ANNEX I

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

SECTION II

GOOD LABORATORY PRACTICE PRINCIPLES

2. Quality assurance programme

2.1. General

1. The test facility should have a documented quality assurance programme to assure that studies performed are in compliance with these principles of good laboratory practice.

2. The quality assurance programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.

3. This individual(s) should not be involved in the conduct of the study being assured.

2.2. Responsibilities of the quality assurance personnel

The responsibilities of the quality assurance personnel include, but are not limited to, the following functions. They should:

(a) maintain copies of all approved study plans and standard operating procedures in use in the test facility and have access to an up-to-date copy of the master schedule;

(b) verify that the study plan contains the information required for compliance with these principles of good laboratory practice. This verification should be documented;

(c) conduct inspections to determine if all studies are conducted in accordance with these principles of good laboratory practice. Inspections should also determine that study plans and standard operating procedures have been made available to study personnel and are being followed.

Inspections can be of three types as specified by quality assurance programme standard operating procedures:

— study-based inspections,
— facility-based inspections,
— process-based inspections.

Records of such inspections should be retained;

(d) inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies;

(e) promptly report any inspection results in writing to management and to the study director, and to the principal investigator(s) and the respective management, when applicable;

(f) prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the study director and

principal investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.