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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 42502-2023

Specification for auditing the quality management of pharmaceutical logistics

医药物流质量管理审核规范

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1 Scope

China's national specification for auditing quality management in pharmaceutical logistics. Distributing medicines is a regulated activity because the product can be destroyed in transit without any visible sign: a vaccine that has been above its temperature range, or frozen when it should not have been, looks identical to one that has not, and its failure appears only as a patient who was not protected. So the whole discipline rests on evidence - a continuous temperature record, a validated container, a qualified route, an audited operator. This standard covers the audit itself: what a pharmaceutical company or a regulator must examine when assessing a logistics provider, from the qualification of the cold chain equipment and the calibration of its monitors through the handling of excursions to the traceability of every consignment. China's cold chain expanded rapidly during the vaccination programmes of recent years, which is the context this was written in.

This document stipulates the basic requirements for pharmaceutical logistics quality management auditors, audit work requirements, as well as audit content, audit judgment, audit results and feedback, and evaluation and improvement requirements. This document is applicable for auditing pharmaceutical logistics service providers by pharmaceutical logistics quality management auditors.

2 Normative references

The following documents contain the provisions which, through normative reference in this document, constitute the essential provisions of this document. For the dated referenced documents, only the versions with the indicated dates are applicable to this document; for the undated referenced documents, only the latest version (including all the amendments)

is applicable to this document.

GB/T 28842 Operation specifications for medicinal product cold chain logistics

GB/T 30335 Service specification of drug logistic

GB/T 34399 Temperature control facilities of pharmaceutical products cold chain logistics - Specification for performance qualification

GB/T 35145 Cold chain temperature logger JT/T 1325 Technical specification and test method for travelling temperature recorder WB/T 1097 General specification for cold-chain insulated container of drug WB/T 1104 Road transport - Requirements of refrigerated vehicle functions for pharmaceutical products

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 audit The process in which the pharmaceutical logistics quality management auditor checks to determine whether the quality management of pharmaceutical logistics service providers meets the audit content and forms documents. [Source: GB/T 19011-2021, 3.1, modified]

3.2 pharmaceutical logistics quality management auditor A legal person organization that implements pharmaceutical logistics quality management audit work. NOTE: It includes pharmaceutical logistics service entrusting parties, quality management full-time audit institutions, etc.

4 Basic requirements for auditors

4.1 An audit management system of pharmaceutical logistics quality management shall be established.

4.2 Quality management personnel with quality management audit capabilities shall be had.

4.3 The audit materials and related information provided by the pharmaceutical logistics service provider shall be kept confidential.

5 Audit work requirements

5.1 The pharmaceutical logistics service entrusting party shall audit the service quality management and other aspects of the pharmaceutical logistics service provider when they cooperate for the first time, during the cooperation period, and when the pharmaceutical logistics service provider undergoes major changes. The frequency of audits during the cooperation period shall comply with relevant regulations.

5.2 The corresponding service quality management audit work plan shall be formulated according to the business model of the pharmaceutical logistics service provider and the types of business it undertakes, and the audit work plan shall be informed to the pharmaceutical logistics service provider in advance.

5.3 The audit work plan shall include but is not limited to the name of the pharmaceutical logistics service provider, audit time, audit location, audit type and method, audit purpose, audit basis, audit scope, audit team members, audit implementation process, audit content, and the list of audit materials required to be and improved for suitability and effectiveness.

6.2.3 For personnel and training, the following contents shall be audited.

a) The suitability of the staffing to the type of business to be undertaken. Whether the personnel in the key positions have no experience of job forbidden. NOTE: Personnel in key positions include quality management personnel, personnel in positions directly in contact with drugs, etc.

b) Whether the relevant operators of cold chain drugs have passed the assessment before starting to work. Whether transport drivers and forklift operators have obtained certificates for operations.

c) The pre-employment and annual health checks of personnel directly in contact with pharmaceuticals, and the establishment of employee health management files. Whether the person suffering from an infectious disease or other diseases that may contaminate the drug is not engaged in work that directly contacts the drug.

d) The formulation and approval of the annual training plan and whether the training is carried out according to the plan.

e) Implementation of pre-employment and regular training for personnel in each position in terms of job responsibilities and job content; whether the training contents include but are not limited to laws and regulations, professional knowledge, job responsibilities, etc.

f) Whether the training archives include training records, photos, videos, assessment materials, and other documents.

6.2.4 For facilities and equipment, the warehouses, vehicles, refrigerators or incubators, temperature recorders, information systems, etc. shall be audited, and the specific requirements are as follows:

a) For the warehouse, the following contents shall be audited: 1) Whether the site selection, design, layout, construction, renovation, and maintenance of the warehouse meet the storage requirements for pharmaceutical products; 2) Whether it is equipped with equipment that meets the storage requirements of pharmaceutical products; Example: Facilities and equipment that are used for light-proof, ventilation, moisture- proof, insect-proof, rodent-proof, bulk picking, and LCL delivery operations and review. 3) Whether

there are work places for receipt and delivery, acceptance inspection, storage, return, storage of packaging materials, storage of unqualified pharmaceutical products, etc.; 4) When cold chain pharmaceutical products are stored, whether the cold storage complies with the provisions of the relevant chapters of GB/T 28842.

b) For the vehicle, the following contents shall be audited: 1) Whether the compartment is closed and whether the refrigerated vehicle meets the requirements of WB/T 1104; 2) Whether it is equipped with a global positioning system or other monitoring system.

c) For the refrigerator or incubator, the following contents shall be audited: 1) Whether it is equipped with temperature monitoring equipment; 2) Whether the incubator complies with the regulations of WB/T 1097.

7 Audit judgment

Pharmaceutical logistics quality management auditors can conduct the audit judgment on Chapter 6 according to GB/T 28842, GB/T 30335, GB/T 34399, GB/T 35145, JT/T 1325, WB/T 1097, WB/T 1104, or higher standards.

8 Audit results and feedback

8.1 The pharmaceutical logistics quality management auditor shall issue an audit report. The audit report shall include but be not limited to the name of the pharmaceutical logistics service provider, audit time, audit location, audit type and method, audit purpose, audit basis, audit scope, audit team members, audit implementation process, audit contents, audit results, etc.

8.2 When necessary, the pharmaceutical logistics quality management auditor shall notify the pharmaceutical logistics service provider to formulate relevant corrective measures based on the audit results, and check and confirm the corrective results.

9 Evaluation and improvement

Note 1. 2. **Search (Optional).** Enter the keyword '**GB/T 42502-2023**' in the search bar, if it is not already shown. 3.

Note 2. 9.

Note 3. 10. **Verification (USD

Notes and Explanations

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