SCHEDULE 1

GOOD LABORATORY PRACTICE PRINCIPLES **[**[F1](BASED ON SECTION II OF ANNEX I TO THE EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE 2004/10/EC)**]**

Textual Amendments

F1 Words in Sch. 1 heading substituted (27.4.2004) by The Good Laboratory Practice (Codification Amendments Etc.) Regulations 2004 (S.I. 2004/994), regs. 1, **2(d)**

PART VIII

PERFORMANCE OF THE REGULATORY STUDY

Study plan

1.—(1) For each regulatory study, a written plan should exist prior to initiation of the study. The study plan should be approved by dated signature of the study director and verified for good laboratory practice compliance by quality assurance personnel as specified in paragraph 2(b) of Part II of this Schedule.

(2) As respects the study plan—

(a) amendments to it should be justified and approved by dated signature of the study director and maintained with the study plan;

(b) deviations from it should be described, explained, acknowledged and dated in a timely fashion by the study director and/or any principal investigators and maintained with the study raw data.

(3) For short-term studies, a general study plan accompanied by a study specific supplement may be used.

Content of the Study Plan

2.—(1) The study plan should contain, but not be limited to, the following information—

Identification of the study, the test item and the reference item

(a) (i) a descriptive title,

(ii) a statement which reveals the nature and purpose of the regulatory study,

(iii) identification of the test item by code or name (IUPAC, CAS number, biological parameters etc.),

(iv) the reference item to be used;

Information concerning the sponsor and the test facility

(b) (i) name and address of the sponsor,

(ii) name and address of any test facilities and test sites involved,

(iii) name and address of the study director,

(iv) name and address of any principal investigator, and the phase of the study delegated by the study director to, and under the responsibility of, the principal investigator;

Dates

(c) (i) the date of approval of the study plan by signature of the study director,

(ii) the proposed experimental starting and completion dates;

Test methods

(d) reference to OECD test guideline or other test guideline or method to be used;

Issues (where applicable)

(e) (i) the justification for selection of the test system,

(ii) characterisation of the test system, such as the species, strain, sub-strain, source of supply, number, body weight range, sex, age, and other pertinent information,

(iii) the method of administration and the reason for its choice,

(iv) the dose levels and/or concentration, frequency, duration of administration or application,

(v) detailed information on the experimental design, including a description of the chronological procedure of the regulatory study, all methods, materials and conditions, type and frequency of analysis, measurments, observations and examinations to be performed, and statistical methods to be used (if any);

Records

(f) a list of records to be retained.

Conduct of the Regulatory study

3.—(1) a unique identification should be given to each regulatory study. All items concerning this regulatory study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.

(2) The regulatory study should be conducted in accordance with the study plan.

(3) All data generated during the conduct of the regulatory study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.

(4) Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.

(5) Data generated as a direct computer input should be identified at the time of data input by the individual responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the person having made those changes, for example by the use of timed and dated (electronic) signatures. Reasons for changes should be given.

Changes to legislation:
There are currently no known outstanding effects for the The Good Laboratory Practice Regulations 1999, PART VIII.