Guidance for Industry: Contract Testing Laboratories

Version 1.0

Drug Office
Department of Health

Contents

1. Introduction

All licensed pharmaceutical manufacturers who contract out any quality control testing will be required to contract it out to a licensed manufacturer certified as a GMP manufacturer by the Committee or a laboratory:

- accredited in accordance with ISO 17025, or equivalent, for the tests required to be performed; or
- inspected by inspectors of the Drug Office and the result of the inspection has shown to the satisfaction of the Committee that the laboratory has complied with such parts of GMP relevant to the quality control testing to be contracted out. To enable such an inspection, the licensed pharmaceutical manufacturer using that laboratory shall make the relevant arrangement with the laboratory.

Where the ISO 17025 accreditation option is selected, evidence of accreditation by a recognised certification body should be provided.

GMP inspections of pharmaceutical manufacturers will include, in relation to contract testing, verification of:

- the assessment of the competency of any contract testing laboratories used by the manufacturer; and
- the compliance with the relevant requirements of Chapter 7 of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PIC/S Guide to GMP), including the availability of suitable written contract describing the arrangements for the contract testing.

2. Purpose of this document

To provide guidance to industry on contract testing laboratories.

3. Scope

This guidance document is applicable to pharmaceutical manufacturers who use external laboratories for conducting analytical and/or microbiological testing.

4. Common asked questions and answers

4.1 What should be included in the contract?

Refer to PIC/S Guide to GMP clauses 7.1, 7.2, and 7.10 to 7.15.

4.2 Is a written contract required for all types of contract testing services?

A written contract should be in place for the following contract testing activities:

- microbiological testing of non-sterile finished products and associated starting materials and intermediates;
- sterility and endotoxin testing relating to sterile finished products and associated starting materials and intermediates;
- physiochemical analysis of sterile and non-sterile finished products and associated starting materials, intermediates and packaging materials;
- stability studies on finished products; and
- microbiological and physiochemical monitoring of manufacturing areas & utilities (e.g. monitoring of environment, purified water, water for injections, compressed gases, etc.).

For other contracted out services (e.g. calibration of instruments), manufacturers need to make a risk-based decision under its own Quality Management System on the need for written contract.

4.3 When selecting a contract testing laboratory, is ISO 17025 necessary?

Refer to the requirements outlined in "Introduction" above.

Note that if ISO 17025 is one of the in-house selection criteria, it is important to check whether the scope of certification is relevant for the test(s) being contracted out.

4.4 Is a pre-approval audit required before approving a contract laboratory?

Manufacturers should use a risk-based approach to determine whether a pre-approval audit is required. Risk factors should include, but not limited to:

- impact of the results generated;
- track record of the laboratory; and
- any relevant accreditation by reputable organizations.

For example, test results for final product release and regulatory submissions are generally considered as high-risk. Pre-approval audit is expected unless there are other factors modifying the risk.

For lower risk situations, the manufacturer can decide if an audit is required provided that the decision is properly justified and documented.

4.5 Can a manufacturer rely on site inspection by a regulatory agency?

Even if the contract laboratory has been inspected by a regulatory agency, the contract giver still has the responsibility to ensure that testing is conducted according to GMP principles and guidelines, marketing authorization and technical agreements. Inspection findings of a regulatory agency can be considered in assessing the risk classification of the laboratory.

4.6 Is periodic assessment of a contract testing laboratory expected?

Yes. The contract giver is responsible for assessing the competency of the contract acceptor and its compliance with the PIC/S Guide to GMP. Initial and periodic assessments are expected. The outcome of an assessment may re-rate the risk classification which can affect the frequency of the next assessment or re-audit.

4.7 What are the differences between GLP and GMP?

The term GLP (Good Laboratory Practice) is a generic term that sometimes causes confusion when used to describe the Quality Control (QC) testing of pharmaceutical products. GLP is a quality standard for non-clinical health and environmental safety studies. In many parts of the world, it is a regulatory requirement to conduct non-clinical, toxicological studies of new chemical or biological substances in compliance with GLP.

There is no legal requirement for the QC of pharmaceutical products to be conducted in accordance with GLP. However, QC testing of pharmaceutical products must be in accordance with the PIC/S Guide to GMP.

Document Information

Version	Date	Description of Change
1.0	27 Dec 2013	First version

References

Document Title
PIC/S Guide to Good Manufacturing Practices for Medicinal Products PE 009-10: Part I, Chapter 7
MHRA Guidance for UK manufacturer's licence and manufacturer's authorization (for investigational medicinal products) holders on the use of UK stand-alone contract laboratories
FDA Guidance for Industry – Contract Manufacturing Arrangements for Drugs: Quality Agreements
APIC Guideline for Qualification & Management of Contract Quality Control Laboratories

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