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

GB/T 22275.2-2008

**Requirements of conduct for Good Laboratory Practice (GLP) --
Part 2: The role and responsibilities of the study director in GLP
studies**

良好实验室规范实施要求 第2部分：良好实验室规范研究中项目负责人的任务和
职责

(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 2.

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. 8. "GLP study project leader roles and responsibilities" [ENV/JM/MONO (99) 24].

This part made the following editorial changes.

- Remove the preface and catalog parts.

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 project leader's task, appointment, training, duties, qualifications, legal status.

Except as expressly exempted national legislation, the provisions of this section apply to the principles of GLP regulations requires all non-clinical health and environmental Safety studies, including registration or apply for a license in medicine, pesticides, food additives and feed additives, cosmetics, veterinary drugs and similar products to and 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 22278 principles of Good Laboratory Practice

3 Terms and Definitions

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

4.1 Project Leader tasks

4.1.1

The project leader is the sole controller of research and, ultimately responsible for the overall, the implementation of scientific research. This is the project leader Main task. Obligations and responsibilities of GLP principles are derived from the provisions of this major task. Experience has shown that only the correct research the delegate responsibility to a specific person responsible, because in order to avoid the researchers received conflicting instructions which led to poor research program carried out. At any given time there may be only a project leader for the study. Some responsibilities project leader may be appointed Pies, such as in sub-contract the study, but the project as a single person in charge of the final control center's research responsibilities can not be delegated.

4.1.2

In this regard, the project leader should ensure that science, management, regulatory and other aspects of the study are controlled, through the coordination of the project leader tube Managers, research and (or) technical personnel and quality assurance programs to control

research.

In the multi-site study involved more than one test site, the person in charge of the control if the project can not be implemented under the direct supervision, of the research process

4.1.3 You can give a trained, qualified and experienced personnel, is the project representative. Project on behalf of the person in charge of the project in accordance with the applicable GLP principles to study the implementation of a specific phase.

4.1.4

From a scientific point of view, the project leader is usually responsible for the design and approval of research plans, supervise data collection, analysis and reporting Technical experts. According to the project leader in charge of the final total draw conclusions. As the chief technical specialist, project leader should cooperate with other Technical experts and (or) project coordinated by the representative, they found that in order to understand the research process, receiving and evaluating their respective reports and studies Include in its final study report.

4.1.5

From a management perspective, the project manager should be responsible for the application of resources (such as personnel, equipment and facilities) and coordination to ensure Expected research process can be carried out properly.

4.1.6

ensure the implementation of regulations and consistent research is the project leader responsibilities. In this role was project leader responsible for ensuring RESEARCH