Management, characterisation and use of test item

Pirkko Puranen, Senior Inspector

New OECD GLP Advisory Document

- **OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING**
- **Number 19, 2018**

- **Advisory Document of the Working Group on Good Laboratory Practice on the Management, Characterisation and Use of Test Items**

Background

- Why an additional advisory document on test item was needed?
- What is said about test item in GLP Principles?

In GLP Principles:

Terms Concerning the Test Item

Test item means an article that is the subject of a study.

Reference item ("control item") means any article used to provide a basis for comparison with the test item.

Batch means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

Vehicle means any agent which serves as a carrier used to mix, disperse, or solubilize the test item or reference item to facilitate the administration/application to the test system.

GLP Principles

Facilities for Handling Test and Reference Items

To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.

Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

Archive Facilities

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

Receipt, Handling, Sampling and Storage

Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained.

Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mixup are precluded.

Storage container(s) should carry identification information, expiry date, and specific storage instructions

Characterisation

Each test and reference item should be appropriately identified (e.g., code, Chemical Abstracts Service Registry Number [CAS number], name, biological parameters).

For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.

In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study.

The stability of test and reference items under storage and test conditions should be known for all studies.

If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g., tank mixes), these may be determined through separate laboratory experiments.

A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies

Reasons to develop more guidance

- GLP Principles explain very little how requirements could be met and requirements are very general
- Therefore may be differences in interpretations of facilities and inspectors in different countries causing different level of standards
- New technologies and tests have been developed after GLP Principles were published (1998)

Drafting group

- Work initiated 2012
- Drafting grop established 2013
- Lead by UK and France from 2016 (originally lead by Canada)
- Members: Brazil, Denmark, Finland, India, Israel, Italy, Japan, South Africa, US (FDA and EPA)
- Draft 2017
- Altogether 700 comments
- Need of compromises
- Document endorsed 2018

What is new in the advisory document?

- Requirements given in GLP Principles are still valid, they cannot be changed by advisory documents
- More detailled examples, how GLP Principles may be applied in different situations
- Importance of communication and responsibilities between sponsor – test facility
- More risk assessment to estimate what is important
- New types of test items

Responsibilities

- Management
  - procedures, resources
- SD
  - confidence to characterization data, suitability of methods to be used in testing
- QA
  - has to cover full chain of characterization, transportation, receiving, storage, testing, archiving
- Archivist
  - archiving of test item

Characterization

- Describes the test item

Identification

- Confirmation that test item is what it is supposed to be
- Checking the test item against provided informationMay or may not include actual testing

Characterization of test item

- May be carried out by sponsor, supplier or test facility
- Integrity and quality of characterisation data has to be verified by the test facility
- Responsibilities have to be described in the study report
- It has to be justified, if some data is not available

Characterization of new types of test items

- Test items in early stage of development
  - has to be shown that test item has been what it was supposed to be

- Biochemical
- antibody, virus etc.
  - biological activity may be a characteristic

- Living organisms
  - case-by-case, passage number, viability etc

- Transgenic organisms
  - ID number, seed certification, host organism etc

- Medical devices

- additional information: picture, sterilization status, is test item is only a part of a device etc

- Complex composition
  - manufacturing process

- Radiolabelled items
  - stability!

Archiving

- Sample for analytical purposes
- Stability has to be known
- Disposed after expiry

Most important:

- Test item is what it is supposed to be
- No mix-ups
- No physical/chemical/biological changes because of storage conditions or transportation
- No contaminations
- Suitable metohods for test item are chosen to study safety
- Integrity of test item is verified by QA

Questions, comments, experiences?