Simone Ferrante

GDP Audit Questionnaire for the Transport and Storage of Medicinal Products for Human Use, Active Substances and Medical Devices

More than 700 questions with references to GMP/GDP regulations and EN ISO 13485 on the preparation and implementation of GDP audits

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Audit questions

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	Good Distribution Practice Audit Questionnaire	checked*	EU GDP MP	EU GDP API	EU GMP	WHO GDP	EN ISO 13485
1.	**General questions regarding the QMS**						
1.1	**First documentation check**: Are wholesale activities (such as procurement, storage, supply and export of medicinal products) performed? If yes: Is a wholesale distribution or manufacturing authorization available? **Tour (premises/warehouse): –** **Second documentation check**: –		1.0		1.0	5.2 5.4	
1.2	**First documentation check**: Are logistic services being provided on behalf of a pharmaceutical company? How was the logistics service provider qualified? *A wholesale distribution authorisation or manufacturing authorisation is not required for this purpose.* How does the pharmaceutical company ensure that it retains control over the medicinal product? How is the process for release to market regulated? For all products: • How is the property of the customer (in this case, the contract giver) protected and secured? • How are quality-related incidents communicated to the customer? **Tour (premises/warehouse)**: – **Second documentation check**: –		1.3	6.16	1.4v, vi, xv 1.9 5.63 5.65 Chapter 7 8.0 Annex 16	12.2 21.1 21.3	7.5.10
1.3	**First documentation check**: Is there a Quality Assurance System (QAS) in place? Are QAS processes and principles clearly defined with regard to the individual distribution activities? Are they appropriate for the size and complexity of the company? **Tour (premises/warehouse)**: – **Second documentation check**: –		1.0 1.2	2.1 2.2 2.3	1.0 1.3	8.1	4.1 5.3

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3.18	**First documentation check**: Are computerized systems in use? *Example: warehouse management system* Are the individual systems (including any diagrams) described in detail in writing and is this documentation up to date? Are the principles, objectives, security measures and the detection range of the system as well as the most important features described? Do the documents describe how the system is used and how it can be incorporated into other systems? **Tour (premises/warehouse)**: Does a computerized system replace a physical separation? **Second documentation check**: *Inspect the validation documentation of the computerized system.*		3.3.1 3.2	4.1 6.10	Annex 11: 4.3, 4.4	8.4	7.1.6 7.5.6
3.19	**First documentation check**: Is proof available (by means of validation or verification study) that a computerized system is able to achieve the desired results accurately, continuously and repeatedly? Is the scope of the validation or verification study based on a documented risk analysis? Does the validation documentation include all the relevant process steps of the life cycle? Are appropriate tests carried out to prove adherence to specification limits? Was the handling of errors also demonstrated? Are records regarding change control and observed deviations available? Is it ensured that actions relating to the quality and performance of the system are checked and tracked? Is the validation status checked regularly? **Tour (premises/warehouse)**: – **Second documentation check**: –		3.3.1		1.4ii, ix, xii, xiii Annex 11:1 4.1 4.2 4.4 4.6 4.7 11		4.1.6 7.5.6 7.6

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9.6	**The following applies to refrigerated warehouses in particular:** **First documentation check**: Are the structure and the assembly of insulated containers (varies according to the season) and the reuse of thermal packs described? Are employees trained in this procedure? How is it ensured that insufficiently cooled packs cannot be used again? **Tour (premises/warehouse)**: *Have an employee explain the assembly of insulated containers.* How is the reuse of freezer packs checked? Is the check sufficient? Are frozen and refrigerated cooling elements adequately and physically separated? **Second documentation check**: *Request employee's training certificate on the assembly of insulation containers.*		9.4		1.8v		7.5.1 7.5.11
9.7	**First documentation check**: Are medicinal products intended for export to third countries? How is it ensured that these medicinal products do not enter the EU market? Was the QRM applied? Was a check carried out as to whether the recipient in the third country is empowered or authorized to obtain medicinal products for wholesale or distribution to the general public in accordance with the applicable legal and administrative regulations of the third country concerned? **Tour (premises/warehouse)**: Is there a separate area for the outgoing medicinal products that are exported to third countries? How were the products prevented from flowing into the flow of goods for the EU market? **Second documentation check**: *Check the recipients in the third country:* • Are they really empowered or authorized to receive medicinal products?		5.9		1.3	5.3 8.8	

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11.4	**First documentation check**: Is there an adequate system in place for the traceability including recalls?		6.5	4.5 7.10 7.11	1.8viii, x 8.0 8.20-8.31	8.9 9.3 12.6 13.11 17.1-17.9	4.2.5 8
	Can recalls be instituted rapidly at any time?						
	Who is responsible for recalls?						
	Is this person independent of the distribution and marketing organization?						
	Is the effectiveness of the relevant precautions assessed regularly (at least once a year)?						
	Has a recall been carried out already?						
	Can the record be easily inspected by the responsible person and, if need be, by the authority?						
	Inspect records: • Was the recording and performance or the recall carried out simultaneously?						
	• Was the recall successful?						
	• Does the documentation include sufficient information on the distributors and on the customers that are supplied directly as well as information regarding exported products and medicinal product samples for medicinal products? *The following information should be included: addresses, telephone and fax numbers during and outside of business hours, the batch numbers at least of those products that have the legally required safety features, delivered amount.*						
	Tour (premises/warehouse): Are recalled products separated and stored in a safe place?						
	Second documentation check: –						

Question	Document No.	Comment

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