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

GB/T 22275.7-2008

**Requirements of conduct for Good Laboratory Practice (GLP) --
Part 7: The application of the GLP principles to the organisation
and management of multi-site studies**

良好实验室规范实施要求 第7部分：良好实验室规范原则在多场所研究的组织和管理中的应用

(English Translation)

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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 22275 Part 7.

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. 13. "GLP principles in the organization and management of multi-site study in the application" [ENV/JM/MONO (2002) 9].

This section includes the following editorial changes.

- Delete information about the OECD, the introduction, preface about the content of the sessions held and directory section.

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

The drafting of this section. Shandong CIQ.

1 Scope

This section GB/T 22275 specifies the multi-site study of management and control, quality assurance, real master schedule, research programs, research Shi, the findings of the report, standard operating procedures, records and materials storage and safekeeping.

Except as expressly exempted national legislation, good laboratory provided for in this part of the normative principles (hereinafter referred to as GLP principles) applicable laws and regulations all non-clinical health and environmental safety studies required, including pharmaceuticals, pesticides, food additives and feed additives, cosmetics, veterinary drugs and similar products registration or application for a permit, as well as industrial chemicals management.

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 22275.4 good laboratory practice - Part 4. Good Laboratory Practice principles in the field of applied research 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 Multi-site study

4.1.1

Multi-site studies, implementation, monitoring, recording, reporting and archiving of a series of potential problems that should be explained to ensure that the principles of GLP affected. Plan different research activities in different places means that the implementation of research, communication, control is very important.

4.1.2

Although more than one workplace study will constitute the work performed in multiple locations (including the testing facility and all test sites). but Multi-site study is a single study should be performed in accordance with the principles of GLP. This means that the program should be the only, the only project leader and sole the final report. In the initial study plan,

participating sites and managers should be aware that they work only part Part of the research project leader control and should not be used as a separate study to implement.

4.1.3

various places of work carried out by the need to clearly explain the initial stage plan. So that the relevant parties can participate in the research Study plan before finalizing an agreement on control measures.

It can clear distribution of responsibilities and effective communication to avoid the implementation of a multi-site study executed between the parties involved 4.1.4 Research on multiple issues. Participants include the Principal, Principal, managers, project representatives, quality assurance and research various places personnel.

4.1.5

All relevant parties should be aware. When a multi-site study execution in many countries, may be due to the national culture, language and Differences GLP compliance program oversight caused some additional problems. In this case, it may be necessary to break the country's GLP