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STATUTORY INSTRUMENTS

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**1999 No. 3106**

**The Good Laboratory Practice Regulations 1999**

**Membership of the United Kingdom good laboratory practice compliance programme**

6.—(1) Subject to paragraph (2) and except where paragraph (5), (6) or (7) applies, the operator of a test facility shall be regarded as being a member of the UKGLP compliance programme in respect of particular test facility premises if—

- (a) he was regarded as being a member of the programme in respect of those premises immediately before these Regulations come into force by virtue of regulation 6 of the Good Laboratory Practice Regulations 1997<sup>(1)</sup>; or
- (b) after having inspected those premises, the GLPMA have informed the operator in writing that they are admitting the operator to membership of the programme in respect of those premises.

(2) The operator of a test facility shall cease to be a member of the UK GLP compliance programme in respect of particular test facility premises if—

- (a) he has informed the GLPMA in writing that regulatory studies are no longer conducted at those premises; or
- (b) membership of the programme in respect of those premises has been withdrawn by the GLPMA in accordance with paragraph (3).

(3) Subject to paragraph (4), the GLPMA may by a notice in writing served on the operator of a test facility withdraw the operator's membership of the UK GLP compliance programme in respect of particular test facility premises if—

- (a) the operator, in the opinion of the GLPMA, no longer intends to conduct regulatory studies at those premises;
- (b) the operator is, in the opinion of the GLPMA, not capable of ensuring that the principles of good laboratory practice are adhered to at those premises; or
- (c) at those premises there is a failure to adhere to the principles of good laboratory practice which, in the opinion of the GLPMA, may contribute towards precipitating a danger to animal or human health or to the environment.

(4) Before serving a notice on an operator of a test facility under paragraph (3)(a) or (b), the GLPMA shall—

- (a) inform the operator in writing that they are considering serving such a notice and explain to him in writing the reasons why they are considering serving such a notice;
- (b) give the operator a specified period within which to make representations to him; and
- (c) consider any representations which are duly made and not withdrawn,

unless, in order to ensure fulfilment of any Community obligation, it is necessary for the GLPMA to serve the notice immediately.

(5) Where an operator of a test facility has ceased to be a member of the UK GLP compliance programme in respect of particular test facility premises on the grounds set out in paragraph (2)(a),

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(1) S.I.1997/654.

or membership of the programme in respect of particular test facility premises has been withdrawn from him on the grounds set out in paragraph (3)(a), he shall again be regarded as being a member of the programme in respect of those premises if—

- (a) he has informed the GLPMA by notice in writing of the intention to conduct further regulatory studies at those premises;
- (b) he has become a prospective member of the programme in respect of those premises in accordance with the procedure set out in regulation 5; and
- (c) after having inspected those premises, the GLPMA has informed the operator in writing of his readmission to membership of the programme in respect of those premises.

(6) Where membership of the UK GLP compliance programme has been withdrawn from an operator of a test facility in respect of particular test facility premises on the grounds set out in paragraph (3)(b), he shall again be regarded as being a member of the programme in respect of those premises if—

- (a) he has informed the GLPMA by notice in writing of the intention to conduct further regulatory studies at those premises; and
- (b) the GLPMA—
  - (i) are of the opinion that the operator is capable of ensuring that the principles of good laboratory practice are adhered to at those premises, and
  - (ii) have informed the operator in writing of his readmission to membership of the programme in respect of those premises.

(7) Where membership of the UK GLP compliance programme has been withdrawn from an operator of a test facility in respect of particular test facility premises on the grounds set out in paragraph (3)(c), he shall again be regarded as being a member of the programme in respect of those premises if—

- (a) he has informed the GLPMA by notice in writing of the intention to conduct further regulatory studies at those premises; and
- (b) the GLPMA—
  - (i) are of the opinion that the possible danger to animal or human health or to the environment which led to membership being withdrawn is no longer present, and
  - (ii) have informed the operator in writing of his readmission to membership of the programme in respect of those premises.