active participation and should be supported by staff commitment.

1.2. Quality system

The system for managing quality should encompass the organisational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the product delivered maintains its quality and integrity and remains within the legal supply chain during storage and/or transportation.

The quality system should be fully documented and its effectiveness monitored. All quality system-related activities should be defined and documented. A quality manual or equivalent documentation approach should be established.

A responsible person should be appointed by the management, who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained.

(2) Article 80(h) of Directive 2001/83/EC

The management of the distributor should ensure that all parts of the quality system are adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities.

The size, structure and complexity of distributor's activities should be taken into consideration when developing or modifying the quality system.

A change control system should be in place. This system should incorporate quality risk management principles, and be proportionate and effective.

The quality system should ensure that:

(i) medicinal products are procured, held, supplied or exported in a way that is compliant with the requirements of GDP;

(ii) management responsibilities are clearly specified;

(iii) products are delivered to the right recipients within a satisfactory time period;

(iv) records are made contemporaneously;

(v) deviations from established procedures are documented and investigated;

(vi) appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.

1.3. Management of outsourced activities

The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply or export of medicinal products. These processes should incorporate quality risk management and include:

(i) assessing the suitability and competence of the Contract Acceptor to carry out the activity and checking authorisation status, if required;

(ii) defining the responsibilities and communication processes for the quality-related activities of the parties involved;

(iii) monitoring and review of the performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis.

1.4. Management review and monitoring

The management should have a formal process for reviewing the quality system on a periodic basis. The review should include:

(i) measurement of the achievement of quality system objectives;

(ii) assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, deviations, CAPA, changes to processes; feedback on outsourced activities; self-assessment processes including risk assessments and audits; and external assessments such as inspections, findings and customer audits;

(iii) emerging regulations, guidance and quality issues that can impact the quality management system;

(iv) innovations that might enhance the quality system;

(v) changes in business environment and objectives.

The outcome of each management review of the quality system should be documented in a timely manner and effectively communicated internally.

1.5. Quality risk management

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of medicinal products. It can be applied both proactively and retrospectively.

Quality risk management should ensure that the evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation of the process should be commensurate with the level of risk. Examples of the processes and applications of quality risk management can be found in guideline Q9 of the International Conference on Harmonisation (ICH).

Chapter 2 - Personnel

2.1. Principle

The correct distribution of medicinal products relies upon people. For this reason, there must be sufficient competent personnel to carry out all the tasks for which the wholesale distributor is responsible. Individual responsibilities should be clearly understood by the staff and be recorded.

2.2. Responsible person

The wholesale distributor must designate a person as Responsible Person. The Responsible Person should meet the qualifications and all conditions provided for by the legislation of the Member State concerned [1]. A degree in pharmacy is desirable. The Responsible Person should have appropriate competence and experience as well as knowledge of and training in GDP.

The Responsible Person should fulfil their responsibilities personally and should be continuously contactable. The Responsible Person may delegate duties but not responsibilities.

The written job description of the Responsible Person should define their authority to take decisions with regard to their responsibilities. The wholesale distributor should give the Responsible Person the defined authority, resources and responsibility needed to fulfil their duties.

The Responsible Person should carry out their duties in such a way as to ensure that the wholesale distributor can demonstrate GDP compliance and that public service obligations are met.

The responsibilities of the Responsible Person include:

(i) ensuring that a quality management system is implemented and maintained;

(ii) focusing on the management of authorised activities and the accuracy and quality of records;

(iii) ensuring that initial and continuous training programmes are implemented and maintained;

(iv) coordinating and promptly performing any recall operations for medicinal products;

[1] Article 79(b) of Directive 2001/83/EC.