

Directive 2004/10/EC of the European Parliament and of the Council
of 11 February 2004 on the harmonisation of laws, regulations and
administrative provisions relating to the application of the principles of
good laboratory practice and the verification of their applications for tests
on chemical substances (codified version) (Text with EEA relevance)

- Article 1 (1) Member States shall take all measures necessary to ensure...
- Article 2 When submitting results, the laboratories referred to in Article
1...
- Article 3 (1) Member States shall adopt the measures necessary for
verification...
- Article 3a The Commission may adapt Annex I to technical progress, with...
- Article 4 (1) The Commission shall be assisted by the Committee
established...
- Article 5 (1) Where Community provisions require application of the
principles of...
- Article 6 Directive 87/18/EEC is hereby repealed, without prejudice to the
obligations...
- Article 7 This Directive shall enter into force on the 20th day...
- Article 8 This Directive is addressed to the Member States.

ANNEX I

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

SECTION I

INTRODUCTION

Preface

1. Scope
2. Definition of terms
 - 2.1. Good laboratory practice
 - 2.2. Terms concerning the organisation of a test facility
 1. Test facility means the persons, premises and operational unit(s) that...
 2. Test site means the location(s) at which a phase(s) of...
 3. Test facility management means the person(s) who has the authority...
 4. Test site management (if appointed) means the person(s) responsible
for...
 5. Sponsor means an entity which commissions, supports and/or submits
a...
 6. Study director means the individual responsible for the overall
conduct...
 7. Principal investigator means an individual who, for a multisite study,...

8. Quality assurance programme: means a defined system, including personnel, which...
9. Standard operating procedures (SOPs) means documented procedures which describe how...
10. Master schedule means a compilation of information to assist in...
- 2.3. Terms concerning the non-clinical health and environmental safety study
 1. Non-clinical health and environmental safety study, henceforth referred to simply...
 2. Short-term study means a study of short duration with widely...
 3. Study plan means a document which defines the objectives and...
 4. Study plan amendment means an intended change to the study...
 5. Study plan deviation means an unintended departure from the study...
 6. Test system means any biological, chemical or physical system, or...
 7. Raw data means all original test facility records and documentation,...
 8. Specimen means any material derived from a test system for...
 9. Experimental starting date means the date on which the first...
 10. Experimental completion date means the last date on which data...
 11. Study initiation date means the date the study director signs...
 12. Study completion date means the date the study director signs...
- 2.4. Terms concerning the test item
 1. Test item means an article that is the subject of...
 2. Reference item (control item) means any article used to provide...
 3. Batch means a specific quantity or lot of a test...
 4. Vehicle means any agent which serves as a carrier used...

SECTION II

GOOD LABORATORY PRACTICE PRINCIPLES

1. Test facility organisation and personnel
 - 1.1. Test facility management's responsibilities
 1. Each test facility management should ensure that these principles of...
 2. At a minimum it should:
 3. When a phase(s) of a study is conducted at a...
 - 1.2. Study director's responsibilities
 1. The study director is the single point of study control...
 2. These responsibilities should include, but not be limited to, the...
 - 1.3. Principal investigator's responsibilities
 - 1.4. Study personnel's responsibilities
 1. All personnel involved in the conduct of the study must...
 2. Study personnel will have access to the study plan and...
 3. All study personnel are responsible for recording raw data promptly...
 4. Study personnel should exercise health precautions to minimise risk to...
2. Quality assurance programme
 - 2.1. General
 1. The test facility should have a documented quality assurance programme...
 2. The quality assurance programme should be carried out by an...
 3. This individual(s) should not be involved in the conduct of...
 - 2.2. Responsibilities of the quality assurance personnel

3. Facilities
 - 3.1. General
 1. The test facility should be of suitable size, construction and...
 2. The design of the test facility should provide an adequate...
 - 3.2. Test system facilities
 1. The test facility should have a sufficient number of rooms...
 2. Suitable rooms or areas should be available for the diagnosis,...
 3. There should be storage rooms or areas as needed for...
 - 3.3. Facilities for handling test and reference items
 1. To prevent contamination or mix-ups, there should be separate rooms...
 2. Storage rooms or areas for the test items should be...
 - 3.4. Archive facilities
 - 3.5. Waste disposal
4. Apparatus, material, and reagents
 1. Apparatus, including validated computerised systems, used for the generation, storage...
 2. Apparatus used in a study should be periodically inspected, cleaned,...
 3. Apparatus and materials used in a study should not interfere...
 4. Chemicals, reagents, and solutions should be labelled to indicate identity...
5. Test systems
 - 5.1. Physical/chemical
 1. Apparatus used for the generation of physical/chemical data should be...
 2. The integrity of the physical/chemical test systems should be ensured....
 - 5.2. Biological
 1. Proper conditions should be established and maintained for the storage,...
 2. Newly received animal and plant test systems should be isolated...
 3. Records of source, date of arrival, and arrival condition of...
 4. Biological test systems should be acclimatised to the test environment...
 5. All information needed to properly identify the test systems should...
 6. During use, housing or containers for test systems should be...
 7. Test systems used in field studies should be located so...
6. Test and reference items
 - 6.1. Receipt, handling, sampling and storage
 1. Records including test item and reference item characterisation, date of...
 2. Handling, sampling, and storage procedures should be identified in order...
 3. Storage container(s) should carry identification information, expiry date, and specific...
 - 6.2. Characterisation
 1. Each test and reference item should be appropriately identified (e.g....
 2. For each study, the identity, including batch number, purity, composition,...
 3. In cases where the test item is supplied by the...
 4. The stability of test and reference items under storage and...
 5. If the test item is administered or applied in a...

6. A sample for analytical purposes from each batch of test...
7. Standard operating procedures
 1. A test facility should have written standard operating procedures approved...
 2. Each separate test facility unit or area should have immediately...
 3. Deviations from standard operating procedures related to the study should...
 4. Standard operating procedures should be available for, but not be...
8. Performance of the study
 - 8.1. Study plan
 1. For each study, a written plan should exist prior to...
 2. Amendments to the study plan should be justified and approved...
 3. For short-term studies, a general study plan accompanied by a...
 - 8.2. Content of the study plan
 - 8.3. Conduct of the study
 1. A unique identification should be given to each study. All...
 2. The study should be conducted in accordance with the study...
 3. All data generated during the conduct of the study should...
 4. Any change in the raw data should be made so...
 5. Data generated as a direct computer input should be identified...
9. Reporting of study results
 - 9.1. General
 1. A final report should be prepared for each study. In...
 2. Reports of principal investigators or scientists involved in the study...
 3. The final report should be signed and dated by the...
 4. Corrections and additions to a final report should be in...
 5. Reformatting of the final report to comply with the submission...
 - 9.2. Content of the final report
10. Storage and retention of records and materials
 - 10.1. The following should be retained in the archives for the...
 - 10.2. Material retained in the archives should be indexed so as...
 - 10.3. Only personnel authorised by management should have access to the...
 - 10.4. If a test facility or an archive contracting facility goes...

ANNEX II

PART A

PART B

ANNEX III

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

- (1) [OJ C 85, 8.4.2003, p. 138.](#)
- (2) Opinion of the European Parliament of 1 July 2003 (not yet published in the Official Journal) and Decision of the Council of 20 January 2004.
- (3) [OJ L 15, 17.1.1987, p. 29.](#) Directive as amended by Commission Directive 1999/11/EC ([OJ L 77, 23.3.1999, p. 8.](#))
- (4) [OJ 196, 16.8.1967, p. 1.](#) Directive as last amended by Regulation (EC) No 807/2003 ([OJ L 122, 16.5.2003, p. 36.](#))
- (5) [OJ L 311, 28.11.2001, p. 1.](#)
- (6) [OJ L 311, 28.11.2001, p. 67.](#) Directive as amended by Commission Directive 2003/63/EC ([OJ L 159, 27.6.2003, p. 46.](#))