ANNEX I

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

SECTION II

GOOD LABORATORY PRACTICE PRINCIPLES

1. Test facility organisation and personnel

1.1. Test facility management's responsibilities

1. Each test facility management should ensure that these principles of good laboratory practice are complied with, in its test facility.

2. At a minimum it should:

(a) ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these 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 of the study;

(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 these 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 responsibility is being performed in accordance with these 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 multisite study, that, if needed, a principal investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a 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 approval study plan available to the quality assurance personnel;

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

(l) ensure that an individual is identified as responsible for the management of the archive(s);

(m) ensure the maintenance of a master schedule;

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

(o) ensure for a multisite study that clear lines of communication exist between the study director, principal investigator(s), the quality assurance programme(s) and study 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 these principles of good laboratory practice.

3. When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions: 1.1.2(g), (i), (j) and (o).

1.2. Study director's responsibilities

1. The study director is the single point of study control and has the responsibility for the overall conduct of the 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 multisite study identify and define the role of any principal investigator(s) 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; 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 these principles of good laboratory practice;

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

1.3. Principal investigator's responsibilities

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

1.4. Study personnel's responsibilities

1. All personnel involved in the conduct of the 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 study plan and appropriate standard operating procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions 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(s).

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 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.