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Webinar:

WHO GOOD STORAGE & DISTRIBUTION PRACTICE FOR PHARMACEUTICAL PRODUCTS

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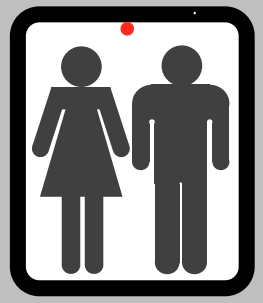
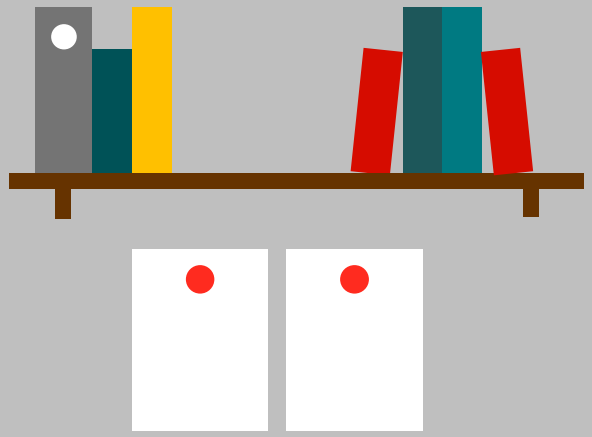
By Royal Charter

Introductions

Introductions

Welcome





Benefits

- Take the first steps towards Thai GOOD STORAGE & DISTRIBUTION PRACTICE FOR PHARMACEUTICAL PRODUCTS –GSDP PHARMA.
- To review and planning of system to complied with GOOD STORAGE & DISTRIBUTION PRACTICE FOR PHARMACEUTICAL PRODUCT
- To preparation for certification audit.

GOOD STORAGE & DISTRIBUTION PRACTICE FOR PHARMACEUTICAL PRODUCTS.

in detail.

GSDP

WHO Technical Report Series, No. 957, 2010

22

Annex 5: WHO good distribution practices for pharmaceutical products

WHO Technical Report Series, No. 908, 2003

8

Annex 9: Guide to good storage practices for pharmaceuticals1

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Scope

Objective

To assist in ensuring the quality and identity of pharmaceutical products during all aspects of the distribution process.

These aspects include, but are not limited to:

- Procurement
- Purchasing
- Storage,
- Distribution
- Transportation
- Repackaging
- Relabeling
- Documentation and record-keeping practices.

GDP: 4. General principles

4.1 Main responsibility ensure that the quality of pharmaceutical products and the integrity of the distribution chain

4.2 Complied with national legislation & guidance for GDP. Mean standard implemtation.

4.3 Cover for both moving forward and backward of product in distribution chain.

4.4 Cover donated pharmaceutical product

4.5 Distribution process shall apply with adherence to the principles of GSDP i.e. traceability.

4.6 Collaboration between all parties i.e. governments, customs agencies, regulatory authorities, manufacturers, distributors.

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GDP: 6. Organization and management

6.1 Organizational structure for each entity defined with the aid of an organizational chart, responsibility, authority and interrelationships of all personnel should be clearly indicated

6.2 Written job descriptions of individuals concerned. Employees should be fully informed and trained in their duties and responsibilities.

6.3 A designated person should be appointed within the organization for ensuring that a quality system is implemented and maintained.

6.4 Managerial and technical personnel must have the authority and resources needed to carry out their duties and to set up and maintain a quality system, identify and correct deviations from the established quality system (see section 8).

GDP: 6. Organization and management

6.5 The responsibilities placed on any one individual should not be so extensive as to present any risk to product quality.

6.6 There should be arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of pharmaceutical products.

6.7 Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, should be in place.

GDP: 7. Personnel / GSP: 3. Personnel

7.1 All personnel involved in distribution activities should be trained and qualified in the requirements of GDP, as applicable. Training should be based on written standard operating procedures (SOPs). Training include the topic of GSDP, their task, product security, product identification, the detection of counterfeits and the avoidance of counterfeits entering the supply chain. A record of all training shall maintained.

7.2 Key personnel involved in the distribution of pharmaceutical products should have the ability and experience appropriate to their responsibility for ensuring that pharmaceutical products are distributed properly.

7.3 There should be an adequate number of competent personnel involved in all stages of the distribution of pharmaceutical products.

7.4 National regulations relating to the qualifications and experience of personnel should be adhered to.

GDP: 7. Personnel / GSP: 3. Personnel

7.5 Personnel dealing with hazardous pharmaceutical products (such as highly active materials, radioactive materials, narcotics) should be given specific training.

7.6 Personnel involved in the distribution of pharmaceutical products should wear garments suitable for the activities that they perform.

7.7 Appropriate procedures relating to personnel hygiene, relevant to the activities to be carried out, should be established and observed. Such procedures should cover health, hygiene and clothing of personnel.

7.8 Procedures and conditions of employment for employees, including contract and temporary staff must be designed and administered to assist in minimizing the possibility of such products coming into the possession of unauthorized persons or entities.

7.9 Codes of practice and punitive procedures should be in place to prevent and address situations where persons involved in the distribution of pharmaceutical products are suspected of, or found to be implicated in, any activities relating to the misappropriation, tampering, diversion or counterfeiting of any product.

GDP: 8 Quality System

8.1 There should be a documented quality policy describing the overall intentions and requirements of the distributor regarding quality

8.2 The quality system should include an appropriate organizational structure, procedure, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service and its documentation will satisfy given requirements for quality

8.3 The quality system should include provisions to ensure that the holder of the marketing authorization, entity identified on the label (if different from the manufacturer), the appropriate national and/or international regulatory bodies, as well as other relevant competent authorities, would be informed immediately in a case of confirmed or suspected counterfeiting of a pharmaceutical product.

8.4 Where electronic commerce (e-commerce) is used, i.e. electronic means are used for any of the distribution steps, defined procedures and adequate systems should be in place to ensure traceability and confidence in the quality of the pharmaceutical products concerned. Electronic transactions (including those conducted via the Internet) should be performed only by authorized persons or entities.

GDP: 8 Quality System

8.5 Authorized procurement and release procedures for all administrative and technical operations performed should be in place to ensure that appropriate pharmaceutical products are sourced only from approved suppliers and distributed by approved entities.

8.6 Inspection, auditing and certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or international guidelines) by external bodies is recommended.

8.7 If measures to ensure the integrity of the pharmaceutical products in transit are in place, they should be managed properly.

8.8 Distributors should from time to time conduct risk assessments to assess potential risks to the quality and integrity of pharmaceutical products. The quality system should be developed and implemented to address any potential risks identified. The quality system should be reviewed and revised periodically to address new risks identified during a risk assessment.

GDP: 8 Quality System

(Traceability of pharmaceutical products)

8.9 There should be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall.

8.10 All parties involved in the supply chain should be identifiable, depending on the type of product and on national policies and legislation.

8.11 Measures should be in place to ensure that pharmaceutical products have documentation that can be used to permit traceability of the products throughout distribution channels from the manufacturer/importer to the entity responsible for selling or supplying the product to the patient or his or her agent. Records including expiry dates and batch numbers may be part of a secure distribution documentation enabling traceability.

8.12 Ideally there should be a procedure in place for the creation and maintenance of a pedigree for pharmaceutical products. (The procedure to be followed when a suspected product is identified should include provisions for notification)

8.13 A suitable and, to the extent possible, internationally compatible product coding, identification system should be in place and developed in collaboration with the various parties involved in the supply chain.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

9.1 Good storage practices (GSP) are applicable in all circumstances where pharmaceutical products are stored and throughout the distribution process.

Refer to the WHO guide to good storage practices for pharmaceuticals

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage area

9.2 Precautions must be taken to prevent unauthorized persons from entering storage areas. Employees should comply with the company policies to maintain a safe, secure and efficient working environment.

9.3 Storage areas should be of sufficient capacity to allow the orderly storage of the various categories of pharmaceutical products, namely commercial and non-commercial products, products in quarantine, and released, rejected, returned or recalled products as well as those suspected to be counterfeits

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GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage area

9.4 Storage areas should be designed or adapted to ensure appropriate and good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage area

9.5 Storage areas should be regular clean and free from accumulated waste and vermin. A written sanitation programme should be available indicating the frequency of cleaning and the methods to be used to clean the premises and storage areas. There should also be a written programme for pest control. The pest control agents used should be safe and there should be no risk of contamination of pharmaceutical products. There should be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage area

9.6 If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures should be in place for the sampling areas.

9.7 Receiving and dispatch bays should protect pharmaceutical products from the weather and to control incoming containers of pharmaceutical products to be cleaned.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage area

9.8 Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and access restricted to authorized personnel. Any system replacing physical quarantine should provide equivalent security. If computerized systems can be used, provided that they are validated to demonstrate security of access.

9.9/9.10 Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled or returned products and suspected counterfeits. The products and the areas concerned should be appropriately identified.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage area

9.11 Radioactive materials, narcotics and other hazardous, sensitive and/ or dangerous pharmaceutical products, as well as products presenting special risks of abuse, fire or explosion should be stored in a dedicated area(s) that is subject to appropriate additional safety and security measures.

9.12 Pharmaceutical products should be handled and stored in such a manner as to prevent contamination, mix-ups and cross-contamination.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage area

9.13 A system should be in place to ensure that the pharmaceutical products due to expire first are sold and/or distributed first (FEFO). Exceptions may be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.

9.14 Broken or damaged items should be withdrawn from usable stock and stored separately

9.15 Storage areas should be provided with adequate lighting to enable all operations to be carried out accurately and safely.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage conditions and stock control

9.16 Storage and handling conditions should comply with applicable national and local regulations (8).

9.17 Storage conditions for pharmaceutical products should be in compliance with the recommendations of the manufacturer.

9.18 Facilities should be available for the storage of all pharmaceutical products under appropriate conditions. Records should be maintained of these conditions if they are critical for the maintenance of the characteristics of the pharmaceutical product stored.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage conditions and stock control

Normal storage conditions

Storage in dry, well-ventilated premises at temperatures of 15–25 °C or, depending on climatic conditions, up to 30 °C. Extraneous odours, other indications of contamination, and intense light must be excluded.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Defined storage instructions

Drug products that must be stored under defined conditions require appropriate storage instructions. Unless otherwise specifically stated (e.g. continuous maintenance of cold storage) deviation may be tolerated only during short-term interruptions, for example, during local transportation.

The use of the following labelling instructions are recommended:

On the label	*Means*
"Do not store over 30 °C"	from +2 °C to +30 °C
"Do not store over 25 °C"	from +2 °C to +25 °C
"Do not store over 15 °C"	from +2 °C to +15 °C
"Do not store over 8 °C"	from +2 °C to +8 °C
"Do not store below 8 °C"	from +8 °C to +25 °C
"Protect from moisture"	no more than 60% relative humidity in normal storage conditions; to be provided to the patient in a moisture-resistant container.
"Protect from light"	to be provided to the patient in a light-resistant container.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage conditions and stock control

9.19 Records of temperature monitoring data should be available for review. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained. All monitoring records should be kept for at least the shelf-life of the stored pharmaceutical product plus one year, or as required by national legislation. Temperature mapping should show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.

GDP: 9. Premises, warehousing and storage
GSP: 4. Premises and facilities / 5. Storage requirement

Storage conditions and stock control

9.20 Equipment used for monitoring of storage conditions should also be calibrated at defined intervals

9.21 Periodic stock reconciliation should be performed by comparing the actual and recorded stocks. This should be done at defined intervals.

9.22 Stock discrepancies should be investigated in accordance with a specified procedure to check that there have been no inadvertent mixups, incorrect issues and receipts and others. Documentation relating to the investigation should be kept for a predetermined period.

GDP: 10. Vehicles and equipment

10.1 Vehicles and equipment used to distribute, store or handle pharmaceutical products should be suitable for their purpose and could not affect their stability and packaging integrity, and to prevent contamination of any kind.

10.2 The design and use of vehicles and equipment must aim to minimize the risk of errors and permit effective cleaning and/or maintenance to avoid contamination, build-up of dust or dirt and/or any adverse effect on the quality of the pharmaceutical products being distributed

10.3 Where feasible, consideration should be given to adding technology, such as global positioning system (GPS) electronic tracking devices and engine-kill buttons to vehicles, which would enhance the security of pharmaceutical products while in the vehicle

10.4 Dedicated vehicles and equipment should be used, where possible, when handling pharmaceutical products.

10.5 Where non-dedicated vehicles and equipment are used, procedures should be in place to ensure that the quality of the pharmaceutical product will not be compromised. Appropriate cleaning should be performed, checked and recorded.

GDP: 10. Vehicles and equipment

10.6 Procedures should be in place to ensure that the integrity of the products is not compromised during transportation.

10.7 Where third-party carriers are used, distributors should develop written agreements with carriers to ensure that appropriate measures are taken to safeguard pharmaceutical products, including maintaining appropriate documentation and records. Such agreements should be in line with national and regional regulatory requirements.

10.8 Defective vehicles and equipment should not be used and should either be labelled as such or removed from service

10.9 There should be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions.

10.10 Vehicles, containers and equipment should be kept clean and dry and free from accumulated waste. Organizations in charge of distribution must ensure that vehicles used are cleaned regularly.

GDP: 10. Vehicles and equipment

10.11 Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should be written programmes and records for such pest control. The cleaning and fumigation agents used should not have any adverse effect on product quality.

10.12 Equipment chosen and used for the cleaning of vehicles should not constitute a source of contamination. Agents used for the cleaning of vehicles should be approved by management

10.13 Special attention should be paid to the design, use, cleaning and maintenance of all equipment used for the handling of pharmaceutical products which are not in a protective shipping carton or case.

10.14 Where special storage conditions (e.g. temperature and/or relative humidity), different from, or limiting, the expected environmental conditions, are required during transportation, these should be provided, checked, monitored and recorded. All monitoring records should be kept for a minimum of the shelf-life of the product distributed plus one year, or as required by national legislation. Records of monitoring data should be made available for inspection by the regulatory or other oversight body.

GDP: 10. Vehicles and equipment

10.15 Equipment used for monitoring conditions, e.g. temperature and humidity, within vehicles and containers should be calibrated at regular intervals.

10.16 Vehicles and containers should be of sufficient capacity to allow orderly storage of the various categories of pharmaceutical products during transportation.

10.17 Where possible, mechanisms should be available to allow for the segregation during transit of rejected, recalled and returned pharmaceutical products as well as those suspected of being counterfeits. Such goods should be securely packaged, clearly labelled, and be accompanied by appropriate supporting documentation.

10.18 Measures should be in place to prevent unauthorized persons from entering and/or tampering with vehicles and/or equipment, as well as to prevent the theft or misappropriation thereof

GDP: 11. Shipment containers and container labelling
GSP: 5. Storage requirements

11.1 Pharmaceutical products should be stored and distributed in shipment containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.

11.2 Shipping containers should bear labels providing sufficient information on handling and storage conditions and precautions to ensure that the products are properly handled and secure at all times. The shipment container should enable identification of the container's contents and source.

11.3 The need for any special transport and/or storage conditions should be stated on the shipment container label. If a pharmaceutical product is intended for transfer to areas outside the control of the manufacturer's products management system, the name and address of the manufacturer, special transport conditions and any special legal requirements, including safety symbols, should also be included on the container label.

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GDP: 11. Shipment containers and container labelling
GSP: 5. Storage requirements

11.4 Normally, internationally and/or nationally accepted abbreviations (Short name), names or codes should be used in the labelling of shipment containers.

11.5 Special care should be taken when using dry ice in shipment containers. In addition to safety issues it must be ensured that the pharmaceutical product does not come into contact with the dry ice, as it may have an adverse effect on the quality of the product.

11.6 Written procedures should be available for the handling of damaged and/or broken shipment containers. Particular attention should be paid to those containing potentially toxic and hazardous products.

GDP: 12. Dispatch and receipt
GSP: 5. Storage requirement / 7. Dispatch and transport

12.1 Pharmaceutical products should only be sold and/or distributed to persons or entities that are authorized to acquire such products in accordance with the applicable national, regional and international legislation. Written proof of such authority must be obtained prior to the distribution of products to such persons or entities.

12.2 Prior to the dispatch of the pharmaceutical products, the supplier should ensure that the person or entity, e.g. the contract acceptor for transportation of the pharmaceutical products, is aware of the pharmaceutical products to be distributed and complies with the appropriate storage and transport conditions.

12. 3 The dispatch and transportation of pharmaceutical products should be undertaken only after the receipt of a valid delivery order or material replenishment plan, which should be documented.

GDP: 12. Dispatch and receipt
GSP: 5. Storage requirement / 7. Dispatch and transport

12.4 Written procedures for the dispatch of pharmaceutical products should be established. Such procedures should take into account the nature of the product as well as any special precautions to be observed. Pharmaceutical products under quarantine will require release for dispatch by the person responsible for quality (see 6.3).

12.5 Records for the dispatch of pharmaceutical products should be prepared and should include at least the following information:

- date of dispatch;
- complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons;
- complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or community clinic);
- a description of the products including, e.g. name, dosage form and strength (if applicable);
- quantity of the products, i.e. number of containers and quantity per container (if applicable);
- applicable transport and storage conditions;
- a unique number to allow identification of the delivery order; and
- assigned batch number and expiry date (where not possible at dispatch, this information should at least be kept at receipt to facilitate traceability).

GDP: 12. Dispatch and receipt
GSP: 5. Storage requirement / 7. Dispatch and transport

12.6 Records of dispatch should contain enough information to enable traceability of the pharmaceutical product. Such records should facilitate the recall of a batch of a product, if necessary, as well as the investigation of counterfeit or potentially counterfeit pharmaceutical products.

12.7 In addition, the assigned batch number and expiry date of pharmaceutical products should be recorded at the point of receipt to facilitate traceability.

12.8 Methods of transportation, including vehicles to be used, should be selected with care, and local conditions should be considered, including the climate and any seasonal variations experienced. Delivery of products requiring controlled temperatures should be in accordance with the applicable storage and transport conditions.

GDP: 12. Dispatch and receipt
GSP: 5. Storage requirement / 7. Dispatch and transport

12.9 Delivery schedules should be established and routes planned, taking local needs and conditions into account. Such schedules and plans should be realistic and systematic. Security risks should also be taken into account when planning the schedules and routes of the delivery.

12.10 Care should be taken to ensure that the volume of pharmaceutical products ordered does not exceed the capacity of storage facilities at the destination.

12.11 Vehicles and containers should be loaded carefully and systematically, where applicable on a first-out/last-in basis, to save time when unloading, prevent physical damage and reduce security risks. Extra care should be taken during loading and unloading of cartons to avoid damage.

GDP: 12. Dispatch and receipt
GSP: 5. Storage requirement / 7. Dispatch and transport

12.12 Pharmaceutical products should not be supplied or received after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.

12.13 Incoming shipments should be examined to verify the integrity of the container/closure system, ensure that tamper-evident packaging features are intact, and that labelling appears intact.

GSP: When required, samples should be taken only by appropriately trained and qualified personnel and in strict accordance with written sampling instructions. Containers from which samples have been taken should be labelled accordingly.

GDP: 13. Transportation and products in transit
GSP: 7. Dispatch and transport

13.1 Products and shipment containers should be secured to prevent or provide evidence of unauthorized access. Vehicles and operators should be provided with additional security, as appropriate, to prevent theft and other misappropriation of products during transportation.

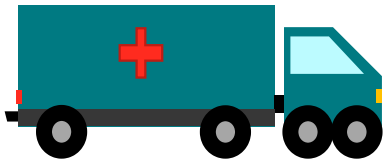
13.2 Product shipments should be secured and include the appropriate documentation to facilitate identification and verification of compliance with regulatory requirements. Policies and procedures should be followed by all persons involved in the transportation, to secure pharmaceutical products.

13.3 The people responsible for the transportation of pharmaceutical products should be informed about all relevant conditions for storage and transportation. These requirements should be adhered to throughout transportation and at any intermediate storage stages..

GDP: 13. Transportation and products in transit
GSP: 7. Dispatch and transport

13.4 Pharmaceutical products should be stored and transported in accordance with procedures such that:

- The identity of the product is not lost.
- The product does not contaminate and is not contaminated by other products.
- Adequate precautions are taken against spillage, breakage, misappropriation and theft.
- Appropriate environmental conditions are maintained, e.g. using cold chain for thermolabile products.

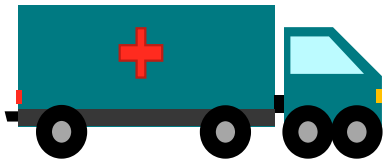


GDP: 13. Transportation and products in transit
GSP: 7. Dispatch and transport

13.5 The required storage conditions for pharmaceutical products should be maintained within acceptable limits during transportation. If a deviation has been noticed during transportation by the person or entity responsible for transportation, this should be reported to the distributor and recipient. In cases where the recipient notices the deviation, it should be reported to the distributor. Where necessary, the manufacturer of the pharmaceutical product should be contacted for information about appropriate steps to be taken.

13.6 Where special conditions are required during transportation that are different from or limit the given environmental conditions (e.g. temperature and humidity) these should be provided by the manufacturer on the labels, monitored and recorded.

13.7 Written procedures should be in place for investigating and dealing with any failure to comply with storage requirements, e.g. temperature Deviations.

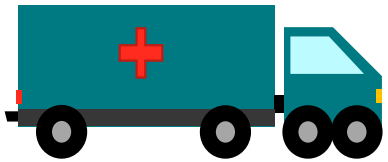


GDP: 13. Transportation and products in transit
GSP: 7. Dispatch and transport

13.8 Physical or other equivalent (e.g. electronic) segregation should be provided for the storage and distribution during transit of rejected, expired, recalled or returned pharmaceutical products and suspected counterfeits. The products should be appropriately identified, securely packaged, clearly labelled and be accompanied by appropriate supporting documentation.

13.9 Products containing narcotics and other dependence-producing substances should be transported in safe and secure containers and vehicles and be stored in safe and secure areas.

13.10 Spillages should be cleaned up as soon as possible to prevent possible contamination, cross-contamination and hazards. Written procedures should be in place for the handling of such occurrences.

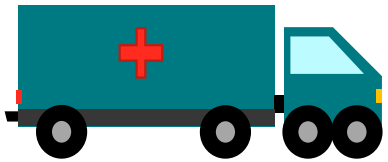


GDP: 13. Transportation and products in transit
GSP: 7. Dispatch and transport

13.11 Transportation and storage of pharmaceutical products containing hazardous substances, such as toxic, radioactive material, and other dangerous pharmaceutical products presenting special risks of abuse, fire or explosion (e.g. combustible or flammable liquids, solids and pressurized gases) should be stored in safe, dedicated and secure areas, and transported in safe, suitably designed, secured containers and vehicles. In addition, the requirements of applicable international agreements and national legislation should be met.

13.12 The interiors of vehicles and containers should remain clean and dry while pharmaceutical products are in transit.

13.13 Packaging materials and shipment containers should be of suitable design to prevent damage of pharmaceutical products during transport. Seal control programmes should be in place and managed properly.

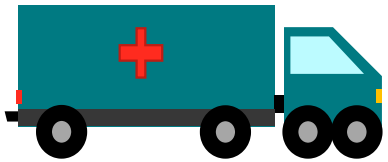


GDP: 13. Transportation and products in transit
GSP: 7. Dispatch and transport

13.14 Drivers of vehicles should identify themselves and present appropriate documentation to demonstrate that they are authorized to transport the load.

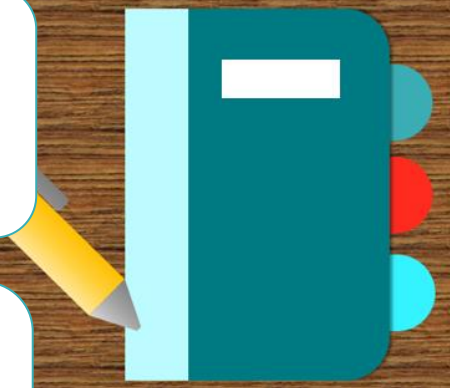
13.15 Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or authority, and investigated.

13.16 Pharmaceutical products in transit must be accompanied by the appropriate documentation



GDP: 14. Documentation

14.1 Written instructions and records which document all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) should be available. Records should be kept for seven years, unless otherwise specified in national or regional regulations.



14.2 Distributors should keep records of all pharmaceutical products received. Records should contain at least the following information:
— date;
— name of the pharmaceutical product;
— quantity received, or supplied; and
— name and address of the supplier.in

14.3 Procedures should be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process. Procedures must be in place for both internally generated documents and those from external sources.

GDP: 14. Documentation

14.4 Documents, and in particular instructions and procedures relating to any activity that could have an impact on the quality of pharmaceutical products, should be designed, completed, reviewed and distributed with care.

14.5 The title, nature and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous. Documents should be laid out in an orderly fashion and be easy to check.

14.6 All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization.

14.7 The nature, content and retention of documentation relating to the distribution of pharmaceutical products and any investigations conducted and action taken, should comply with national legislative requirements. Where such requirements are not in place, the documents should be retained for at least one year after the expiry date of the product concerned.

GDP: 14. Documentation

14.8 The distributor must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

14.9 All records must be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

14.10 Documents should be reviewed regularly and kept up to date. When a document has been revised, a system should exist to prevent inadvertent use of the superseded version.

14.11 Mechanisms should exist to allow for transfer of information, including quality or regulatory information, between a manufacturer and a customer, as well as the transfer of information to the relevant regulatory authority as required.

GDP: 14. Documentation

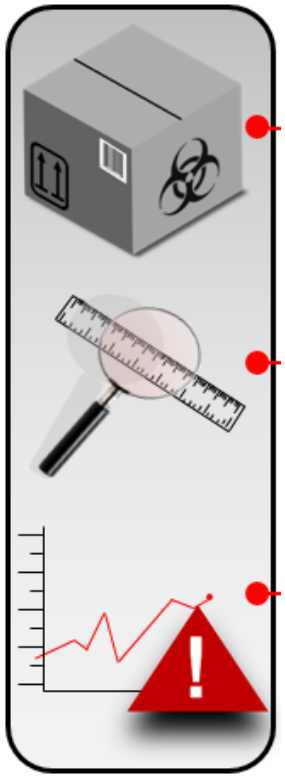
14.12 Records relating to storage of pharmaceutical products should be kept and be readily available upon request in accordance with the WHO guidelines on good storage practice for pharmaceuticals (1).

14.13 Permanent records, written or electronic, should exist for each stored product indicating recommended storage conditions, any precautions to be observed and retest dates. Pharmacopoeial requirements and current national regulations concerning labels and containers should be respected at all times.

14.14 Procedures should be in place for temperature mapping, security services to prevent theft or tampering with goods at the storage facilities, destruction of unsaleable or unusable stocks and on retention of the records.

14.15 Where the records are generated and kept in electronic form, back ups should be maintained to prevent any accidental data loss..

GDP: 15. Repackaging and relabelling



15.1 Repackaging and re-labelling of pharmaceutical products should be limited, as these practices may represent a risk to the safety and security of the supply chain.

15.2 Where they do occur, they should only be performed by entities appropriately authorized to do so and in compliance with the applicable national, regional and international guidelines, i.e. in accordance with GMP principles.

15.3 In the event of repackaging by companies other than the original manufacturer, these operations should result in at least equivalent means of identification and authentication of the products.

15.4 Procedures should be in place for the secure disposal of original packaging.

GDP: 16. Complaints

16.1 There should be a written procedure in place for the handling of complaints. A distinction should be made between complaints about a product or its packaging and those relating to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/or marketing authorization holder should be informed as soon as possible.

16.2 All complaints and other information concerning potentially defective and potentially counterfeit pharmaceutical products should be reviewed carefully according to written procedures describing the action to be taken, including the need to consider a recall where appropriate.

16.3 Any complaint concerning a material defect should be recorded and thoroughly investigated to identify the origin or reason for the complaint (e.g. repackaging procedure or original manufacturing process).

GDP: 16. Complaints

16.4 If a defect relating to a pharmaceutical product is discovered or suspected, consideration should be given to whether other batches of the product should also be checked.

16.5 Where necessary, appropriate follow-up action should be taken after investigation and evaluation of the complaint. There should be a system in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.

16.6 Product quality problems or suspected cases of counterfeit products should be documented and the information shared with the appropriate national and/or regional regulatory authorities.

GDP: 17. Recall
GSP: 8. Product recall

17.1 There should be a system, which includes a written procedure, to effectively and promptly recall pharmaceutical products known or suspected to be defective or counterfeit, with a designated person(s) responsible form recalls. The system should comply with the guidance issued by the national or regional regulatory authority. This procedure should be checked regularly and updated as necessary.

17.2 The original manufacturer and/or marketing authorization holder should be informed in the event of a recall. Information on a recall should be shared with the appropriate national or regional regulatory authority.

17.3 The effectiveness of the arrangements for recalls should be evaluated at regular intervals. All recalled pharmaceutical products should be stored in a secure, segregated area pending appropriate action.

GDP: 17. Recall
GSP: 8. Product recall

17.4 Recalled pharmaceutical products should be segregated during transit and clearly labelled as recalled products. Where segregation in transit is not possible, such goods must be securely packaged, clearly labelled, and be accompanied by appropriate documentation.

17.5 The particular storage conditions applicable to a pharmaceutical product which is subject to recall should be maintained during storage and transit until such time as a decision has been made regarding the fate of the product in question.

17.6 All customers and competent authorities of all countries to which a given pharmaceutical product may have been distributed should be informed promptly of any intention to recall the product because it is, or is suspected to be, defective or counterfeit.

GDP: 17. Recall
GSP: 8. Product recall

17.7 All records should be readily available to the designated person(s) responsible for recalls. These records should contain sufficient information on pharmaceutical products supplied to customers (including exported products).

17.8 The progress of a recall process should be recorded and a final report issued, which includes a reconciliation between delivered and recovered quantities of products.

17.9 When necessary emergency recall procedures should be implemented.

GDP: 18. Returned products
GSP: 6. Returned goods

18.1 A distributor should receive pharmaceutical product returns or exchanges pursuant to the terms and conditions of the agreement between the distributor and the recipient. Both distributors and recipients should be accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of counterfeit products.

18.2 The necessary assessment and decision regarding the disposition of such products must be made by a suitably authorized person. The nature of the product returned to the distributor, any special storage conditions required, its condition and history and the time elapsed since it was issued, should all be taken into account in this assessment. Where any doubt arises over the quality of a pharmaceutical product, it should not be considered suitable for reissue or reuse.

18.3 Provision should be made for the appropriate and safe transport of returned products in accordance with the relevant storage and other requirements.

GDP: 18. Returned products
GSP: 6. Returned goods

18.4 Rejected pharmaceutical products and those returned to a distributor should be appropriately identified and handled in accordance with a procedure which involves at least:
— the physical segregation of such pharmaceutical products in quarantine in a dedicated area; or

— other equivalent (e.g. electronic) segregation

18.5 Provision should be made for the appropriate and safe transport of rejected pharmaceutical products prior to their disposal.

18.6 Destruction of pharmaceutical products should be done in accordance with international, national and local requirements regarding disposal of such products, and with due consideration to protection of the environment.

18.7 Records of all returned, rejected and/or destroyed pharmaceutical products should be kept for a predetermined period.

GDP: 19. Counterfeit pharmaceutical products

19.1 Counterfeit pharmaceutical products found in the distribution chain should be kept apart from other pharmaceutical products to avoid any confusion. They should be clearly labelled as not for sale and national regulatory authorities and the holder of the marketing authorization for the original product should be informed immediately.

19.2 The sale and distribution of a suspected counterfeit pharmaceutical product should be suspended and the national regulatory authority notified without delay.

19.3 Upon confirmation of the product being counterfeit a formal decision should be taken on its disposal, ensuring that it does not re-enter the market, and the decision recorded.

GDP: 20. Importation

20.1 Consideration should be given to the WHO guidelines on import procedures for pharmaceutical products (6). The following aspects should be given particular attention.

20.2 The number of ports of entry in a country for the handling of imports of pharmaceutical products should be limited by appropriate legislation. Such ports could be designated by the state.

20.3 The chosen port(s) of entry should be those most appropriately located and best equipped to handle imports of pharmaceutical products.

20.4 At the port of entry, consignments of pharmaceutical products should be stored under suitable conditions for as short a time as possible.

GDP: 20. Importation

20.5 All reasonable steps should be taken by importers to ensure that products are not mishandled or exposed to adverse storage conditions at wharves or airports.

20.6 Where necessary, persons with pharmaceutical training should be involved with the customs procedures or should be readily contactable.

20.7 The WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce should be used to provide data regarding quality assessment of imported pharmaceutical products.

20.8 Customs, enforcement agencies and regulatory agencies responsible for supervision of pharmaceutical products should establish means for cooperation and information exchange in order to prevent importation of counterfeit pharmaceutical products.

GDP: 21. Contract activities

21.1 Any activity relating to the distribution of a pharmaceutical product which is delegated to another person or entity should be performed by parties appropriately authorized for that function and in accordance with the terms of a written contract.

21.2 The contract should define the responsibilities of each party including observance of the principles of GDP and relevant warranty clauses. It should also include responsibilities of the contractor for measures to avoid the entry of counterfeit medicines into the distribution chain, such as by suitable training programmes.

21.3 All contract accepters should comply with the requirements in these guidelines.

21.4 Subcontracting may be permissible, under certain conditions and subject to the written approval of the contract giver; however, the subcontractors should be authorized for the function.

21.5 Contract accepters should be audited periodically.

GDP: 22. Self-inspection

22.1 The quality system should include self-inspections. These should be conducted to monitor implementation and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures.

22.2 Self-inspections should be conducted in an independent and detailed way by a designated, competent person.

22.3 The results of all self-inspections should be recorded. Reports should contain all observations made during the inspection and, where applicable, proposals for corrective measures. There should be an effective follow-up programme. Management should evaluate the inspection report and the records of any corrective actions taken.

Reflective quiz

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