GDP Questionnaire - Transportation

An excerpt from the new [GDP Questionnaire]

by Simone Ferrante

	Good Distribution Practice Audit Questionnaire	checked*	EU GDP MP	EU GDP API	EU GMP	WHO GDP	EN ISO 13485
10.	**Transportation**						
10.1	**First documentation check:** What are the specifications for loading the goods onto the means of transport (vehicle, container)? Were the type and scope of requirements determined on the basis of the QRM? Is it ensured that the products are not exposed to any conditions that could affect their quality or integrity? What measures are taken to ensure this? Is the effectiveness of the measures monitored? Is a check carried out to see if the driver is authorized for the transport? **Tour (premises/warehouse):** *Observe the loading operation:* • Are the goods adequately secured for transport? • Is the possibility of containers or pallets toppling eliminated? • Are the goods adequately protected against vibration? • What security precautions have been taken with regard to theft? **Second documentation check:** Are records kept on the loading operation? Have products been damaged due to inadequate securing of the load or have packages disappeared? How often does this happen? How were these occurrences documented and what actions were taken?		9.1 9.2	2.1 6.14	1.3 1.8ii, vii	8.8 8.11 11.1 12.8 12.11 13.14-13.16	7.5.1 7.5.8 7.5.9 7.5.11 8.3 8.5
10.2	**First documentation check:** How is it guaranteed that the rerquired storage conditions are complied with on the entire transport route? *EU-GDP Guidelines: storage conditions = transport conditions. Declarations on the outer packaging of the medicinal product or manufacturers' instructions must be observed and adhered to. The conditions stipulated by the manufacturer apply to APIs.* **Tour (premises/warehouse):** – **Second documentation check:** –		9.1 9.2	6.14	1.4xvi 5.2	11.3 13.5	7.5.1 7.5.11
10.3	**First documentation check:** How is it ensured that the temperature conditions are maintained within acceptable limits during transportation? When, how and where is the temperature measured? Is the temperature measured near the product? What happens if a particular temperature value is exceeded or undercut? Is there an alarm, for example? Who is informed about temperature deviations? Can the temperature be returned to a value within the acceptance range quickly enough? How are temperature deviations documented and investigated? How are dealers and recipients informed thereof? Is the procedure on how to behave in the event of temperature deviations described in an SOP? Are the responsible employees appropriately trained?		9.1 9.2 9.4	6.14	1.4ix 1.8iii, iv 8.7 8.8 Annex 15	10.1 10.2 10.6 11.1 11.3 12.8 13.3-13.7	6.2 6.3 7.5.1 7.6

	Tour (premises/warehouse): Are the vehicles and the equipment suitable for the respective application?						
	How is the means of transport (vehicle, container) equipped?						
	Can the required temperature conditions be maintained regardless of the external temperature?						
	Where are the temperature loggers located?						
	Are the temperatures measured in critical locations?						
	How was the product packed?						
	Does the packaging ensure that the temperature is maintained?						
	Is the temperature within the container monitored?						
	Second documentation check: Is the means of transport (vehicle, container) qualified?						
	Inspect qualification documents: • Can it be demonstrated that the required temperature is adhered to at extreme external temperatures? *(Summer and winter scenario/temperature distribution studies)*						
	• Is the temperature monitoring equipment serviced regularly?						
	• Have the temperature loggers been calibrated? *Calibration has to be repeated every year.*						

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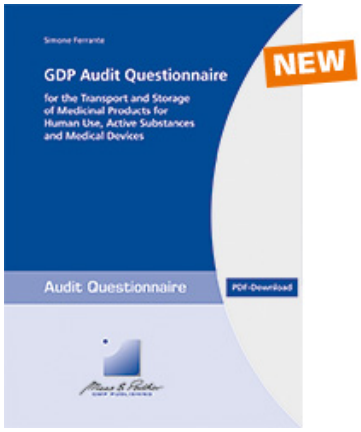

The checklist is a practice-oriented tool for preparing and implementing self-inspections with an emphasis on GDP (Good Distribution Practice). Compliance with GDP requirements during the product life cycle of medicinal products for human use, their active substances, and medical devices can be monitored, checked and directly documented using a list of questions.

The checklist is aimed at companies involved in the distribution chain of healthcare products, including:

- manufacturers of pharmaceutical and medical products
- distributors of APIs
- providers of logistics services
- wholesalers and agents

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