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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 22275.6-2008

**Requirements of conduct for Good Laboratory Practice (GLP) --
Part 6: The application of the principles of GLP to computerised
systems**

良好实验室规范实施要求 第6部分：良好实验室规范原则在计算机化的系统中的
应用

(English Translation)

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Table of Contents

- Foreword
- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Requirements
- 4.1 Scope
- 5 GLP Principle in computerized systems

Foreword

GB/T 22275 "to implement the requirements of Good Laboratory Practice" is divided into seven sections.

- Part 1. Quality Assurance and Good Laboratory Practice;
- Part 2. Good Laboratory Practice Research project leader roles and responsibilities;
- Part 3. Laboratory Supplier of Good Laboratory Practice Principles compliance;
- Part 4. Good Laboratory Practice principles in the field of applied research;
- Part 5. Application of the principles of Good Laboratory Practice in short term studies;
- Part 6. Application of the principles of Good Laboratory Practice in the computerized system;
- Part 7. application of the principles of good laboratory practice in the organization and management of multi-site studies.

This section GB/T Part of 622,275.

This section is equivalent to using the Organisation for Economic Cooperation and Development (OECD) Good Laboratory Practice (GLP) principles and a series of documents for compliance monitoring no. 10. "GLP principles computerized system application" [OCDE/GD (95) 115].

This part of the editorial changes as follows.

- Remove the foreword and introduction of the original;
- Remove the original definition Note 1.

Appendix A of this section is an informative annex.

This part of the National Chemicals Management Standardization Technical Committee dangerous (SAC/TC251) and focal points.

The drafting of this section. Shandong CIQ, the Dangerous Chemicals Management Standardization Technical Committee.

1 Scope

This section GB/T 22275 specifies the application and management of GLP principles under the computerized system, including the responsibilities of various departments, phase Requirements related to training, equipment and instruments, computerized system maintenance and disaster recovery, the recording and processing of data, computerized system Safety, computerized system validation procedures, on their development, validation, operation and maintenance documentation requirements.

This section applies to applications under GLP principles computerized system.

2 Normative references

The following documents contain provisions which, through reference GB/T 22275 in this section constitute provisions of this section. For dated reference documents Member, all subsequent amendments (not including errata content) or revisions do not apply to this section, however, encouraged to reach under this section Parties to research agreement to use the latest versions of these documents. For undated reference documents, the latest versions apply to this section.

GB/T 19001 Quality Management System Requirements GB/T 22278 principles of Good Laboratory Practice

3 Terms and Definitions

GB/T 22278 in the terms and definitions apply to this section.

4.1 Scope

4.1.1

All parties used to generate computerized system measurement and evaluation of data submitted to the Governing Body shall be consistent with the principles of GLP Formula development, validation, operation and maintenance.

4.1.2

in the plan, perform and report on the study may be for a variety of purposes using multiple systems computerized. These objects can be it can include direct or indirect acquisition of data from automated instruments, operation and control of automation equipment and processing, reporting and storage number according to. For these different activities,

computerized systems are different, can be a programmable analytical instrument, it can be a Computer connected to the laboratory information management system for multi-purpose personal computer. In the scope of any computer-related, GLP should in principle be application.

Step 4.2

4.2.1 applied to a study submitted to the Governing Body for the purpose of implementation of the computerized system shall be properly designed, can be enough and apply force to its intended purpose. It should have appropriate procedures to control and maintain these systems, which should follow the principles of GLP Approach to the development, validation and operation.

4.2.2 Demonstration computerized system is suitable for its intended purpose is very important, which is called to confirm the computer.

4.2.3 confirmation process will ensure strict computerized system to achieve its design requirements. This shall take a formal confirmation of the plan and in making Performed before use.

5 GLP Principle in computerized systems

The following considerations mentioned above, will be referred to the application of the principles of GLP in the computerized system to help.