委托方在GLP试验中的职责与作用

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浙江省化工研究院化工产品检测中心

委托方在GLP试验中的职责与作用

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING
Number 11

Advisory Document of the Panel on Good Laboratory Practice

The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING

Number 21
OECD Position Paper Regarding Possible Influence of Sponsors on Conclusions of GLP Studies

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01

委托方的定义

委托方的定义

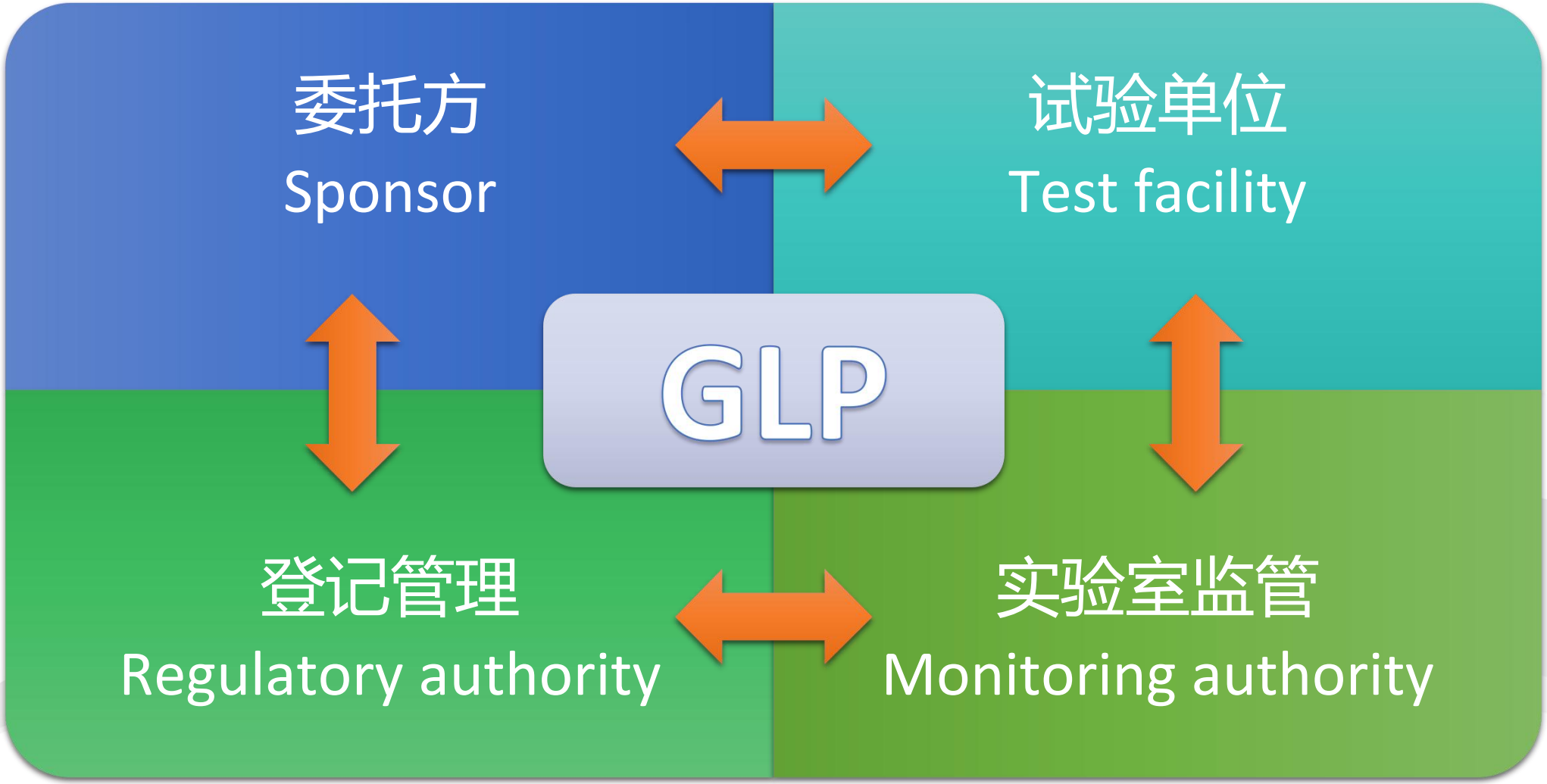
项目委托

An entity who initiates and support, by provision of financial or other resources, non-clinical health and environmental safety studies.

申请登记

An entity who submits non-clinical health and environmental safety studies to regulatory authorities in support of a product registration or other application for which GLP compliance is required.

委托方的定义


委托方
Sponsor
试验单位
Test facility
GLP
登记管理
Regulatory authority
实验室监管
Monitoring authority

02

委托方的职责与作用

委托方的职责与作用

项目开展前

项目进行中

项目完成后

委托准备

选择试验单位

确认项目内容

提供相关信息

准备试验样品

签署委托协议

选择试验单位

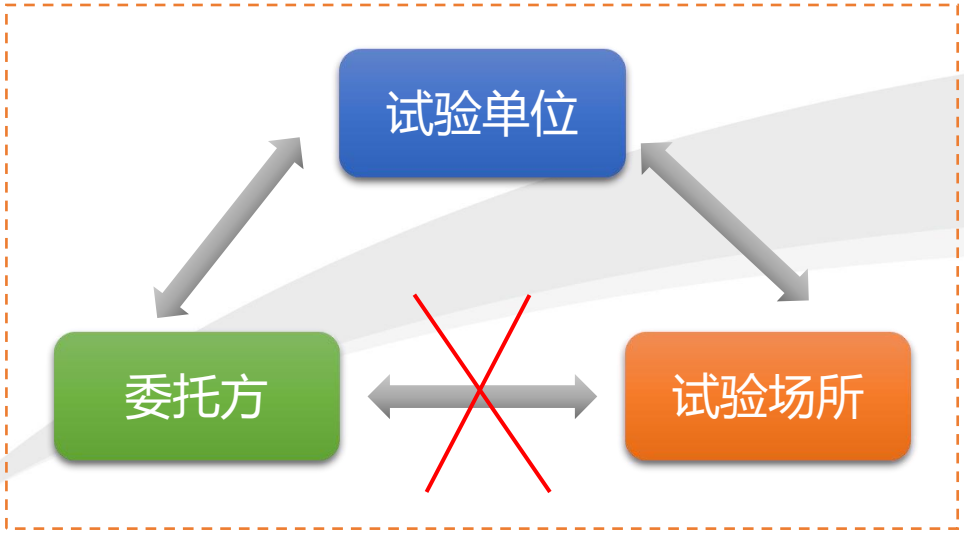
- 样品运输

The transportation of the test item to the test facility is also a critical phase for the integrity of the test item and is often managed by the sponsor.

- 试验范围
- 有效期

- 机构设施
- 仪器设备
- 人员经验
- SOPs
- 样品管理
- 档案管理
- 保密要求

选择试验单位



- 试验场所/分包商可由委托方选择，但必须明确SD对试验全过程和最终试验报告负责。
- 试验单位应保留和委托方之间的沟通记录，以便对所有研究决定和委托方提供的信息进行充分核实。
- 试验单位应保留和试样场所之间的沟通记录，以确保SD对试验项目是单点控制。
- 在没有SD参与的情况下，试验场所和委托方之间要避免与研究相关的直接沟通。

确认项目内容

中国	http://www.chinapesticide.org.cn/
阿根廷	http://www.senasa.gov.ar
澳大利亚	http://www.apvma.gov.au
巴西	http://www.agricultura.gov.br/
德国	https://portal.bvl.bund.de/psm/jsp/
俄罗斯	http://www.mcx.ru/
加拿大	http://www.mcahonduras.hn/
美国	http://www.epa.gov/pesticides/
墨西哥	http://www.cofepris.gob.mx/
欧盟	http://ec.europa.eu/food/plant/pesticides/
EPPO	http://www.eppo.int/PPPRODUCTS/
……	

确认项目内容

- OECD Guideline for Testing of Chemicals
- EU Regulations
- US EPA OPPTS 830 Series
- CIPAC Methods
- ASTM Guidelines
- ISO Series
- UN, Recommendations on the transport of dangerous goods

方法要求?

提供相关信息

有效成分信息

- 中英文通用名称、CAS号、化学名称、分子式、结构式、相对分子量、外观、溶解度、稳定性、生物活性等内容，并注明出处

被试物信息

- 名称、标称值、剂型、样品批号、外观、重量、生产日期、有效日期、来样日期、生产企业、生产企业地址、储存条件等

参照物信息

- 通用名称、化学名称、外观、纯度、来源、批号、生产日期、有效日期、接收日期、储存条件、定值方法等

委托方信息

- 名称、地址、生产商、联系人、联系方式

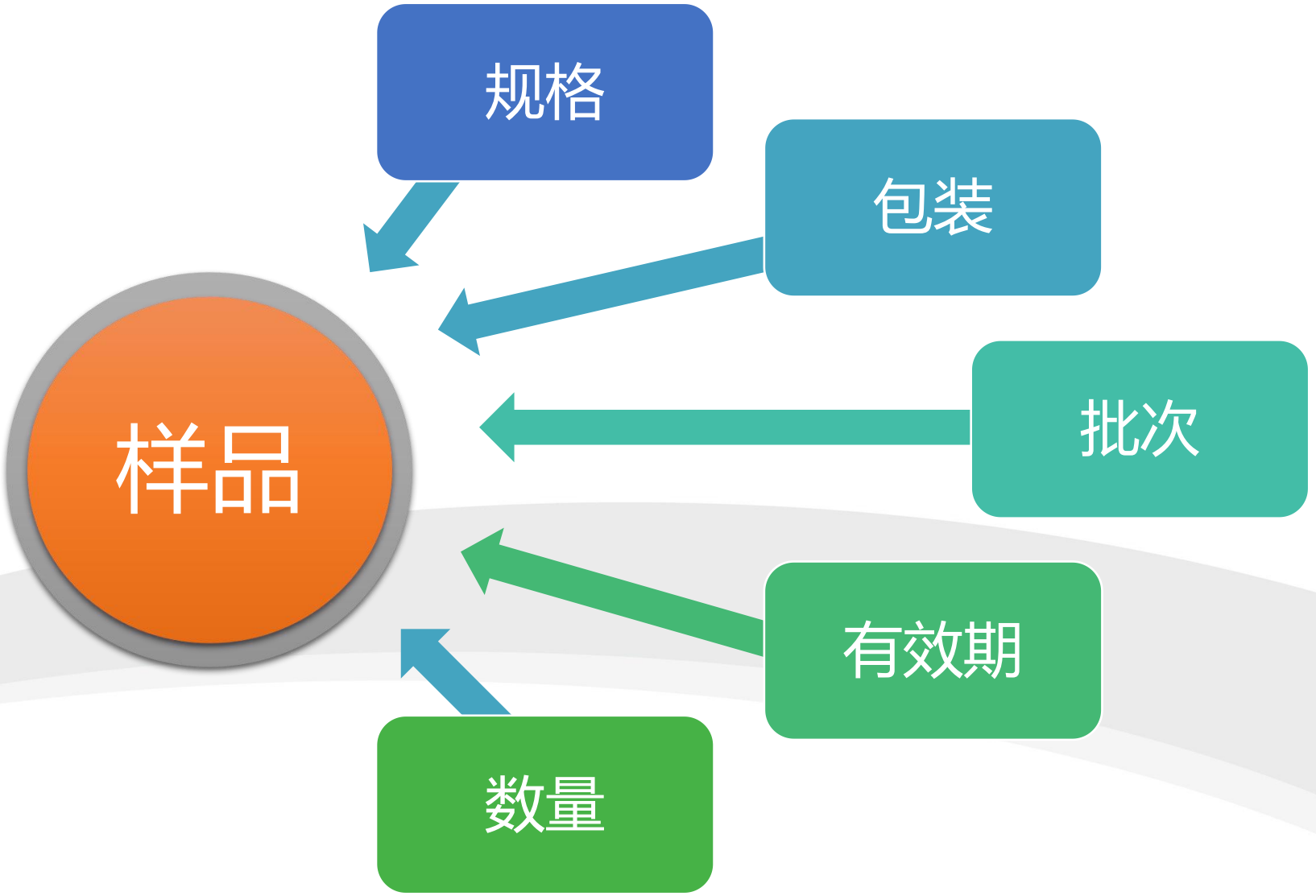
运输条件　储存条件　人员健康　环境安全

准备试验样品

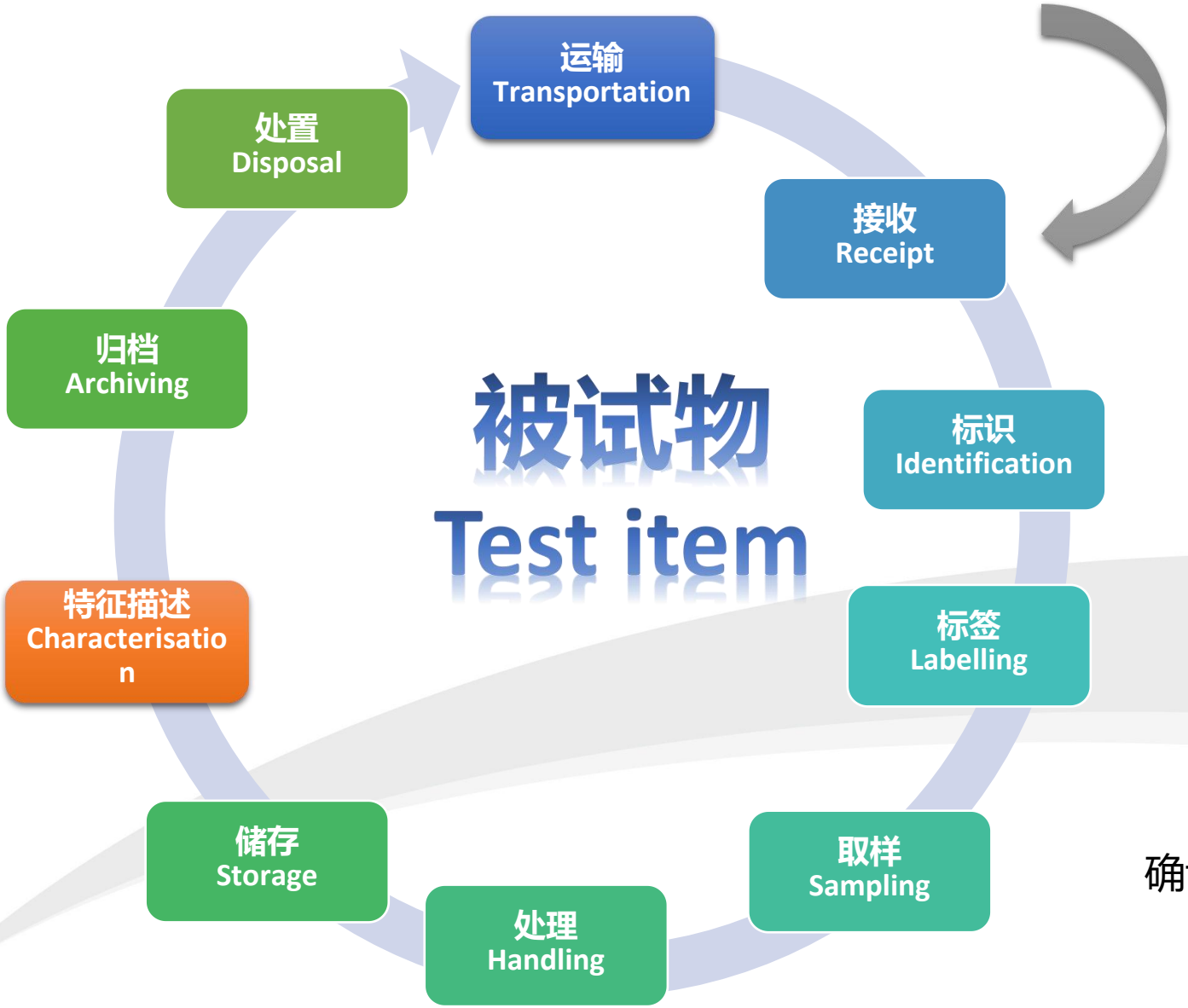
封样

备案

送样



准备试验样品



委托方 → 试验单位

确认被试物运输条件

确认被试物完整性

签署委托协议

项目明细

周期

费用

委托方的职责与作用

项目开展前

计划审阅

项目进行中

项目跟进

项目完成后

报告审阅

- 委托方参与研究?
- 委托方提供资源?
- 委托方回收样品?
- 计划的修订/偏离?
- 项目的终止/变更?
- 项目中期出具报告?

计划审阅

合规性
Compliant

计划中声明试验按照GLP要求开展

明确样品保存和使用、报告格式、存档要求等

一致性
Consistent

委托方信息、生产商信息

被试物信息、参照物信息、COA等

科学性
Scientific

技术要求、登记要求

时间要求、样品用量等

特殊情况及处理

委托方参与研究

A sponsor who may directly be involved in the study

- The sponsor and the test facility belong to the same organisation.
- In a multi-site context, the sponsor and one of the test sites involved in the study belong to the same organisation.
- In a multi-site context, the sponsor conducts the pathology peer-review.
- In a multi-site context, the test facility and the sponsor are in the same organisation and the role of the test facility is limited to the location of the study director.

- 在SOP中明确各人员关系（委托方、TFM、SD），确保人员关系符合GLP原则
- 明确SD对项目负全部责任， PI与委托方避免直接沟通，确保对试验项目单点控制
- 沟通记录要予以保留（委托方、TFM、SD 、QA、SP），以便项目重建
- 最终报告及项目中产生的所有数据应保留在SD所在的试验单位

特殊情况及处理

委托方参与研究

A sponsor who may directly be involved in the study

- Staff from the sponsor can act as study personnel. This may occur when the routes for administration to animals require a specific surgical procedure or in viral clearance studies where the experience of sponsor staff is requested to mimic the process in a reduced scale.

- The sponsor assumes the role of Quality Assurance (QA) for the study (or nominates a contractor to conduct the study specific audits), for example specific critical phases that require specialist QA personnel to be inspected.

· 事先签订合同，并通过TFM批准

· 相关人员进行GLP培训，由TFM任命

· 试验计划中详细阐述，并说明合理性

· 试验报告中详细说明，并对结果的影响进行评估

· 必要时应事先获得监管部门的认可

特殊情况及处理

在non-GLP区域开展GLP试验

- In a multi-site context, some sponsors indicate that a phase of a study is too technically difficult to be performed at a GLP test facility and wish to conduct the phase in their own non-GLP laboratory, even if potentially suitable GLP test facilities exist.

· 委托方事先认可

· 明确SD对项目负全部责任

· 试验计划中详细描述，QA审核

· 试验报告中说明情况，并进行影响评估

· 必要时应事先获得监管部门的认可

特殊情况及处理

委托方提供资源

Sometimes a sponsor can supply specific reagents, equipment or other resources for the conduct of the study.

- TFM确保这些资源的一致性，并保留相关的证明文件
- 特别注意运输过程造成的影响（如设备搬迁后需重新校准）
- SD评估GLP的遵从性，及对数据有效性的影响（在试验计划、试验报告中体现）

委托方收集样品

Some sponsors may request the test facility to collect specific samples of the preparations of the test item or of specimens.

- SD在试验计划中明确安排，以告知试验人员具体的处理方式
- SD事先进行风险评估，确保额外的取样对GLP试验不造成干扰
- SD在试验报告中对相关活动进行详细说明，并评估其影响

项目跟进

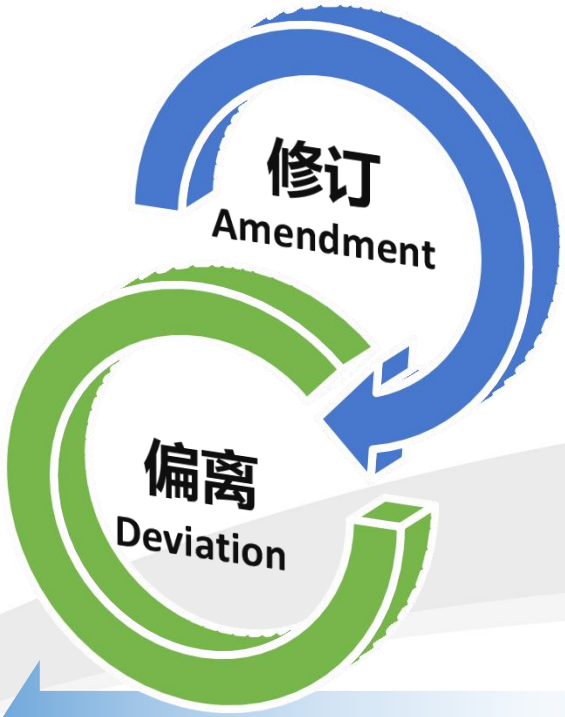
• 签署试验计划

试验项目启动
Study initiation date

试验开始
Experimental starting date

试验完成
Experimental completion date

试验项目完成
Study completion date



• 签署试验报告

项目开展过程中可能会涉及的特殊情况

委托方要求终止项目或进行non-GLP变更

- A sponsor may decide to terminate the study in progress before it has concluded.
- The early termination of a study may occur prior to, or after, the completion of the experimental phase of the study, but before the data has been assessed or incorporated in a final report.
- The same process about documentation should apply when the sponsor asks for a GLP study to be changed to a non-GLP study.

委托方出具书面说明

↓

SD修订试验计划

↓

TFM变更主计划表

↓

SD出具总结报告，QA审核

↓

项目结束，资料归档

项目开展过程中可能会涉及的特殊情况

浙江省化工产品质量检验站有限公司
ZHEJIANG PROVINCE CHEMICAL PRODUCTS QUALITY INSPECTION STATION CO. ,LTD

委托方要求出具中期报告

Sponsors can request test facilities to generate interim reports or intermediate results of studies that are conducted in accordance with GLP

- An interim report is a report of a non-completed study.
- Interim reports are requested by some receiving authorities in specific circumstances.

·原则上GLP只认可最终报告

·无监管部门的事先认可，中期报告一般不被接受

·不反对发布不包含SD声明的中期报告

报告审阅

委托方推迟对报告草案的审阅
Delay the review

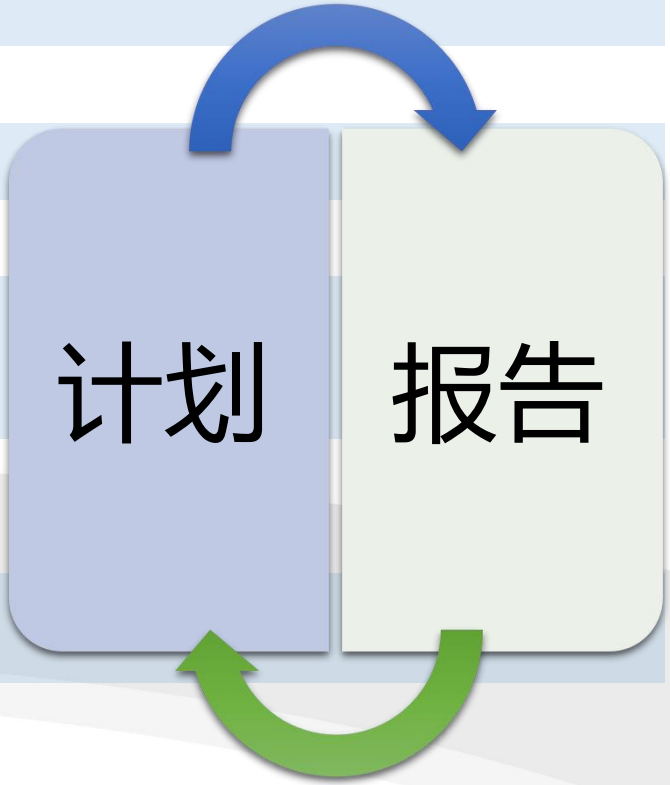
- Delay in the prompt reporting of the study
- Failure to close the study
- Delay in study archiving

增加数据完整性的风险
Increases the risk

- **Define the timelines** in the study plan or in any service agreements or contracts.
- **Define a maximum time** for the sponsor to review the draft report after which the final report will be issued by the SD with or without comments or additional required information from the sponsor.
- This scenario should also be considered in multi-site studies.

报告审阅

• 符合性声明:	SD签署
• 质量保证声明:	QA签署
• 保密声明:	如有需要
• 委托方信息:	如出现更名的情况，需要做修订
• 参照物信息:	应与报告中所附的COA一致
• 被试物信息:	被试物COA
• 被试物（参照物）:	物料平衡（接收质量=消耗质量+剩余质量） 消耗量应与报告内容一致
• 结果汇总:	与正文中结果一致性 与规格、文献值的差异
• 日期问题:	时间逻辑顺序、项目时间节点、QA检查时间
• 试验方法:	与试验计划一致 过程描述要详实 计算（必要时提供举例说明）
• 附件信息:	谱图信息完整、参照物COA、委托协议

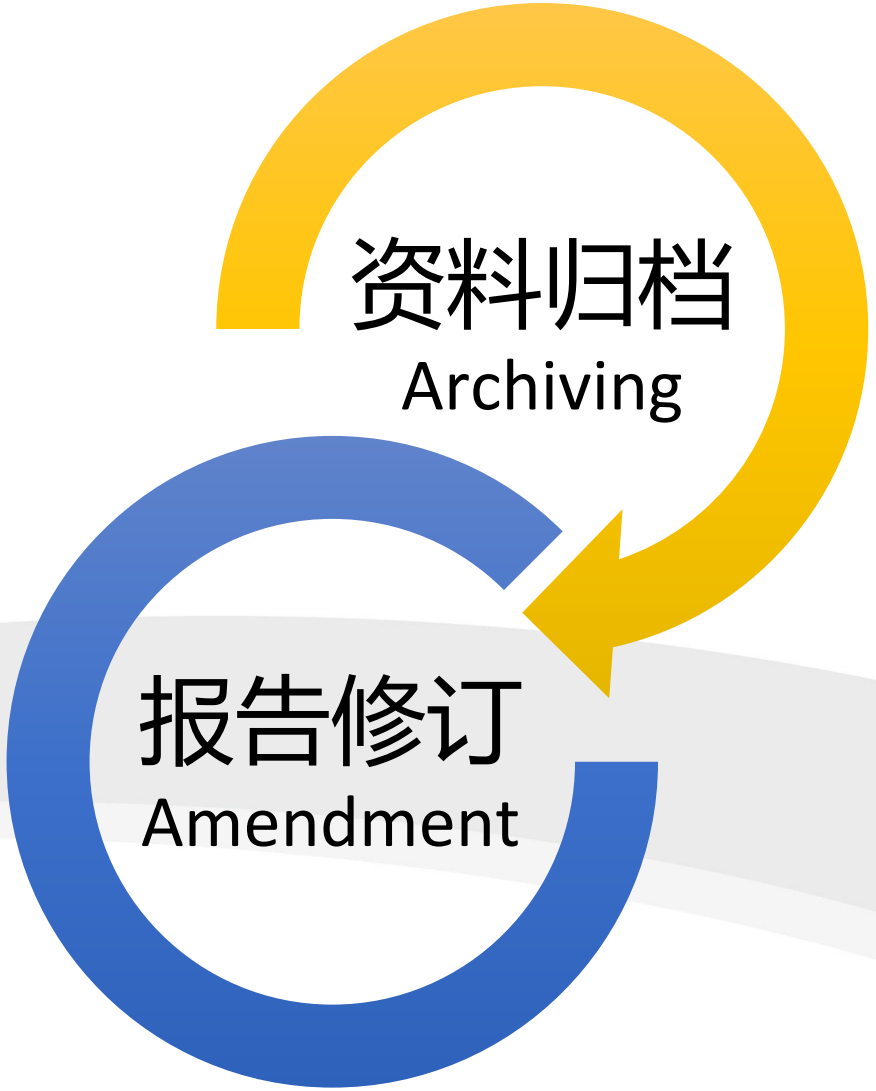


委托方的职责与作用

项目开展前

项目进行中

项目完成后



资料归档

归档材料?

归档期限?

到期处理?

报告修订

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING

Number 1

OECD Principles on Good Laboratory Practice (as revised in 1997)

9.1.4 Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.

9.1.5 Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

Sponsors may request CROs to reopen reports by amending them to add additional data.

Test items?

Study plan?

Final report?

新增数据

原则上不允许新增数据，除非监管部门提出相关要求或经监管部门同意

- It would not be appropriate to use a study report amendment to facilitate the reanalysis of data or the addition of new data to a final report except under exceptional circumstances.
- Exceptional circumstances would include requests from receiving authorities to reopen a GLP study. Such requests are usually made so that data can be reanalysed.
- Monitoring authorities will usually not allow a study to be reopened if the test facility or study sponsor wants to reanalyse or add data. However, most monitoring authorities will assess each request to reopen a study on a case-by-case basis.

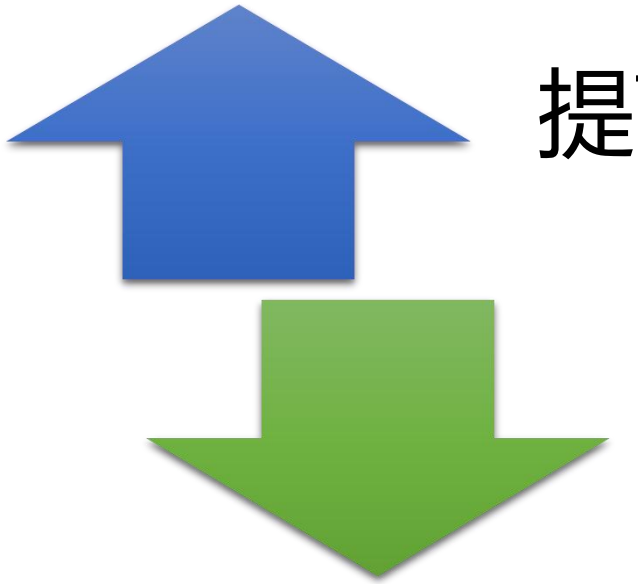
新增数据不在原计划范围内，需要修订试验计划

- If additional work is performed that was not required in the original study plan, it should be covered by a study plan amendment.

新增数据的报告以修订的方式出具，并说明修订原因

- If a GLP study is reopened, any changes to the original text or the addition of new text must be presented in the form of a report amendment.

小结 *Summary*



提高通过率

缩短登记周期

项目进展顺利

报告质量过硬

存档资料详实

实现MAD互认

机构介绍

浙江省化工产品质量检验站有限公司
ZHEJIANG PROVINCE CHEMICAL PRODUCTS QUALITY INSPECTION STATION CO. ,LTD

□ **浙江省化工产品质量检验站有限公司** 与 **浙江省化工研究院化工产品检测中心** 为同一实体，简称“**浙化检测**”。

□经过四十年的发展，现已成为专业从事**化学品性能测试、理化性质测定、GLP试验、危化品分类鉴定、货物运输鉴定、环境检测、农残检测、危废鉴别、配方剖析和还原、环保综合咨询**等业务，在华东地区具有区域影响力的综合性权威检验检测机构。

机构介绍

浙江省化工产品质量检验站有限公司
ZHEJIANG PROVINCE CHEMICAL PRODUCTS QUALITY INSPECTION STATION CO. ,LTD

农药登记试验单位证书

编号:	SD2019007
试验单位名称:	浙江省化工研究院化工产品检测中心
统一社会信用代码:	91330000717614261R
法定代表人(负责人):	张建君
住所:	杭州市天目山路387号
实验室地址:	杭州市天目山路387号
试验范围:	产品化学试验:(全)组分分析试验、理化性质测定试验、产品质量检测试验/储存稳定性试验
有效期:	2019 年 03 月 04 日 至 2024 年 03 月 03 日

中华人民共和国农业农村部
2019 年 03 月 04 日

2019 农业农村部农药登记试验单位（产品化学）

3 OECD GLP实验室（德国 BfR）

Bundesinstitut für Risikobewertung /
German Federal Institute for Risk Assessment

BfR
Bundesinstitut für Risikobewertung

GUTE LABORPRAXIS /
GOOD LABORATORY PRACTICE

GLP-Bestätigung / Statement of GLP Compliance

(gemäß / according to § 19b Abs. 2 Nr. 3 Chemikaliengesetz / Chemical Act)

Eine initiale GLP-Inspektion sowie eine GLP-Inspektion wurde durchgeführt in /
A initial GLP inspection and a GLP-inspection was carried out at

Prüfeinrichtung / Test facility

Test Center for Chemical Products of,
Zhejiang Chemical Industry Research Institute (ZCTC)
No.387, Tianmushan Road
Hangzhou, Zhejiang Province
P.C. 310023, P.R. China

Prüfkategorien / Area of Expertise

Prüfungen zur Bestimmung der physikalisch-chemischen Eigenschaften und Gehaltsbestimmungen /
Physical-chemical testing

Datum der Inspektionen / Date of inspections

October 27, 28, 31, 2016
Februar 12 – 15, 2018

Auf der Grundlage des Inspektionsberichtes und der Besprechung über zu erfolgende Maßnahmen wird hiermit bestätigt, dass in dieser Prüfeinrichtung die oben genannten Prüfungen unter Einhaltung der GLP-Grundsätze durchgeführt werden können. /
Based on the inspection report and the discussion of follow up activities it can be confirmed, that the test facility is able to conduct the aforementioned studies in compliance with the Principles of GLP.

Eine Überprüfung dieser GLP-Bestätigung ist spätestens zwei Jahre nach der o. g. Inspektion zu beantragen. Ohne diesen Antrag wird nach Ablauf der Frist die Prüfeinrichtung aus dem deutschen GLP-Überwachungsprogramm genommen und diese GLP-Bestätigung verliert ihre Gültigkeit. /
Verification of this Statement of GLP Compliance has to be applied two years after the above mentioned inspection at the latest. Elapsing this term, the test facility will be taken out of the German GLP Monitoring Programme and this Statement of GLP Compliance becomes invalid.

November 22, 2018
Im Auftrag / For the Director

Professor Dr. Matthias Greiner
GLP-Bundesstelle / GLP Federal Bureau

Bundesinstitut für Risikobewertung / German Federal Institute for Risk Assessment
Max-Dohrn-Straße 8-10
10589 Berlin – GERMANY

- 2012 农业部GLP试验单位（全组分分析）
- 2010 筹建GLP实验室

机构介绍

浙江省化工产品质量检验站有限公司
ZHEJIANG PROVINCE CHEMICAL PRODUCTS QUALITY INSPECTION STATION CO. ,LTD

CMA

CNAS

网址：http://www.chem-testing.com

地址：杭州天目山路387号，310023

电话：0571-81182363

Email：xiepeijin@sinochem.com

Thank You!

感谢聆听！