GOOD LABORATORY PRACTICE

GLPMA EXPECTATIONS WHEN USING A CONTRACT QUALITY ASSURANCE SERVICE

Background

Establishment of an effective quality assurance programme is one of the fundamental requirements if a test facility is to comply with the principles of GLP. Test facility management should designate personnel to assume responsibility for the quality assurance programme, and these personnel should not be involved in the conduct of the regulatory work being assured.

In the smallest test facilities there may not be sufficient staff for there to be a person who is independent of study conduct, or there may be insufficient work to support the employment of a dedicated quality assurance (QA) person. In these cases, the services of a contract quality assurance service may need to be considered. Whilst the GLP principles do not preclude this arrangement, there are a number of aspects that require further consideration if GLP compliance is not to be compromised.

The purpose of this note is to provide guidance to test facility management if the use of a contract quality assurance service is being considered.

GLP Requirements

Test facility management should 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 GLP. {Schedule 1, Part I, 1.-(2)(f)}. Whilst it is common for the designated quality assurance personnel to be employees of the test facility, this need not be the case.

There should be sufficient personnel resource to maintain the established quality assurance programme. {Part I, 1.-(2)(b)}

Whoever is designated to assume the quality assurance function must have appropriate qualifications, experience and training to enable them to undertake the role assigned to them. {Part I 1.-(2)(b), (c) and (d)}

The designated quality assurance personnel will be required to perform the activities described in Part II of Schedule 1.

GLPMA Expectations

The following GLPMA expectations only relate to those roles and responsibilities of the quality assurance function that are required by the GLP principles. Any other service provided by the contractor at the request of test facility management is outside the scope of this guidance.

The GLPMA expects that a contract quality assurance service should:

- be suitably qualified and experienced. *(The background and experience of the staff concerned should be relevant to the activities of the test facility, and should include experience of working within a regulated laboratory environment, preferably GLP.)*

- be aware of relevant UK, EC and OECD documentation relating to GLP, and aware of current GLP

- concerns and issues. *(For the contract service to provide an adequate quality assurance programme, it is important that they are familiar with current GLP concerns and issues, and therefore able to provide appropriate guidance and advice to test facility management.)*

- be able to provide evidence of continuing professional development, e.g. by attendance at appropriate seminars, symposia and meetings. *(This is no different to the GLPMA expectation that test facility personnel should receive periodic "refresher" training in GLP.)*

- normally attend during regulatory inspections by the GLPMA. If they are not present during the inspection, the GLPMA may arrange a separate meeting with the contractor as allowed for by Section 9.-(1)(g) of the GLP Regulations. *(Quality assurance is such an important part of a test facility's GLP system that it would be extremely difficult for the Inspector to assess the GLP compliance status of the test facility if the contract QA service is not available to be interviewed.)*

- provide test facility management with copies of their CV and relevant training records. *(The GLP principles require that test facility management retain records of the qualifications and experience of all staff – this applies equally to any contract staff.)*

- report directly to test facility management.

The following aspects also need to be addressed if using a contract QA service.

- There should be a detailed service level agreement or other appropriate documentation that clearly identifies the services to be provided, and defines the responsibilities of the two parties

- Frequency of site visits should be defined. They must be sufficiently frequent to ensure that all required inspections, audits or other necessary activities are carried out in a timely manner. This is of particular importance in test facilities that conduct routine and repetitive short term studies, and where quality assurance monitoring is achieved by means of a process based inspection programme. Site visits must be sufficiently frequent to ensure that all of the routine and repetitive activities are adequately monitored. The GLPMA expects that such activities should be inspected at least once every three months. *(Failure to conduct process based inspections at a sufficient frequency can result in studies being out of Compliance)*

- The SOPs to be followed should be specified. If the test facility's SOPs are used, there needs to be a mechanism to ensure that the contractor receives any revised or new SOPs that are applicable to the services they provide. If the SOPs to be used are produced and maintained by the contractor, then this should be specified in the service level agreement that is signed by test facility management. Test facility management should hold copies of the SOPs used by the contractor.

- There should be a contingency plan to cover unforeseen absences of the designated contractor, or periods when the contractor has obligations to other clients.

- Details of the contract quality assurance service should appear on the test facility organisation chart or other relevant documentation.

- Test facility management is responsible for ensuring that the contract quality assurance service operates in accordance with the applicable principles of GLP. To this end there should be a mechanism whereby the effectiveness of the quality assurance function can be verified. The

GLPMA has published a separate guidance document on this subject *("GLPMA Expectations for the Audit of the Quality Assurance Programme.")*.

Summary

Test facility management is responsible for ensuring that there is an effective quality assurance programme operating within the test facility.

If it is necessary to use a contract quality assurance service, test facility management is responsible for ensuring that the service provided meets the GLP requirements.