

Directive 2004/9/EC of the European Parliament and of the Council
of 11 February 2004 on the inspection and verification of good
laboratory practice (GLP) (Codified version) (Text with EEA relevance)

Article 1	(1) This Directive shall apply to the inspection and verification...
Article 2	(1) Using the procedure laid down in Article 3, Member...
Article 3	(1) Member States shall designate the authorities responsible for the...
Article 4	(1) Each year, Member States shall draw up a report...
Article 5	(1) Without prejudice to Article 6, the results of laboratory...
Article 6	(1) Where a Member State has sufficient reason to believe...
Article 6a	(1) The power to adopt delegated acts is conferred on...
Article 7	(1) The Commission shall be assisted by the Committee established...
Article 8	(1) The Committee may examine any question which is referred...
Article 9	Directive 88/320/EEC is hereby repealed, without prejudice to the obligations...
Article 10	This Directive shall enter into force on the 20th day...
Article 11	This Directive is addressed to the Member States.

ANNEX I

The provisions for the inspection and verification of GLP which...

PART A

REVISED GUIDES FOR COMPLIANCE MONITORING PROCEDURES FOR GLP

Definitions of terms

Components of good laboratory practice compliance monitoring procedures

Confidentiality

Personnel and training

(National) GLP compliance programmes

Follow-up to test facility inspections and study audits

Appeals procedures

PART B

REVISED GUIDANCE FOR THE CONDUCT OF TEST FACILITY INSPECTIONS AND STUDY AUDITS

Introduction

Definitions of terms

Test facility inspections

Inspection procedures

Starting conference

Organisation and personnel

Quality assurance programme

Facilities

Care, housing and containment of biological test systems

Apparatus, materials, reagents and specimens

Test systems

Physical and chemical systems

Biological test systems

Test and reference substances

Standard operating procedures

Performance of the study

Reporting of study results

Storage and retention of records

Study audits

Completion of inspection or study audit

ANNEX II

PART A

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.

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. 137.](#)
- (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 145, 11.6.1988, p.35.](#) Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (4) See page 44 of this Official Journal.
- (5) [OJ L 358, 18.12.1986, p. 1.](#)
- (6) [OJ 196, 16.8.1967, p. 1.](#) Directive as last amended by Council Regulation (EC) No 807/2003 ([OJ L 122, 16.5.2003, p. 36](#)).
- (7) [OJ L 184, 17.7.1999, p. 23.](#)