TEST ITEMS – THE DIVERSITY OF REGULATORY STUDIES

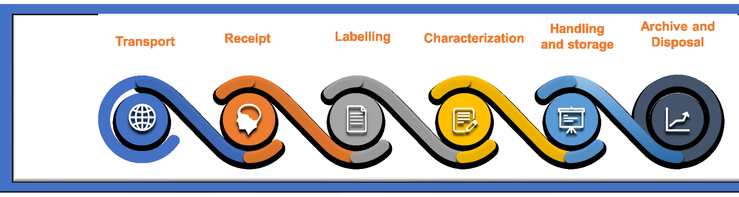
Cate Ovington Principal Associate and Rita Silvestre Associate, TMQA.

QUESTIONS

What is a test item? "..an article that is the subject of a study"

What is characterisation? "determines the attibutes of the test item and provides the evidence to support its suitability for use in GLP Studies"

What is identification? "the process of checking and assessing the test item against the supplied information to determine whether the test item is as expected"



RESPONSIBILITY

Who is responsible?

Sponsor

- Provides information on the test item.
- May carry out characterization of test item. If conducted by nominated supplier, the sponsor must ensure the information is provided to the Test Facility.

Test Facility Management

- Ensure test items are appropriately characterised.
- Procedures should be in place for transport, receipt, identification, labelling, handling, storage, characterisation, archiving and destruction of test items. Responsibility should be included.
- Handling and storage facilities should be designed to ensure the integrity of the test item before and during its use on the study.
- Provide resources for test item characterization whether in house or subcontracted.

Study Director

- Verifies the identity and nature of the test item. Documents the test item received agrees with study specification.
- Determines the characterisation provided is considered to be sufficient, accurate and reliable.

CHARACTERISATION

With the diversity of test items' the characterisation cannot be a one size fits all. In a perfect world the test item will be provided with information on identity (name, code, CAS number, batch number, purity, composition, concentration) and stability under storage and test conditions).

There should be a mechanism between the test facility and the sponsor to ensure sufficient information is provided. Inadequate information on the characterisation of the test item constitutes a devation from the principles of GLP.

Ideal Test Item	Early Stage	Biochemical	Organisms	Medical Devices	Radiolabelled
☐ Batch number	☐ Batch number	☐ Batch number	☐ Name	☐ Batch number	☐ Batch number
☐ Expiry date	☐ Expiry date	☐ Expiry Date	☐ Unique Identifier	☐ Description	☐ Radiopurity
☐ Appearance	☐ Appearance	☐ Biological activity	☐ Biological properties	☐ Drawings	☐ Specific Activity
☐ Purity				☐ Composition	
☐ Composition				☐ Expiry date	
☐ Concentration					
☐ Certificate of Analysis					

The stability of the test item under storage and test conditions must be known. For some test items it is not possible to obtain due to instability (radiolabelled) or it is not appropriate (organisms, re-usable medical devices). Either the suitability of the test item is demonstrated through testing i.e. specific activity, radiopurity or if it is not appropriate the lack of an expiry data and its impact on the validity of a study should be justified in the report.

Test items may be supplied with an expiry date or a retest date. It should be clear in the study plan and report which is provided. The terms are not equal.

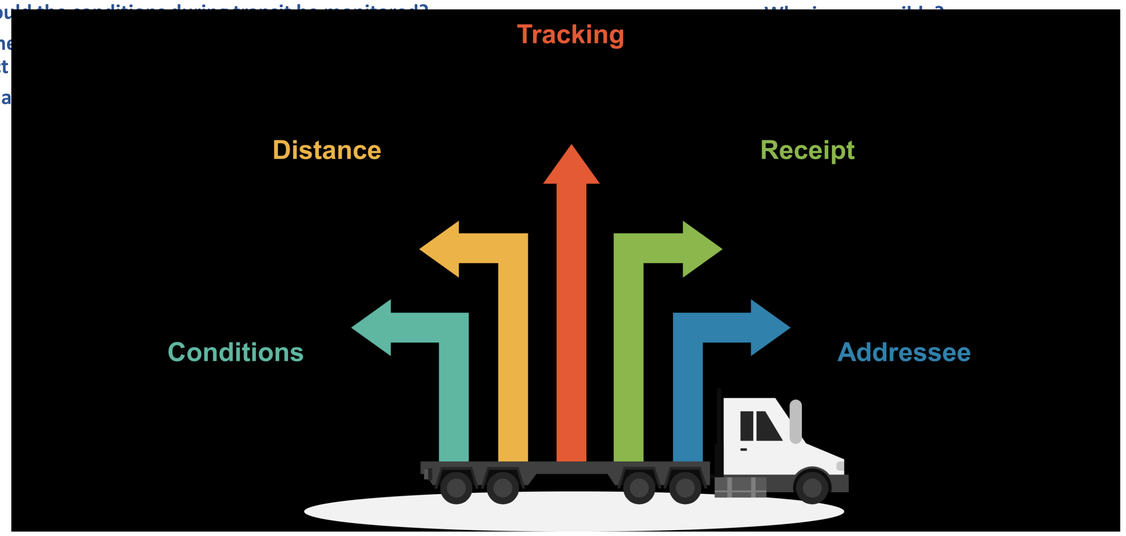
- **Expiry date defines the total shelf life of a product if stored under defined conditions.**
- **Retest date is when a material should be re-examined to ensure that it is still suitable for use.**

Expiry ≠ Retest

TRANSPORT

Consideration of the conditions the test item will be subjected to during transportation should be undertaken prior to dispatch.

- **Does the test item have specific storage conditions?**
  - **Are these critical?**
  - **Should the conditions during transit be monitored?**
- **Will the impact**
  - **Wha**
- **What if the test item arrived outside of normal hours?**
  - **Who is responsible?**



GENERATION OF INFORMATION

Sponsor

Where charaterisation is performed outside the test facility, there must be procedures to verify the integrity and quality of the information provided. The Study Director must understand how the testing was conducted and be confient in the accuracy and reliability of the data. Preferably this is performed prior to the experimental phase commences.
Suggested solution is to ask for information to enable verification of the information provided on the test item in a pre-study questionnaire.

Test Facility

Information should be made available to the Study Director to provide confidence in the accuracy and reliability of the data.
Test Facility Management should ensure there is a mechanism between the department generating the data and provision to the test facility.

References

OECD The Role and responsibilities of the sponsor in the application of the principles of GLP. Paris: OECD; 1998 (OECD Series on principles of GLP and Compliance Monitoring. No. 11, ENV/MC/CHEM(98)16).
OECD Management, Characterisation and Use of Test Items; 2018 (OECD Series on principles of GLP and Compliance Monitoring. No. 19 ENV/JM/MONO(2018)6)
OECD The Role and responsibilities of the study director in GLP studies; 1999 (OECD Series on principles of GLP and Compliance Monitoring. No. 8 ENV/JM/MONO(99)24).
ICH Q7. Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients