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Drug Records and Data Management Requirements (Trial)

Chapter 1 General Provisions

Article 1 In order to standardize the record and data management of drug development, production, distribution and use activities, in accordance with the "Pharmaceutical Administration Law of the People's Republic of China", the "Vaccine Administration Law of the People's Republic of China", the "Regulations on the Implementation of the Drug Administration Law of the People's Republic of China" and other laws, Administrative regulations to formulate these requirements.

Article 2 These requirements shall apply to the records and data that shall be provided to the drug supervision and administration department for the records and data that are generated in the activities of drug research and development, production, distribution and use within the territory of the People's Republic of China. Article 3 Data refers to the information reflecting the implementation of the activities generated in the activities of drug development, production, operation and use, including: words, numerical values, symbols, images, audio, pictures, maps, barcodes, etc.; records refer to the above-mentioned data. A voucher formed through one or more data records in an activity, reflecting the execution process and results of the relevant activity.

Chapter II Basic Requirements

Article 4 Records can be classified into different types such as ledger, log, identification, process and report according to their purpose. In the activities of drug development, production, operation and use, one or more types of records shall be adopted according to the needs of the activities to ensure the authenticity, accuracy, integrity and traceability of the information in the whole process.

The record carrier may take one or more forms, such as paper, electronic or hybrid.

Article 5 Where a computerized (computerized) system is used to generate records or data, corresponding management measures and technical means shall be taken to ensure the authenticity, accuracy, integrity and traceability of the generated information.

Article 6 Electronic records shall at least achieve the same functions as the original paper records and meet the requirements of activity management. For the coexistence of electronic records and paper records, the corresponding operating regulations should be

Procedures and management systems clearly define the form as benchmarks.

Article 7 According to the purpose, type and form of records, records management procedures shall be formulated, the responsibilities of record management shall be specified, and the control methods of records shall be standardized. Article 8 Activities such as data collection,

processing, storage, generation, retrieval, and reporting shall meet the requirements for record filling or data entry of the corresponding data type, and ensure the authenticity, accuracy, integrity and traceability of the data.

Article 9 According to the source and purpose of the data, the data can be divided into basic information data.

Appropriate management measures and technical means should be adopted for different types of data, data, behavioral activity data, measuring instrument data, electronic data and other types of data.

Article 10 Personnel engaged in record and data management shall receive necessary training,

Master the corresponding management requirements and operational skills, and abide by the code of professional ethics.

Article 11 Records and data generated by third parties through contractual agreements shall be

Comply with this requirement and clarify the management responsibilities of the parties to the contract.

Chapter 3 Management Requirements for Paper Records

Article 12 The design and creation of record files shall meet the actual purpose, the format shall be convenient for identification, recording, collection, preservation, traceability and use, and the content shall be comprehensive,

Complete and accurate reflection of the corresponding activities.

Article 13 shall stipulate the review and approval responsibilities of record documents, clarify the management requirements for the effective version of record documents, and prevent the use of invalid versions. Article 14 The printing and distribution of records shall be based on the different purposes and types of records, and shall adopt controlled methods commensurate with the importance of records, to prevent replacement or tampering of records.

Article 15 The duty of recording shall be clearly defined and shall not be arbitrarily replaced by others, and tools or methods that can be preserved for a long time and cannot be easily removed shall be adopted. Raw data should be recorded directly on the prescribed records, not through uncontrolled
The vector is scratched or transcribed. Article
16 Any modification of the records shall be signed with the name of the modification person and the modification date, and the original information shall be kept clear and identifiable. The reason for the change should be stated if necessary. Article 17 The collection time, filing method, storage location, storage period and management personnel of records shall be clearly stipulated, and appropriate preservation or backup measures shall be taken. The retention period of records shall comply with relevant regulations. Article 18 Use and reproduction of records Appropriate measures shall be taken to prevent the loss, damage or tampering of records. When duplicating records, the approval, distribution and control methods for duplication of records shall be specified, and the original and photocopies of the records shall be clearly distinguished.

Article 19 Appropriate record destruction methods shall be determined, and corresponding destruction methods shall be established. destroy records.

Chapter IV Requirements for Electronic Records Management

Article 20 A computerized (system) system using electronic records shall meet the following requirements:

Facilities and

configuration: (1) Installed in an appropriate location to prevent interference from external factors;

(2) A server or host that supports the normal operation of the system; (3) A stable and secure

network environment and a reliable information security platform; (4) Realize information transmission and

data sharing between relevant departments and posts

the local area network environment;

(5) Application software and related data that meet relevant legal requirements and management needs

database;

(6) Terminal equipment and ancillary devices capable of recording operations; (7) Operation

manuals, drawings and other technical materials of the supporting system.

Article 21 A computerized (system) system using electronic records shall at least meet the following functional

requirements:

(1) Ensure the authenticity, accuracy and consistency of the recording time and the system time; (2) Be able to

display all data recorded electronically, and the data generated can be read and printed; (3) The data generated by

the system should be backed up regularly, The backup and recovery process must

After verification, the backup and deletion of data should be recorded accordingly;

(4) When the system is changed, upgraded or decommissioned, measures shall be taken to ensure the

The data can be inspected and traced within the specified retention period. Article 22

Electronic records shall realize operation authority and user login management, including at least:

(1) Establish different authority for operation and system management. The user authority of the person in charge of

the business process shall match the responsibilities he undertakes, and shall not be assigned to his system (including operation

system, application, database, etc.) administrator rights;

(2) It has the function of setting and assigning user rights, and can track and inquire about the modification of rights;

It shall comply with the relevant provisions of the "Electronic Signature Law of the People's Republic of China";

(4) Relevant information on system operation shall be recorded, including at least the operator, operation time, operation process, and reason for operation; data generation, modification, deletion, reprocessing, renaming, and transfer; setting of computerized system , configuration, parameter and timestamp changes or modifications. Article 23 The verification project of a computerized (system) system using electronic records shall determine the scope and degree of verification according to the system's infrastructure, system functions and business functions, and integrate multiple factors such as the degree of maturity and complexity of the system to ensure system functions. fit for the intended purpose.

Chapter 5 Data Management Requirements

Article 24 For the basic information data of activities and the behavioral activity data generated through operations, inspections, verifications, manual calculations, etc., the relevant operating procedures and management systems shall specify who to record, the time to record, the content to be recorded, and the confirmation of records. and review method requirements. Article 25 When reading data from measuring instruments, the measuring instruments shall be verified or calibrated according to law. Article 26 Obtained through the collection, processing and reporting of the computerized system

necessary management measures and technical means shall be taken:

(1) For the electronic data obtained by manual input and processed by the application software, the software functions and settings shall be prevented from being arbitrarily changed, and the input data and data generated by the system shall be reviewed, and the original data shall be preserved in accordance with relevant regulations;

(2) For the electronic data generated after being collected and processed by the computerized system, the system shall comply with the corresponding specification requirements, and the metadata shall be saved and backed up, and the backup and recovery process must be verified.

Article 27 Other types of data refer to data contained in the form of documents, images, audio, pictures, maps, etc. Other types of data that meet the following conditions are deemed to meet the requirements of this requirement:

(1) It can effectively represent the content and can be retrieved and used at any time; (2) If the data format is converted, it should be ensured that the converted data is the same as the original data Data is consistent.

Chapter VI Supplementary Provisions

Article 28 The meanings of the following terms in this requirement are:

(1) Original data

Refers to unprocessed data collected at the primary or source.

(2) Electronic records

Refers to a record in a digital format consisting of text, graphics, data, sounds, illustrations, or other digital information. Its creation, modification, maintenance, filing, reading, distribution and use are all realized by computerized systems.

(3) Electronic signature

means contained in an electronic record in electronic form, attached to identify the signatory and

Data indicating that the signer approves of its contents.

(4) Metadata

Metadata is the data used to define and describe data. By defining and describing data, it can support many management tasks such as positioning, query, exchange, tracking, access control, evaluation and preservation of the described data objects. Article 29 Those engaged in drug research and development, production, distribution and use activities shall abide by laws, regulations, rules, standards and norms, formulate operating procedures and management systems, and clarify the management requirements for records and data. Article 30 These requirements shall come into force on December 1, 2020.