

ICS 03.120.20
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**CERTIFICATION AND ACCREDITATION INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

RB/T 193-2015

**Guidance for the application of good laboratory practice for
peer review of histopathology
(English Translation)**

Issued on: December 17, 2015

Implemented on: July 1, 2016

Issued by: National Certification and Accreditation Administration

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard was proposed by the China National Accreditation Center for Conformity Assessment.

This standard is under the jurisdiction of the National Certification and Accreditation Standardization Technical Committee (SAC/TC261).

This standard was drafted. China National Accreditation Center for Conformity Assessment, China National Institute for Food and Drug Control, National Drug Safety Evaluation and Monitoring Xin, Institute of New Drug Safety Evaluation, Peking Union Medical College, Chinese Academy of Medical Sciences, Institute of Chemical Safety, China Academy of Inspection and Quarantine.

Introduction

This standard refers to the Organization for Economic Cooperation and Development (Organization for Economic Cooperation and Development, OECD) Good Laboratory Practice (GLP) Principles and Compliance Monitoring Series Document No. 16 Application Guidelines for Laboratory Standards in Pediatric Peer Review [OECDENV/JM/MONO (2014) 30].

Good laboratory practices in histopathology Application Guide in Peer Review

1 Scope

This standard gives the application of the GLP principle in the peer review of histopathology, and is responsible for pathologists, test institution managers, and projects.

Human and quality assurance personnel provide guidance on peer-reviewed histopathology.

This standard applies to all non-clinical health and environmental safety studies required by regulations, including medicines, pesticides, food additives and feed.

Registration or application for additives, cosmetics, veterinary drugs and similar products, as well as industrial chemicals management.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 22278-2008 Good Laboratory Practice Principles

3 Terms and definitions

The terms and definitions defined in GB/T 22278-2008 apply to this document.

4.1 Background

Pathological evaluation of tissue samples is an important part of toxicity studies, and pathological evaluation results are crucial for toxicity studies.

The evaluation of the tissue sample is based on the professional opinion of the reading pathologist. The peer review by the testing organization is usually another disease.

The physiologist reads the pieces of the tissue. This guide ensures the quality and accuracy of professional advice and regulates peer review. Although at There is no clear provision for peer review in the GLP principles given in GB/T 22278-2008, but most research data acceptance departments still it is hoped that the results of histopathological diagnosis will be peer-reviewed to some extent. This guide focuses on the organization, implementation, and documentation of peer review.

The result of the program.

Peer review may result in changes in histopathological findings and reported results, which may alter research findings and conclusions. This standard to provide guidance to pathologists, test facility managers, project leaders, and quality assurance personnel in the implementation of histopathology How to plan, manage, record and report in peer review to comply with GLP principles. Specific implementation of peer-reviewed histopathology can be refer to Section 3.6.3.7 of the OECD Test and Evaluation Series Document No. 116 (Appendix A).

For some special research projects, the client may require some or all of the histopathological sections to be peer-reviewed by a special pathologist.

Negotiation. The pathologist who participated in the review may be a well-known expert in the field of specific pathophysiology, or a physiological effect on the study of the test substance.

Have specialized experience. This ensures that the effects of the same test in different studies are consistent in terminology and interpretation. Due to phase Experts are not necessarily employed by GLP testing facilities, so it is not possible for all peer review to be implemented in the same GLP institution.

4.2 Application of GLP Principles

4.2.1

Any information that is peer-reviewed within the testing organization or peer-reviewed by an external consultant, in a research plan or plan