

Summary of European Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use

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Guideline Summary

- Guidelines replaces the Guidelines on Good Distribution Practice (GDP) of Medicinal Products for Human Use published in 1994.
- Deadline for coming into operation is **7 September 2013**.
- These guidelines lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain.
- Distributors and manufacturers distributing their own products must comply with the principles and guidelines of GDP.
- Brokers of medicinal products shall be subject to certain provisions applicable to wholesale distributors, as well as specific provisions for brokering.

Chapter 1 - Quality Management

- System for managing quality should 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 documented monitored for effectiveness.
- A quality manual or equivalent approach should be established.
- A management appoint responsible person is responsible for ensuring that a quality system is implemented and maintained.
- A change control system, incorporating risk management principles, should be in place, proportionate, and effective.
- The quality system should ensure 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.
- The quality management system should extend to the control and review of any outsourced activities.
- The management should have a formal process for reviewing the quality system on a periodic basis.

Chapter 2 - Personnel

- The Responsible Person should fulfill his/her responsibilities personally and should be permanently available.
- It is desirable that the Responsible Person have a degree in Pharmacy, appropriate competence, and experience/knowledge/ training in GDP.
- All personnel involved in wholesale distribution activities should be qualified/trained in GDP requirements and have the appropriate competence/experience prior to commencing their tasks.
- Appropriate procedures relating to personnel hygiene, relevant to the activities being carried out, should be established and observed.

Chapter 3 - Premises and Equipment

- There should be segregated areas, separated from saleable product, designated for the storage of:
 - any product suspected of falsification,
 - Returned, rejected, or recalled product,
 - products received from a third country but not intended for the Union market.
- Equipment used to control or to monitor the environment, should be calibrated and their correct operation/suitability verified at defined intervals by the appropriate methodology.
- Records of repair, maintenance and calibration of key equipment must be maintained.
- Computer systems, before being brought into use, must be validated or verified as being capable of achieving the desired results accurately, consistently and reproducibly.
- Equipment and processes should be respectively qualified and/or validated before commencing use and after any significant changes.

Chapter 4 - Documentation

- Documentation of the wholesale distributor's activities should be in a language understood by personnel.
- Each employee should have ready access to all necessary documentation for the tasks executed.
- Version control should be applied to procedures.
- Documents and computerized data should be retained for a period stated in national legislation but not shorter than 5 years.

Chapter 5 - Operations

- Wholesale distributors must obtain their supplies of medicinal products only from wholesale distribution or manufacturing authorization holders.
- When entering into a new contract with new suppliers the wholesale distributor should carry out 'due diligence' checks in order to assess the suitability, competence and reliability of the other party.
- Wholesale distributors must supply medicinal products only to distribution authorization holders or persons who are authorized or entitled to supply medicinal products the Member State concerned.
- Medicinal products should be stored separately from other products and protected from harmful effects of light, temperature, moisture or other external factors.
- Stock should be rotated according to the first expiry, first out (FEFO).
- Stock inventories should be performed regularly.
- Records should be kept so that the actual location of the product can be known.
- Must hold a wholesale distribution authorization or a manufacturing authorization to export medicinal products .

Chapter 6 - Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls

- No significant changes to current requirements.
- There should be a written procedure in place for the handling of complaints.
- A distinction should be made between complaints about the quality of a medicinal product and those relating to distribution.
- In the case of a complaint about the quality of a medicinal product, the manufacturer and/or marketing authorization holder should be informed without delay.
- Any suspected falsified medicinal products found in the supply chain should be immediately segregated from legitimate medicinal products: Distributors must immediately inform the competent authority and, where applicable, the marketing authorization holder of the medicinal products.

Chapter 7 – Outsourced Activities

- Any activity covered by the GDP Guide that is outsourced should be contractually defined, agreed and controlled.
- The Contract Giver is responsible for assessing the competence of the Contract Acceptor to successfully carry out the work following GDP.

Chapter 8 - Self-inspections

- A self-inspection program should be implemented to cover all aspects of GDP.
- In the event that irregularities and/or deficiencies are observed, their cause should be determined and the corrective and preventive actions (CAPA) should be documented and followed up.
- Audits by independent external experts may also be useful but may not be used as a substitute for self-inspection.

Chapter 9 - Transportation

- The required storage conditions for medicinal products should be maintained during transportation.
- If a deviation such as temperature excursion or product damage has occurred during transportation, this should be reported and investigated.
- Risk assessment of delivery routes should be used to determine where temperature controls are required.
- Dedicated vehicles and equipment should be used, where possible.
- There should be a protocol to address the occurrence of any theft.

Chapter 10 - Specific Provisions for Brokers

- The quality system of a broker should be defined in writing, approved and kept up-to-date: it should set out the responsibilities, processes and risk management in relation to their activities.
- Any member of personnel involved in the brokering activities should be trained in the applicable EU and national legislation and in the issues concerning falsified medicinal products.

Thank you

For More Information



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