ANNEX I

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

SECTION I

INTRODUCTION

2. Definition of terms

2.1. Good laboratory practice

Good laboratory practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

2.2. Terms concerning the organisation of a test facility

1. Test facility means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multisite studies, those which are conducted at more than one site, the test facility comprises the site at which the study director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

2. Test site means the location(s) at which a phase(s) of a study is conducted.

3. Test facility management means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these principles of good laboratory practice.

4. Test site management (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these principles of good laboratory practice.

5. Sponsor means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.

6. Study director means the individual responsible for the overall conduct of the non-clinical health and environmental safety study.

7. Principal investigator means an individual who, for a multisite study, acts on behalf of the study director and has defined responsibility for delegated phases of the study. The study director's responsibility for the overall conduct of the study cannot be delegated to the principal investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable principles of good laboratory practice are followed.

8. 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 these principles of good laboratory practice.

9. Standard operating procedures (SOPs) means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.

10. Master schedule means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

2.3. Terms concerning the non-clinical health and environmental safety study

1. Non-clinical health and environmental safety study, henceforth referred to simply as 'study', means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

2. Short-term study means a study of short duration with widely used, routine techniques.

3. Study plan means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

4. Study plan amendment means an intended change to the study plan after the study initiation date.

5. Study plan deviation means an unintended departure from the study plan after the study initiation date.

6. Test system means any biological, chemical or physical system, or a combination, thereof used in a study.

7. 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 study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10 below.

8. Specimen means any material derived from a test system for examination, analysis, or retention.

9. Experimental starting date means the date on which the first study-specific data are collected.

10. Experimental completion date means the last date on which data are collected from the study.

11. Study initiation date means the date the study director signs the study plan.

12. Study completion date means the date the study director signs the final report.

2.4. Terms concerning the test item

1. Test item means an article that is the subject of a study.

2. Reference item (control item) means any article used to provide a basis for comparison with the test item.

3. Batch means a specific quantity or lot of a test item 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 and should be designated as such.

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