Mitti

GDP Audit Compliance Checklist

31 Aug 2023 / Shay Kelly

Complete

Score	182 / 183 (99.45%)	Flagged items	1	Actions	1

Conducted on	31 Aug 2023 14:00 PST
Prepared by	Shay Kelly
Location	Rhode Island, USA (41.5800945, -71.4774291)

Flagged items & Actions

1 flagged, 1 action

Flagged items

1 flagged, 1 action

Quality System

Quality manual or equivalent documentation approach established

Fail

While we have a quality manual established, updates for this year haven't been finalized and documented in our SOPs. Even if all stakeholders in our organization are well aware of such updates and are implementing them in our operations, the quality manual must still be kept updated.

[2022 Q4 Update] Quality Manual.pdf

To do | Assignee: SafetyCulture Staff | Priority: Low | Due: 7 Sep 2023 14:19 PST | Created by: SafetyCulture Staff

Follow up with project owners and key teams on updating the quality manual.

Other actions

0 actions

Quality System

1 flagged, 1 action, 3 / 4 (75%)

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Fail

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[2022 Q4 Update] Quality Manual.pdf

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Follow up with project owners and key teams on updating the quality manual.

Change control system in place for changes to critical processes

Pass

Appropriate corrective and preventive actions (CAPA) are taken to correct deviations and prevent them

Pass

System for Management Review in place

Pass

Personnel	11 / 11 (100%)
Organisational structure of the distributor is defined in an organisational chart. The responsibility, role and interrelationships of all personnel is clearly indicated	Pass
Responsibilities and roles of employees working in key positions is defined in written job descriptions, incl. deputyship arrangements	Pass
All personnel involved in wholesale distribution activities is qualified in GDP requirements	Pass
Training includes aspects of product identification and avoidance of falsified medicines entering the supply chain	Pass
Specific training is provided where indicated (e.g. handling of hazardous products, radioactive materials as well as products presenting special risks of abuse, narcotics or psychotropic substances, or temperature sensitive products)	Pass
Personnel receives initial and continuing training relevant to their tasks, based on written standard operating procedures (SOPs) according to a written training programme	Pass
The practical effectiveness of training is periodically assessed and documented	Pass
Responsible Person (RP) appointed	Pass
Written job description for RP in place	Pass
The qualifications of the RP meet the conditions provided by the legislation of the Member State concerned	Pass
Responsible Person fulfils relevant obligations	Pass

Premises and Equipment	33 / 33 (100%)
Outsourcing activities	1 / 1 (100%)
A contract is in place where premises are not directly operated by the wholesale distributor and the premises are covered by a wholesale distribution authorisation	Pass
Layout of premises:	6 / 6 (100%)
Unauthorised access to all areas of the authorised premises is prevented	Pass
Receiving and dispatch bays protect products from prevailing weather conditions	Pass
Segregated areas are designated for the storage of any product suspected of falsification, returned product, rejected product, product awaiting disposal, recalled product and medicinal products not intended for the EU market	Pass
Radioactive materials other hazardous products and products presenting special risks of fire or explosion are stored in a dedicated area(s) with appropriate safety and security measures	Pass
There is adequate separation between the receipt and dispatch areas and storage areas	Pass
Rest, wash and refreshment rooms for employees are adequately separated from the storage areas	Pass
Hygiene	6 / 6 (100%)
Procedures relating to personnel hygiene like health, hygiene and clothing are established and observed	Pass
Storage of food, drink, smoking materials or medication for personal use in the storage areas is prohibited	Pass
Cleaning instructions and records are in place	Pass
Premises and storage facilities are clean and free from litter and dust	Pass
Facilities are designed and equipped so as to afford protection against the entry of insects, rodents or other animals.	Pass
A preventive pest control programme is in place	Pass

Temperature and Environment Control	8 / 8 (100%)
Suitable equipment and procedures are in place to ensure adequate control of the environment	Pass
Storage areas are temperature mapped	Pass
Temperature monitoring equipment is located according to the results of the mapping exercise	Pass
Controls are adequate to maintain all parts of the relevant storage area within defined temperature, humidity or light parameters	Pass
Equipment used to control or to monitor the environment, are calibrated and their correct operation and suitability is verified at defined intervals by the appropriate methodology	Pass
Appropriate alarm systems are in place to provide alerts when there are deviations from pre- defined storage conditions	Pass
Alarm levels are appropriately set	Pass
Alarms are regularly tested	Pass
Equipment	7 / 7 (100%)
Planned preventive maintenance is in place for key equipment	Pass
Calibration of equipment is traceable to a primary standard	Pass
Adequate records of repair, maintenance and calibration activities for key equipment is made and the results are retained	Pass
Extent of validation and qualification activities are determined by a documented risk assessment approach and are documented in a plan	Pass
Systems are validated/qualified prior to implementation and after any significant changes or upgrades to ensure correct installation and operation	Pass
Evidence of satisfactory validation/qualification and acceptance of a process or piece of equipment is produced and approved by appropriate personnel	Pass
Re-qualification following repair or maintenance is considered dependant on the scope of the changes made.	Pass

Such decisions are justified utilising a risk based approach.	
Computer Systems	5 / 5 (100%)
Detailed written descriptions of the systems are available (describing the principles, objectives, security measures and scope of the system and the main features, how the computerised system is used and the way it interacts with other systems)	Pass
Data is entered into the computerised system or amended only by persons authorised to do so	Pass
Data is secured by physical or electronic means against wilful or accidental damage	Pass
Data is protected by backing up at regular intervals	Pass
Back up data is stored for a period stated in national legislation but at least 5 years at a separate, secure location	Pass

Documentation	14 / 14 (100%)
Documents are retained for a period stated in national legislation but at least 5 years at a separate, secure location	Pass
SOPs	6 / 6 (100%)
SOPs are reviewed regularly and kept up-to-date	Pass
SOPs are approved, signed and dated by appropriate authorised persons	Pass
Version control is applied to SOPs	Pass
Superseded SOP versions are archived	Pass
Inadvertent use of the superseded versions is prevented	Pass
Superseded or obsolete SOPs are removed from workstations	Pass
Records	7 / 7 (100%)
For any transaction in medicinal products received, supplied or brokered, records are kept either in the form of purchase/sales invoices, delivery slips, or on computer or in any other form	Pass
Records include the following information:	
o Date	Pass
o name of the medicinal product	Pass
o quantity received, supplied or brokered	Pass
o name and address of the supplier, broker or consignee, as appropriate	Pass
o batch number where required	Pass
Distribution records contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and quantities delivered), including those for exported products and medicinal product samples	Pass

Operations	51 / 51 (100%)
All medicinal products distributed in the have a marketing authorisation granted by the EU or by a Member State	Pass
For distributors, not being the marketing authorisation holder: the marketing authorisation holder and the competent authority in the Member State - to which the medicinal product is imported of his intention - is notified of importation	Pass
For products being exported: a wholesale distribution authorisation or a manufacturing authorisation is in place. This is also the case if the exporting wholesale distributor is operation from a free zone.	Pass
Supplier Qualification	14 / 14 (100%)
All supplies of medicinal products are obtained only from persons/organisations who are in possession of a wholesale distribution authorisation, or who are in possession of a manufacturing authorisation which covers the product in question	Pass
When medicinal product is obtained from another wholesale distributor: compliance with the principles and guidelines of good distribution practices of the supplying wholesale distributor is verified	Pass
When medicinal product is obtained from manufacturer or importer: manufacturer or importer holds a manufacturing authorisation	Pass
When medicinal product is obtained from a broker: broker is registered and complies with the requirements in Chapter 10 of the Commission Guidelines on Good Distribution Practice of Medicinal Products for Human Use	Pass
The purchase of medicinal products is controlled by written procedures	Pass
The supply chain of medicinal products is known and documented	Pass
Appropriate qualification is performed prior to any procurement	Pass
Qualification and approval of suppliers is controlled by a standard operating procedure	Pass
The results of qualification and approval of suppliers are documented	Pass

The results of qualification and approval of suppliers are periodically rechecked	Pass
Qualification and approval of new suppliers: A risk based approach is used considering	
o searches for the new supplier's reputation or reliability and its authorised activities	Pass
o possible target of falsification	Pass
o large offers of medicinal product which are generally only available in limited quantities	Pass
o out of range prices	Pass
Qualification of Customers	5 / 5 (100%)
Medicinal products are only supplied to persons/organisations who are themselves in possession of a distribution authorisation or who are authorized or entitled to supply medicinal products to the public	Pass
Qualification of customers and periodic re-checks include:	
o requesting copies of customer's authorisations	Pass
o verifying status on an authority website	Pass
o requesting evidence of qualifications or entitlement according to national legislation.	Pass
Qualification of customers are appropriately documented	Pass
Receipt of Goods	8 / 8 (100%)
When receiving medicinal products from third countries for the purpose of importation: manufacturing/import authorisation is in place	Pass
It is ensured that that the arriving consignment is correct, the medicinal products originate from approved suppliers and have not been damaged or altered during transportation	Pass
Medicinal products which require special storage or security measures, are transferred to appropriate storage facilities immediately after appropriate checks have been conducted	Pass
In the event of any suspicion of falsified medicinal product, the batch is immediately segregated	Pass

In the event of any suspicion of falsified medicinal product, the batch is immediately reported to the national competent authority	Pass
In the event of any suspicion of falsified medicinal product, the batch is immediately reported to the marketing authorisation holder (where applicable)	Pass
Batches of medicinal products intended for the Union market are only transferred to saleable stock before assurance has been obtained that they are authorised and released for sale for the market in question	Pass
Incoming containers of medicinal products are cleaned, if necessary, before storage	Pass
Storage	9 / 9 (100%)
Medicinal products are stored separately from other products	Pass
Medicinal products are protected from harmful effects of light, temperature, moisture or other external factors.	Pass
Particular attention is paid to products where specific storage conditions are required	Pass
Stock rotation according to the expiry dates of batches of medicinal products is performed ("first expired first out" –FEFO- basis.)	Pass
Medicinal products beyond their expiry date or shelf life are withdrawn immediately from saleable stock either physically or through other equivalent electronic segregation	Pass
Physical removal of unsuitable stock is performed regularly	Pass
Medicinal products are not stored directly on the floor	Pass
Stock inventories are performed regularly (timings are defined using a risk based approach)	Pass
Inventory irregularities are investigated and documented	Pass
Segregation of Goods	2 / 2 (100%)
Segregation is provided for the storage of rejected, expired, recalled or returned products and suspected falsified medicinal products	Pass

Any system replacing physical segregation such as electronic segregation based on a computerised system provides equivalent security and is validated	Pass
Destruction of obsolete Goods	3 / 3 (100%)
Medicinal products intended to be destroyed are kept separately and handled in accordance with a written procedure.	Pass
Destruction of medicinal products is in accordance with national or international requirements for disposal of such products	Pass
Records of all destroyed medicinal products are maintained	Pass
Picking and packing	4 / 4 (100%)
Controls are in place to ensure the correct product is picked	Pass
Products have an appropriate remaining shelf life when picked	Pass
Products are picked on a "first expired first out" (FEFO) basis	Pass
Packing is adequate to maintain the storage conditions of the product during transport	Pass
Export (exceptions)	3 / 3 (100%)

The rules for wholesale distribution apply in their entirety in the case of export of medicinal products, with the following exceptions:

a. The medicinal product does not have to be covered by a marketing authorisation of the EU or a Member State;	Pass
b. The customer does not have to be holder of a distribution authorisation;	Pass
c. Moreover, where the medicinal product intended for exportation has been obtained directly from another third country, without the product being prior to that placed on the market (ie without prior import), the supplier does not have to bear a wholesale distribution authorisation.	Pass

Complaints, Returns & Recalls	30 / 30 (100%)
Complaints	7 / 7 (100%)
A written procedure is in place for the handling of complaints	Pass
Distinction is made between complaints about the quality of a medicinal product and those relating to distribution	Pass
A person is appointed for handling the complaints with sufficient supporting personnel	Pass
Any complaint concerning a potential product defect or a potential falsified product is recorded with all the original details and investigated	Pass
The national competent authority is notified without delay in case of a potential product defect or a potential falsified product	Pass
Any product distribution complaint is thoroughly investigated	Pass
Appropriate follow-up actions are taken after investigation and evaluation of the complaint	Pass
Returned Medicinal Products	14 / 14 (100%)
Written procedures are in place for the handling and acceptance of returned medicinal products	Pass
Medicinal products which have left the premises of the distributor are only returned to saleable stock if:	
o the medicinal products are in their unopened and undamaged secondary packaging and in good condition	Pass
o medicinal products returns from a customer not holding a wholesale distribution are returned within five days of original dispatch;	Pass
o it is demonstrated that the medicinal products have been transported, stored and handled under proper specified/predefined conditions;	Pass
o they have been examined and assessed by a sufficiently trained and competent person authorised to do so;	Pass
o the distributor has reasonable evidence that the product was supplied to that customer	Pass

o the batch number of the dispatched product is known	Pass
o a copy of the original delivery note is attached	Pass
o there is no reason to believe that the product has been falsified	Pass
o there is evidence that the product has been stored within the authorised storage conditions throughout the entire time	Pass
A risk assessment is performed taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched	Pass
Returned medicinal products are kept segregated from saleable stock until a decision is taken regarding their disposition	Pass
Products returned to saleable stock are placed that the "first expired first out" (FEFO) system operates effectively	Pass
All handling of returned medicinal products including their return to saleable stock or disposal are approved by the Responsible Person and recorded	Pass
Suspected falsified Medicinal Products	4 / 4 (100%)
The staff is aware of the risks of falsified medicinal products entering the supply chain	Pass
A procedure is in place describing immediate information of the competent authority and, where applicable, the marketing authorisation holder of the medicinal products they identify as falsified or suspect to be falsified	Pass
Any suspected falsified medicinal products found in the supply chain is immediately physically and securely segregated from legitimate medicinal products	Pass
All relevant activities are recorded	Pass
Medicinal Product Recalls	5 / 5 (100%)
There is a written procedure for the management of recalls	Pass
The management of recalls and its effectiveness is periodically tested and evaluated (Mock Recall)	Pass
Any recall operation is recorded at the time it is carried out	Pass

The distribution records are readily available to the person(s) responsible for the recall	Pass
The progress of a recall process is recorded and a final report issued (including reconciliation between the delivered and recovered quantities of the medicinal products)	Pass

Transportation	40 / 40 (100%)
Vehicles and equipment	12 / 12 (100%)
Required storage conditions are maintained during transportation	Pass
Vehicles and equipment are suitable and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind	Pass
Procedures are in place for the operation and maintenance of all vehicles and equipment, including cleaning and safety precautions	Pass
Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) are used to ensure correct transport conditions	Pass
If refrigerated vehicles are used temperature mapping is performed under representative conditions including seasonal variations	Pass
Equipment used for temperature monitoring during transport within vehicles and/or containers, is maintained and calibrated at regular intervals at least once a year	Pass
If cool-packs are used in insulated boxes, they are located such that the product does not come in direct contact with the cool-pack	Pass
If cool-packs are used in insulated boxes, staff is trained on the procedures for assembly of the insulated boxes (seasonal configurations) and on the reuse of cool-packs.	Pass
The process for delivery of sensitive products and control of seasonal temperature variations is described in written procedures	Pass
Procedures cover management of unexpected occurrences such as vehicle breakdown or non- delivery.	Pass
A procedure is in place for investigating and handling temperature excursions	Pass
Where non-dedicated vehicles and equipment are used procedures are in place to ensure that the quality of the medicinal product will not be compromised	Pass
Delivery	4 / 4 (100%)

Delivery drivers (including contract drivers) are trained in the relevant areas of GDP	Pass
Deliveries are made directly to the address stated on the delivery note	Pass
Deliveries are handed into the care of the consignee.	Pass
Deliveries are not left on alternative premises	Pass
Transportation hubs	4 / 4 (100%)
When using transportation hubs, has the maximum time limit for storage in these locations been defined	Pass
When using transportation hubs, premises are audited and approved prior to deployment	Pass
is there a specification for transport hubs	Pass
is there a list of Hubs used by the transportation company?	Pass
Deviations	2 / 2 (100%)
Deviations are reported to the distributor and recipient	Pass
Where necessary in the case of deviations, the manufacturer of the medicinal product is contacted for information about appropriate steps to be taken	Pass
Containers, packaging and labelling	15 / 15 (100%)
Container and packaging is selected based on:	
o the storage and transportation requirements	Pass
o the space required for the amount of medicines	Pass
o the anticipated external temperature extremes	Pass
o the estimated maximum time for transportation including transit storage at customs	Pass
o the validation status of the packaging and shipment containers	Pass
The containers in which medicinal products are shipped are sealed	Pass

A document is enclosed to ascertain the following:

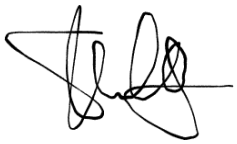
o Date	Pass
o name and pharmaceutical form of the medicinal product	Pass
o batch number at least for products bearing the safety features, where required	Pass
o quantity supplied	Pass
o name and address of the supplier	Pass
o name and delivery address of the consignee (actual physical storage premises, if different)	Pass
o applicable transport and storage conditions	Pass
Containers bear labels providing sufficient information on handling and storage requirements and precautions	Pass
Containers bear labels enable identification	Pass
Transportation of Products requiring special Conditions	3 / 3 (100%)
Requirements laid down by the concerned Member States are met	Pass
Additional control systems in place	Pass
Transportation is performed in safe, dedicated and secure containers and vehicles	Pass

Completion

Final observations recommendations

While our GDP implementation fairly passed our standards, we only have one recommended action to be taken urgently. This is to address the updates needed on our quality manual.

Sign off



Shay Kelly
31 Aug 2023 14:34 PST

Media summary

File summary

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