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STATUTORY INSTRUMENTS

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**1999 No. 3106**

**HEALTH AND SAFETY**

**The Good Laboratory Practice Regulations 1999**

*Made - - - - 18th November 1999*

*Laid before Parliament 19th November 1999*

*Coming into force 14th December 1999*

**THE GOOD LABORATORY PRACTICE REGULATIONS 1999**

1. Citation and commencement
2. Interpretation
3. The Good Laboratory Practice Monitoring Authority
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 of entry etc.
10. Disclosure of confidential information
11. Obstruction etc. of authorised persons
12. False good laboratory practice instruments
13. Offences by bodies corporate and Scottish partnerships
14. Defence of due diligence
15. Penalties
16. Fees
17. Revocation  
Signature

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SCHEDULE 1 — GOOD LABORATORY PRACTICE PRINCIPLES (BASED ON SECTION II OF ANNEX I TO THE EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 2004/10/EC)

PART I — TEST FACILITY ORGANISATION AND PERSONNEL

1. Facility management's responsibilities

*Changes to legislation: There are currently no known outstanding effects for the  
The Good Laboratory Practice Regulations 1999. (See end of Document for details)*

2. Study director's responsibilities
  3. Principal investigator's responsibilities
  4. Study personnel's responsibilities
  - PART II — QUALITY ASSURANCE PROGRAMME
  1. General
  2. Responsibilities of the quality assurance personnel
  - PART III — FACILITIES
  1. General
  2. Test System Facilities
  3. Facilities for handling test and reference items
  4. Archive Facilities
  5. Waste Disposal
  - PART IV — APPARATUS, MATERIALS AND REAGENTS
  1. Apparatus, including validated computerised systems, used for the generation, storage...
  2. Apparatus used in a regulatory study should be periodically inspected,...
  3. Apparatus and materials used in studies should not interfere adversely...
  4. Chemicals, reagents and solutions should be labelled to indicate identity...
  - PART V — TEST SYSTEMS
  1. Physical/Chemical
  2. Biological
  - PART VI — TEST AND REFERENCE ITEMS
  1. Receipt, handling, sampling and storage
  2. Characterisation
  - PART VII — 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 regulatory study...
  4. Standard operating procedures should be available for, but not be...
  - PART VIII — PERFORMANCE OF THE REGULATORY STUDY
  1. Study plan
  2. Content of the Study Plan
  3. Conduct of the Regulatory study
  - PART IX — REPORTING OF REGULATORY STUDY RESULTS
  1. General
  2. Content of the Final Report
  - PART X — STORAGE AND RETENTION OF RECORDS AND MATERIALS
  1. (1) The following should be retained in the archives for...
  2. Material retained in the archives should be indexed so as...
  3. Only personnel authorised by management should have access to the...
  4. If a test facility or an archive contracting facility goes...
- SCHEDULE 2 — REVISED GUIDANCE FOR THE CONDUCT OF TEST  
FACILITY INSPECTIONS AND STUDY AUDITS (BASED  
ON PART OF PART B OF ANNEX I TO THE EUROPEAN  
PARLIAMENT AND COUNCIL DIRECTIVE 2004/9/EC)
- 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. Test and reference items
10. Standard operating procedures
11. Performance of the study
12. Reporting of study results
13. Storage and retention of records

PART II — STUDY AUDITS

1. Test facility inspections will generally include, inter alia, study audits,...
2. In some cases, inspectors may need assistance from other experts...
3. When conducting a study audit, the inspector should— —obtain names,...
4. In studies in which animals (i.e. rodents and other mammals)...

Explanatory Note

**Changes to legislation:**

There are currently no known outstanding effects for the The Good Laboratory Practice Regulations 1999.