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

GB/T 22275.3-2008

**Requirements of conduct for Good Laboratory Practice (GLP) --
Part 3: Compliance of laboratory suppliers with GLP principles**

良好实验室规范实施要求 第3部分：实验室供应商对良好实验室规范原则的符合
情况

(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 3.

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. 5. "laboratory suppliers GLP principles compliance" [ENV/JM/MONO (99) 21].

This part of the following editorial changes.

- Remove the preface and the background portion of the original;
- Delete the original text in Notes 1 and 2.

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 requirements of GLP laboratory supplier under the principle, including the following. standards and conformity assessment Set plan, test system, animal feed, bedding and water, chemicals with a radiolabeled, computer systems, application software, reference materials, Instruments, sterile materials, conventional reagents, detergents and disinfectants, microbiology testing needs.

This section applies to GLP principles under laboratory supplier requirements.

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 22278-2008 principles of Good Laboratory Practice General specifications EN45001-1990 laboratory work

3 Terms and Definitions

GB/T 22278-2008 The terms and definitions apply to this standard.

4.1 Standards and conformity assessment program

4.1.1

The laboratory study in a variety of materials supplied to follow the implementation of the principles of GLP. Suppliers trying to produce to meet to make Products fulfill obligations GLP principles listed in the wearer. Many suppliers to adopt production methods conform to national or international standards of production, or to obtain certification in various national qualification system. This initiative has been expected, because the only way to provide product it can be asked to follow the implementation of the principles of GLP study administration accepted.

4.1.2

recommend suppliers to implement GB/T 19001. The standard may be made EN45001-1990 support, the latter stressed on 5.4.7 the importance of subcontracting.

4.1.3

If the appropriate conformity assessment is particularly useful for suppliers concerned. Conformity assessment systems are often supervised members of the national and international standards Implementation, so the supplier or manufacturer of the assessment certificate can be displayed to the customer in addition to other aspects of the conformity assessment, for Good implementation of standards. Recommended that suppliers where appropriate feasible efforts to obtain membership in the national assessment system.

4.1.4

While this conformity assessment is to follow the principles of GLP complementary tool to support effective, but it can not serve as GLP compliant an acceptable alternative, it can not satisfy the listed OECD Mutual Acceptance of Data in the Council Act required in the circumstances under international recognition.

4.2 Test System

GB/T 22278-2008 in 3.8.2.5b) requirements, test systems (animals, plants and other organisms) should be in the nature of the research program Below. This requirement can be provided directly by the supplier of information to meet. GLP has been implemented in some countries, the supplier owned by the state Management or voluntary conformity assessment systems (for example, for laboratory animals), they are using can provide up to a user