
STATUTORY INSTRUMENTS

1999 No. 3106

The Good Laboratory Practice Regulations 1999

False good laboratory practice instruments

12.—(1) A person who—

- (a) makes a false good laboratory practice instrument; or
- (b) makes a copy of an instrument which is, and which he knows or believes to be, a false good laboratory practice instrument,

with the intention that he or another shall use it to induce a regulatory authority to accept it as a genuine good laboratory practice instrument or a copy of a genuine good laboratory practice instrument shall be guilty of an offence.

(2) A person who has in his possession—

- (a) a false good laboratory practice instrument which he knows or believes to be a false good laboratory practice instrument;
- (b) a copy of an instrument which he knows or believes to be a false good laboratory practice instrument,

with the intention that he or another shall supply it to a regulatory authority with the intention of inducing the regulatory authority to accept it as a genuine good laboratory practice instrument or a copy of a genuine good laboratory practice instrument shall be guilty of an offence.

(3) A person who supplies to a regulatory authority—

- (a) a false good laboratory practice instrument which he knows or believes to be a false good laboratory practice instrument;
- (b) a copy of an instrument which he knows or believes to be a false good laboratory practice instrument,

with the intention of inducing the regulatory authority to accept it as a genuine good laboratory practice instrument or a copy of a genuine good laboratory practice instrument shall be guilty of an offence.

(4) A good laboratory practice instrument is “false” for the purposes of this regulation if—

- (a) it is not that which it purports to be for any reason including where—
 - (i) it purports to have been made by a person who did not make it,
 - (ii) it purports to have been made in the form in which it is made by a person who did not in fact make it in that form,
 - (iii) it purports to have been altered in any respect on the authority of a person who did not in fact authorise the alteration in that respect; or
- (b) it includes information which is false or misleading in a material particular,

and a person shall be treated for the purposes of this regulation as making a false good laboratory practice instrument if he alters a good laboratory practice instrument so as to make it false in any respect (whether or not it is false in some other respect apart from that alteration).

(5) A person may be guilty of an offence—

- (a) under paragraph (1) or (2) if the regulatory authority is outside the United Kingdom;
- (b) under paragraph (3) if the supply is from outside the United Kingdom to a United Kingdom regulatory authority or from within the United Kingdom to a regulatory authority outside the United Kingdom.

Changes to legislation:

There are currently no known outstanding effects for the The Good Laboratory Practice Regulations 1999, Section 12.