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STATUTORY INSTRUMENTS

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**1999 No. 3106**

**The Good Laboratory Practice Regulations 1999**

**Requirement to adhere to the principles of good laboratory practice**

7.—(1) No person shall conduct a regulatory study at any premises of a test facility unless with regard to that study the principles of good laboratory practice are adhered to—

- (a) as respects the organisational structure surrounding the study; and
- (b) as respects the conditions under which the study is planned, performed, monitored, recorded, archived and reported.

(2) If the GLPMA have reasonable grounds for believing that a person has contravened paragraph (1) and is responsible for a serious deviation from the principles of good laboratory practice which may have affected the validity of a regulatory study, they may by a notice served on the operator of the test facility at whose premises the alleged contravention took place (in these Regulations referred to as a “warning notice”)—

- (a) state the GLPMA’s grounds for believing that the person—
  - (i) has contravened paragraph (1), and
  - (ii) is responsible for a serious deviation from the principles of good laboratory practice which may have affected the validity of a regulatory study;
- (b) specify the measures which, in the opinion of the GLPMA, the operator of the test facility must take in order to ensure that the serious deviation from the principles of good laboratory practice which may have affected the validity of a regulatory study will not recur;
- (c) require the operator of the test facility to take those measures, or measures which are at least equivalent to them, within such period as may be specified in the warning notice; and
- (d) inform the operator of the test facility of—
  - (i) his right of appeal against the warning notice under regulation 8,
  - (ii) the period within which such an appeal may be brought, and
  - (iii) the effect that such an appeal will have on any criminal proceedings relating to the operator’s alleged failure to comply with the warning notice.

(3) Any operator of a test facility who fails to comply with a warning notice shall, unless that notice has been withdrawn by the GLPMA or cancelled by a court, be guilty of an offence.