STATUTORY INSTRUMENTS

1999 No. 3106

The Good Laboratory Practice Regulations 1999

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

"batch" means a specific quantity or lot of a test or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character;

"experimental starting date" means the date on which the first study specific data are collected;

"experimental completion date" means the last date on which data are collected from the study;

"good laboratory practice instrument" means a document which comprises, or includes—

(a) an endorsement by a monitoring authority of a claim by a test facility that the tests that it carries out comply with the principles of good laboratory practice;

(b) a statement by a monitoring authority on the level of adherence of a test facility or a test site to the principles of good laboratory practice (including a statement that the facility or site has been found to be operating in compliance with the said principles or with these Regulations);

(c) a statement by any other person for submission, or which may be submitted, to a regulatory authority on the level of adherence of a test facility or test site, or any part of a test facility or test site, to the principles of good laboratory practice (including a statement that the facility or site operates in compliance with the said principles or with these Regulations);

(d) a statement by any person for submission, or which may be submitted, to a regulatory authority that he is a member of the United Kingdom good laboratory practice compliance programme;

(e) a report issued by a monitoring authority as a result of a study audit or a test facility or test site inspection;

(f) a statement by any person for submission, or which may be submitted, to a regulatory authority about the level of adherence of a regulatory study, or any phase of a regulatory study, to the principles of good laboratory practice (including a statement that the study, or phase of a study, was conducted in compliance the said principles or with these Regulations),

and for the purposes of this definition, the "principles of good laboratory practice" means the said principles howsoever described;

"master schedule" means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility;

"monitoring authority" means an authority in any country or territory which is responsible (either solely or jointly with other such authorities) for monitoring the good laboratory practice compliance of test facilities;

"OECD" means the Organisation for Economic Co-operation and Development;

"OECD test guideline" means a test guideline which the OECD has recommended for use in its member countries;

"operator", in relation to a test facility, means the person having control of the test facility;

"premises", in relation to a test facility, includes field sites at which phases of regulatory studies are conducted;

"principal investigator" means an individual who, for a multi-site regulatory study, acts on behalf of the study director and has defined responsibility for one or more delegated phases of the study;

"principles of good laboratory practice" means—

(a) the principles of good laboratory practice set out in Schedule 1, which are based on the Good Laboratory Practice Principles set out in Section II of the Annex to Council Directive 87/18/ECC(**1**) on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances, as amended by Commission Directive 1999/11/EC(**2**) adapting to technical progress the principles of good laboratory practice as specified in Council Directive 87/18/EEC; read with

(b) the revised guidance for the conduct of test facility inspections and study audits set out in Schedule 2, which is based on part of the Revised Guidance for the Conduct of Test Facility Inspections and Study Audits in the Annex to Council Directive 88/320/EEC(**3**) on the inspection and verification of good laboratory practice (GLP), as amended by Commission Directive 1999/12/EC(**4**) adapting to technical progress for the second time the Annex to Council Directive 88/320/EEC;

"quality assurance programme" means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with the principles of good laboratory practice;

"raw data" means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a regulatory study;

"reference item" means any article used to provide a basis for comparison with a test item;

"regulatory authority" means any authority in any country or territory with legal responsibility for aspects of the control of chemicals or items of natural or biological origin;

"regulatory study" means a non-clinical experiment or set of experiments—

(a) in which an item is examined under laboratory conditions or in the environment in order to obtain data on its properties or its safety (or both) with respect to human health, animal health or the environment;

(b) the results of which are, or are intended, for submission to the appropriate regulatory authorities; and

(c) compliance with the principles of good laboratory practice is required in respect of that experiment or set of experiments by the appropriate regulatory authorities (whether or not compliance with the said principles in respect of that experiment or set of experiments is also a legislative requirement);

"short-term study" means a regulatory study of short duration with widely used, routine techniques;

"specimen" means any material derived from a test system for examination, analysis, or retention;

"sponsor" means a person who commissions, supports and/or submits a regulatory study;

(**1**) OJNo. L 15, 17.1.1987, p. 29.
(**2**) OJ No. L 77, 23.3.1999, p. 8.
(**3**) OJ No. L 145, 11.6.1988, p. 35.
(**4**) OJ No. L 77, 23.3.1999, p. 22.

"standard operating procedures" means the documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines;

"study completion date" means the date the study director signs the final report;

"study director" means the individual responsible for the overall conduct of the regulatory study;

"study initiation date" means the date the study director (first) signs the study plan;

"study plan" means a document which defines the objectives and experimental design for the conduct of a regulatory study, and includes any study plan amendments;

"study plan amendment" means an intended change to the study plan after the study initiation date;

"study plan deviation" means an unintended departure from the study plan after the study initiation date;

"test facility" means a facility which conducts or intends to conduct regulatory studies;

"test item" means an article that is the subject of a regulatory study;

"test site" means a location at which a phase of a regulatory study is conducted;

"test system" means any biological, chemical or physical system or a combination thereof used in a regulatory study;

"vehicle" means any agent which serves as a carrier used to mix, disperse, or solubilise the test or reference item to facilitate the administration or application to the test system.

(2) In these Regulations, unless the context otherwise requires, a reference—

(a) to a numbered regulation or Schedule is to the regulation in or Schedule to these Regulations bearing that number;

(b) in a regulation to a numbered or lettered paragraph is to the paragraph of that regulation bearing that number or letter; and

(c) in a paragraph to a numbered or lettered sub-paragraph is to the sub-paragraph in that paragraph bearing that number or letter.