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 I

TEST FACILITY ORGANISATION AND PERSONNEL

Facility management's responsibilities

1.—(1) Each test facility management should ensure that the principles of good laboratory practice are complied with in its test facility.

(2) As a minimum it should—

(a) ensure that a statement exists which identifies the individuals within a test facility who fulfil the responsibilities of management as defined by the principles of good laboratory practice;

(b) ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct or regulatory studies;

(c) ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;

(d) ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for those functions;

(e) ensure that appropriate and technically valid standard operating procedures are established and followed, and approve all original and revised standard operating procedures;

(f) ensure that there is a quality assurance programme with designated personnel and assure that the quality assurance programme is being performed in accordance with the principles of good laboratory practice;

(g) ensure that for each study an individual with the appropriate qualifications, training and experience is designated by the management as the study director before the study is initiated. Replacement of a study director should be done according to established procedures, and should be documented;

(h) ensure, in the event of a multi-site study, that, if needed, a principal investigator is designated, who is appropriately trained, qualified and experienced to supervise any delegated phase of the study. Replacement of the principal investigator should be done according to established procedures, and should be documented;

(i) ensure documented approval of the study plan by the study director;

(j) ensure that the study director has made the approved study plan available to the quality assurance personnel;

(k) ensure maintenance of a historical file of all standard operating procedures;

(l) ensure that an indivdual is identified as reponsible for the management of the archives;

(m) ensure maintenance of a master schedule;

(n) ensure that test facility supplies meet requirements appropriate to their use in a study;

(o) ensure for a multi-site study that clear lines of communication exist between the study director, principal investigator, quality assurance programme and personnel;

(p) ensure that test and reference items are appropriately characterised;

(q) establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with the principles of good laboratory practice.

(3) When a phase of a study is conducted at a test site, test site management (if appointed) will have the responsibilities set out in sub-paragraph (2)(a) to (f), (h), (k) to (n), (p) and (q).

Study director's responsibilities

2.—(1) The study director is the single point of study control and has the responsibility for the overall conduct of the regulatory study and for its final report.

(2) These responsibilities should include, but not be limited to, the following functions. The study director should—

(a) approve the study plan and any amendments to the study plan by dated signature;

(b) ensure that the quality assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the quality assurance personnel as required during the conduct of the study;

(c) ensure that study plans and amendments and standard operating procedures are available to study personnel;

(d) ensure that the study plan and the final report for a multi-site study identify and define the role of any principal investigators and any test facilities and test sites involved in the conduct of the study;

(e) ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; and acknowledge deviations from standard operating procedures during the conduct of the study;

(f) ensure that all raw data generated are fully documented and recorded;

(g) ensure that computerised systems used in the study have been validated;

(h) sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with the principles of good laboratory practice;

(i) ensure that after completion (including termination) of the regulatory study, the study plan, the final report, raw data and supporting material are archived.

Principal investigator's responsibilities

3. The principal investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable principles of good laboratory practice.

Study personnel's responsibilities

4.—(1) All personnel involved in the conduct of the regulatory study must be knowledgeable in those parts of the principles of good laboratory practice which are applicable to their involvement in the study.

(2) Study personnel will have access to the regulatory study plan and appropriate standard operating procedures applicable to their involvement in the study. It is their responsiblity to comply with the intructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the study director and/or, if appropriate, the principal investigator.

(3) All study personnel are responsible for recording raw data promptly and accurately and in compliance with these principles of good laboratory practice, and are responsible for the quality of their data.

(4) Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the regulatory study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.

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