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

**GB/T 22277-2008**

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**Advisory document for good laboratory practice -- The role and  
responsibilities of the sponsor in the application of the  
principles of GLP**

良好实验室规范建议性文件 在良好实验室规范原则的应用中委托方的任务和职责  
**(English Translation)**

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### Foreword

This standard is identical with the Organisation for Economic Co-operation and Development (OECD) Good Laboratory Practice (GLP) principles and a series of documents for compliance monitoring no. 11. "The application of the principal tasks and responsibilities GLP principles" [ENV/MC/CHEM (98) 16].

The standards for the following editorial changes.

--- Remove the preamble of the original.

This standard is managed by the National Standardization Technical Committee chemicals dangerous (SAC/TC251) and focal points.

This standard drafting unit. Shandong CIQ.

### 1 Scope

This standard applies to trials and studies carried out in accordance with good laboratory practice (GLP) principles for the tasks and responsibilities entrusted to parties begging. When commissioned a non-clinical health and environmental safety studies when the commissioning party should ensure that the test bodies to follow the principles of GLP requirements to conduct research and provide relevant information on chemical safety and characterization data.

### 2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this standard, however, encourage the parties to

the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB/T 22278-2008 principles of Good Laboratory Practice

### 3 Terms and Definitions

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

#### 4.1 Description

Although the GB/T 22278-2008 merely clarified the research part of the duties of the Principal, Principal and some unspecified level Responsibility, because this is in fact the principal is often initiated by one or more research, and the results will be submitted directly to the management of people. Principal should play an active role in the confirmation of all non-clinical health and environmental safety study whether the principles of compliance with GLP issues. Entrust Party can not rely solely on the guarantee contract testing organizations or institutions to implement these studies. Guidelines are given below describe the Principal shall fulfill it has a clear and undefined responsibilities.

#### 4.2 Defining

Principal means an entity that commission, support and (or) to submit a non-clinical health and environmental safety studies (see GB/T 22278-2008 2.2.5).

**Note 1:** The Client may include.

Initiating a non-clinical health and environmental safety studies and provide support through financial or other resources of the entity.

Submit a non-clinical health and environmental safety studies to management, to register for the product or other needs in line with the principles of GLP support applications Entities.

**Note 2:** The "entity" may include one individual, partnership, business, association, scientific or academic institutions, government departments, or organizational unit in which, or on other legal Identifiable groups.

#### 4.3 Liability of Principal

Principal shall understand the requirements of GLP principles, particularly those responsible for people involved in the testing facility managers and project/program on behalf of duties Claim.

**NOTE:** If you subcontract part of the study by the commission to the subcontractor, the client should understand the responsibility of the entire study is still borne by the person in charge of the project, including the original number According to the effectiveness and reporting.

4.4 When the health and environmental safety studies commissioned by a non-clinical time, the client should ensure that the testing facility to be able to follow the principles of GLP