

---

STATUTORY INSTRUMENTS

---

**1997 No. 654**

**HEALTH AND SAFETY**

**The Good Laboratory Practice Regulations 1997**

<i>Made</i>	- - - -	<i>6th March 1997</i>
<i>Laid before Parliament</i>		<i>7th March 1997</i>
<i>Coming into force</i>		<i>1st April 1997</i>

**THE GOOD LABORATORY PRACTICE REGULATIONS 1997**

1. Citation and commencement
  2. Interpretation
  3. Functions of the Secretary of State
  4. Requirement to be a member or a prospective member of the United Kingdom good laboratory practice compliance programme
  5. Prospective membership of the United Kingdom good laboratory practice compliance programme
  6. Membership of the United Kingdom good laboratory practice compliance programme
  7. Requirement to adhere to the principles of good laboratory practice
  8. Appeals against warning notices
  9. Powers and duties of inspectors
  10. Appointment of inspectors
  11. Disclosure of confidential information
  12. Obstruction etc. of inspectors
  13. Offences by bodies corporate and Scottish partnerships
  14. Defence of due diligence
  15. Penalties
  16. Fees
  17. Amendment of the Medicines (Applications for Grant of Product Licences —Products for Human Use) Regulations 1993
  18. Amendment of the Notification of New Substances Regulations 1993
  19. Amendment of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994
- Signature

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

---

SCHEDULE 1 — PRINCIPLES OF GOOD LABORATORY PRACTICE (BASED ON ANNEX 2 TO THE DECISION OF 12TH MAY 1981 OF THE COUNCIL OF THE OECD ON THE MUTUAL ACCEPTANCE OF DATA FOR THE EVALUATION OF CHEMICAL PRODUCTS)

PART I — LABORATORY ORGANISATION AND PERSONNEL

1. The management's responsibilities
2. The study director's responsibilities
3. Personnel responsibilities

PART II — QUALITY ASSURANCE PROGRAMME

4. General
5. Responsibilities of the quality assurance personnel

PART III — FACILITIES

6. General
7. Test system facilities
8. Facilities for handling test and reference substances
9. Archive facilities
10. Waste disposal

PART IV — APPARATUS, MATERIALS AND REAGENTS

11. Apparatus
12. Materials
13. Reagents

PART V — TEST SYSTEMS

14. Physical/chemical
15. Biological

PART VI — TEST AND REFERENCE SUBSTANCES

16. Receipt, handling, sampling and storage
17. Characterisation

PART VII — STANDARD OPERATING PROCEDURES

18. General
19. Application

PART VIII — PERFORMANCE OF THE SAFETY STUDY

20. Study plan
21. Content of the study plan
22. Conduct of the safety study

PART IX — REPORTING OF SAFETY STUDY RESULTS

23. General
24. Content of the final report

PART X — STORAGE AND RETENTION OF RECORDS AND MATERIAL

25. Storage and retrieval
26. Retention

SCHEDULE 2 — INSPECTION PROCEDURES AND STUDY AUDITS (BASED ON ANNEX B TO THE GLP INSPECTION AND VERIFICATION DIRECTIVE)

PART I — INSPECTION PROCEDURES

1. Pre-inspection
2. Starting conference
3. Organisation and personnel
4. Quality assurance programme
5. Facilities

6. Care, housing and containment of biological test systems
  7. Apparatus, materials, reagents and specimens
  8. Test systems
  9. Physical and chemical systems
  10. Biological test systems
  11. Test and reference substances
  12. Standard operating procedures
  13. Performance of the study
  14. Reporting of study results
  15. Storage and retention of records
- PART II — STUDY AUDITS
16. Laboratory inspections will generally include inter alia(limited) study audits. These...
  17. In some cases, inspectors may need assistance from other experts...
  18. When conducting a study audit, the inspector should— obtain names,...
  19. In studies in which animals (i.e. rodents and other mammals)...

Explanatory Note