PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

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Questions & Answers document regarding the PIC/S GDP Guide (PE 011-1)

by the PIC/S Expert Circle on GDP

Editor: PIC/S Secretariat
e-mail: info@picscheme.org
web site: https://www.picscheme.org

GDP Guide - Chapter Number & Title	Paragraph Number	Question	Answer*
Chapter 1, Quality Management, Principle	1.1	Is a quality management system necessary for a one-person company?	Yes, See also 1.2.5.
Chapter 1, Quality Management, Quality System	1.2.1	Does the quality system need to be in written format?	Yes, in paper or electronic form. See also Chapter 4.
Chapter 1, Quality Management, Quality System	1.2.2	What is a quality manual?	The quality manual defines the philosophy and policies of the Quality Management System (QMS). E.g., includes mission and vision of the company and organizational chart. Defines and displays the different documents that are used in the QMS, e.g., SOP, work instructions etc.
Chapter 1, Quality Management, Quality System	1.2.2	Is a quality manual necessary?	Yes. The content of any quality manual should be proportionate to the complexity and size of an individual organisation.
Chapter 1, Quality Management, Quality System	1.2.2	How is the effectiveness of the quality system monitored?	The effectiveness of the QMS can be measured in many specific ways. This list is not exhaustive, however, may include but is not limited to deviation and CAPA analysis, the impact of quality risk management functions, proactive measures taken such as preventive maintenance, training and retraining, periodic inspections, etc., the result of self-inspections, any relevant comments or observations made by the result of self-inspections, any relevant comments or observations made by

* References in this column refer to the PIC/S GDP Guide (PE 011-1)

			subject matter experts, an assessment of Key Performance Indicators (KPIs). See also 1.4.1 ii.
Chapter 1, Quality Management, Quality System	1.2.3	Can the designated Responsible Person (RP) also be the Licence Holder/Director of the wholesaler?	There are some instances where both posts may be fulfilled by the same person, however, this is subject to national legislation. Where the same person fulfils both functions, the company should ensure that conflicts of interest have been appropriately declared and controls are in place to minimise the impact.
Chapter 1, Quality Management, Quality System	1.2.6	What is meant by change control system?	A change control system is a formalised process for the management of all changes to the business that may impact on the quality of medicinal products. Change control systems should effectively control the identification, evaluation, risk-assessment, planning, implementation, verification, and approval of changes in accordance with risk management practices to ensure that changes do not negatively impact operations or compromise product quality.
Chapter 1, Quality Management, Management of outsourced Activities	1.3	Is the wholesaler responsible for ensuring GDP compliance of the outsourced activity?	The contract giver (wholesaler) is ultimately responsible for the compliance of all activities they choose to outsource, and which are conducted on their behalf, and responsible for assessing whether the

			contract acceptor is capable of undertaking activities appropriately, see 7.2.1
Chapter 1, Quality Management, Management Review and Monitoring	1.4.1	What is a good periodic review frequency?	An appropriate review frequency will vary on many factors and there are no specific minimum criteria as to what is considered a good periodic review frequency. A company should formulate their own rationale as to the periods of time left between reviews. Factors to consider may include but are not limited to: activities undertaken by the company, volume of activities undertaken, types of medicines handled and complexity of operations. Any review period should be justified on a risk basis, but not exceed 12 months at the lowest areas of risk.
Chapter 1, Quality Management, Management Review and Monitoring	1.4.2	What is a timely manner?	It should be defined in the quality system with a rationale.
Chapter 2, Personnel, General	2.2.2	Does the organizational structure of the wholesaler have to be separated from the rest of the company?	No.
Chapter 2, Personnel, General	2.2.2	Do the roles, responsibilities etc. must be described in the organizational chart?	Job Titles should be included within an organizational chart, however, generally responsibilities will not encompass this document. Refer to 2.2.3 for roles and responsibilities of key persons.
Chapter 2, Personnel, General	2.2.2	Does name of personnel acquiring the job titles have to be described/mentioned in the organizational chart?	No, there is no requirement to name specific persons on organization charts, however, job descriptions, curriculum vitae's and

			where required, qualifications, of persons in these posts should be available on inspection.
Chapter 2, Personnel, General	2.2.3	What are key positions?	Designated responsible persons appointed by the management.
Chapter 2, Personnel, Designation of responsibilities	2.3.1	Are the personnel above the same as the responsible persons in 1.2.3.?	Key positions will include responsible persons (RPs).
Chapter 2, Personnel, Designation of responsibilities	2.3.2	Can a delegation be permanent?	No. Whereas a duty may be delegated within a job description on what may appear to be a practical permanent basis, the ultimate duty is still the responsibility of the RP and should be treated as such with appropriate oversight.
Chapter 2, Personnel, Designation of responsibilities	2.4.1	Is it acceptable to outsource staffing and personnel to other warehouses?	Yes, temporary or agency staff may be utilised to fulfil certain GDP functions. In some instances, these will qualify as outsourced activities for a specific post, such as the RP, and should be managed as such. In other instances where temporary staff are employed, although acceptable a company must ensure staff are appropriately experienced, qualified, and that GDP training is undertaken prior to commencement of duties.
Chapter 3, Premises and Equipment	3.1	What is meant with “acceptable temperature limits”?	In accordance with the storage conditions on the outer labelling of the products. If no conditions are stated on the labelling, the wholesaler must clarify any expectations with their Licensing or Competent Authority

			and justify the storage conditions.
	3.3.2	Should initial temperature mapping be done for each storage area?	Yes, with exception if justified, for example for very small storage areas at room temperature of no more than a few meters squared. This may, for example, consist of a shelf within a small storage area used for GDP functions. This exemption should not be applied to large spaces with small GDP storage areas, where it is likely that the wider environment may have an impact on GDP. Where this exemption is utilised, the company should still consider other methods of validation where appropriate. . See last paragraph 3.3.2.
	3.3.2	For products required to be frozen, are freezers required to be temperature mapped?	All equipment storing cold chain or frozen products must undergo qualification. This will include a form of temperature mapping.
	3.3.1	Is it acceptable to use Mean Kinetic Temperature key parameter in temperature monitoring?	No, not for routine monitoring and control of the storage area. The application of Mean Kinetic Temperature (MKT) to temperature monitoring of wholesale products is only appropriate where an acceptable MKT value is provided by the MA holder for a specific product, and the recording of temperature can be confirmed to be consistent and complete from the moment of leaving the manufacturer's

			premises. In practice the application of MKT fails where a complete chain of temperature recording cannot be allocated to a specific consignment of a product. Attempts to apply MKT have been proposed by wholesalers as an alternative to having adequate temperature control within their warehouses as well as attempting to downgrade the impact of temperature excursions. The use of MKT in the wholesale environment without robust supporting information and methodology is therefore discouraged.
Chapter 4, Documentation, General	4.2.1	What is readily available/retrievable?	Documents including procedures and records should be available or easily accessible to the personnel doing the operation described in the document.
Chapter 4, Documentation, General	4.2.4	Who is a designated person?	The authority to approve documents should be authorized by management and documented as such. Where these authorisations pertain to Responsible Person (RP) functions, this should be appropriately documented.
Chapter 4, Documentation, General	4.2.5	What is “where appropriate “?	The reason should be clearly stated, unless obvious. Inspectors should refer to the PIC/S “Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments” (PI 041-1)

Chapter 4, Documentation, General	4.2.8	What is meant by kept up to date?	SOP should reflect current regulatory requirements, local practices, and company specific operations.
Chapter 5, Operations, Qualification of Suppliers	5.2.3	What is meant by periodically rechecked?	Periodic assessments of bona fides should be undertaken on a risk basis. This may include but is not limited to: functions undertaken by the company, reliability of the organisation, any history of regulatory action, length of time in business and types of medicines offered. Where additional guidance may be published, such as regulatory suspension or revocation notice, these should be examined on the frequency published by the Licencing or Competent Authority.
Chapter 5, Operations, Qualification of Customers	5.3.2	Does authorization for distribution mean holding a licence?	Yes, however, it may also include other authorisations or entitlements. Relevant national legislation should be reviewed to ascertain entitlements.
Chapter 5, Operations, Qualification of Customers	5.3.3	Are there any best practices for the investigation of “unusual sales patterns”?	It is recommended to check for unusual repetition of orders, sudden increases of orders, and unusually low prices.
Chapter 5, Operations, Storage	5.5.1	What are “healthcare products “?	Wholesalers should refer to relevant national legislation.
Chapter 5, Operations, Storage	5.5.3	What are “appropriate storage conditions”?	As defined on the outer packaging of the product. Where no conditions are cited, the company should ascertain storage conditions from Licencing or Competent Authorities. Where no guidance exists, the manufacturer should

			be consulted for further guidance.
Chapter 5, Operations, Storage	5.5.7	What is meant by stock irregularities?	Unexplained stock anomalies.
Chapter 5, Operations, Picking	5.5.6 and 5.7	What is “near expiry date” or “ appropriate remaining shelf life”?	There is sufficient shelf life left that based on the time of supply to the pharmacy/retailer and then the patient, the product will still be within shelf life when it is consumed.
Chapter 6, Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls, Returned Medicinal Products	6.3.2	Must all conditions be met in this section to return to saleable stock?	Yes
Chapter 6, Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls, Returned Medicinal Products	6.3.2 ii	What is acceptable time limit for return to saleable stock?	10 days, or in accordance with the relevant national legislation.
Chapter 7, Outsourced Activities, Contract Giver	7.2.2	Is the audit required to be physical on-site audit?	Most initial audits should be conducted on site, with any consideration of ongoing remote or physical assessments considered because of the audit and on a risk basis. However, it is recognised there are some circumstances where this is not possible to conduct on-site audits immediately, such as during the Covid-19 pandemic. In this instance, risk-based principles and justifications should be applied and a physical audit should be completed as soon as practicable.
Chapter 7, Outsourced Activities, Contract Giver	7.2.2	What is the requirement of the person who conduct the on-site audit?	The person should have knowledge and expertise in the contracted operation.
Chapter 8, Self-Inspections	8.2.2	Are their circumstances where external audits are	No, a self-inspection must always be

		acceptable as a substitute to self-inspection?	undertaken by the company and external audits, or regulatory inspections are not acceptable replacements for this function, however, a company may take into consideration any external audits conducted by subject matter experts when assessing the scope of their self-inspections.
Chapter 9, Transportation	9.2.1	Do set temperature or humidity limits/values as required by the products' labelling have to be continuously monitored during transportation and the data be available for review, if so, required by the MAH, and/or inspector or any other relevant party	Whereas GDP does not specifically cite continuous monitoring as a requirement, a company must be able to demonstrate that storage conditions as defined on the product have been maintained. Practically, it is challenging to demonstrate goods have been transported in label conditions without continuous monitoring for longer journeys, however, may be practical for short journeys outside of climatic extremes. Local legislative requirements pertaining to the monitoring or management of relative humidity where applicable should also be considered.
Chapter 9, Transportation	9.2.2	Who is responsible to inform the Manufacturer Authorisation Holder (MAH) or the manufacturer in case of any significant deviations (e.g. temperature excursions)?	The MAH or manufacturer does not need to be made aware by default; for example, if goods are to be destroyed following an excursion, there is no need to report this unless local legislative provisions to do so are in place. However, when

			investigating temperature deviations, MAHs or manufacturers may be consulted to assess the impact on product quality. Where such deviations are identified, this is the responsibility of the distributing wholesaler. It is important to note that stability data in itself does not justify the use of medicines subject to temperature excursions due to lack of accumulative data and the impact of such excursions must be considered proportionately Local legislative requirements pertaining to the monitoring or management of relative humidity where applicable should also be considered.
Chapter 9, Transportation	9.2.9	Should the transportation company hold a wholesaler's licence?	Where required by the national legislation.
Chapter 9, Transportation	9.2.9	When the products are stored by the transportation company, during transportation, how long can they be stored before a wholesaler's licence is necessary?	As required by the national legislation. An organisation should ensure that appropriate assurances are in place to ensure the quality of medicinal products is maintained from point of dispatch regardless of localised licencing requirements of entities, such as transport companies.
Chapter 9, Transportation, Products requiring controlled conditions	9.4.5	What is the definition of the customer?	The recipient of the product, e.g., wholesaler, pharmacy.