GOOD LABORATORY PRACTICE

GLPMA EXPECTATIONS FOR AUDIT OF THE QUALITY ASSURANCE PROGRAMME

Why is there a need for us to inspect our quality assurance (QA) activities?

All elements of a test facility's quality system should be inspected; QA is a key part of the GLP quality system. The inspection of QA activities should be used to determine the extent to which the QA programme meets the requirements of GLP and the extent to which it complies with the requirements of the test facility's own processes and procedures

In addition during routine GLP compliance monitoring inspections the GLPMA has been raising deficiencies relating to quality assurance. In extreme cases, the failures identified in the quality assurance programme have caused the GLP compliance of studies to be compromised.

Some of these deficiencies are the result of an inappropriate quality assurance programme, i.e. the established programme of inspections and audits does not provide a sufficient degree of quality assurance monitoring to assure the GLP compliance of the work performed at the test facility. In other cases, the deficiencies were the result of the quality assurance function failing to follow the test facility's own policies or procedures.

The purpose of this guidance note is to provide test facility management with information that will assist them in ensure compliance with the principles of GLP.

GLP Requirements

The GLP Regulations require that test facility management should ensure that the principles of GLP are complied with in the test facility. 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.-(1)(f) and 1.-(2)(f)} For the quality assurance programme to comply with the principles of GLP it should include all of the elements described in Part II of Schedule 1. Failure to establish an appropriate quality assurance programme is one of the underlying causes of the types of deficiency referred to above.

Test facility management should also ensure that standard operating procedures are established and followed {Schedule 1, Part I, 1.-(2)(e)}. Failing to ensure that the quality assurance function is complying with established policies and procedures is often the root cause of the second type of deficiency referred to above.

GLPMA Expectations

In order that test facility management can demonstrate that these responsibilities have been discharged, they should implement an internal review or audit of quality assurance. This internal monitoring should be undertaken at least on an annual basis. In this way it should be confirmed that the quality assurance programme complies with the principles of GLP, and that the quality assurance function is consistently complying with the test facility's own documented policies and procedures.

Aspects of the quality assurance programme that should be verified will include, but not necessarily be limited to, the following.

- Is there a documented quality assurance programme?
  {Part I, 1.-(2)(f), Part II, 1.-(1), Part VII, 4(e)}
- Are there sufficient adequately qualified (QA) personnel?
  {Part I, 1.-(2)(b)}
- Are QA personnel directly responsible to management, and are they independent of the activities being quality assured?
  {Part II, 1.- (2) and (3)}
- Are appropriate personnel records maintained for QA staff?
  {Part I, 1.-(2)(c)}
- Are QA SOPs readily available to QA staff?
  {Part VII, 2}
- Does the QA function have access to study plans, test facility SOPs and the master schedule?
  {Part II, 2(a)}
- Are study plans verified for GLP compliance, and the verification recorded?
  {Part II, 2 (b)}
- Are the necessary inspections planned, conducted and reported?
  {Part II, 2(c)}
- Are inspection findings promptly reported, in writing, to study directors and to management?
  {Part II, 2(e)}.
- When GLP deviations are identified, is appropriate corrective and/or preventative action taken in a timely manner? *[Although this expectation is not explicitly stated in the GLP principles, it is self evident that failure to address GLP deviations that have been identified represents a failure to ensure that the principles of GLP have been complied with – Part I, 1.-(1)]*
- Are all final reports inspected?
  {Part II, 2(d)}
- Are appropriate quality assurance statements prepared for inclusion in final reports?
  {Part II, 2(f)}
- Are all applicable test facility policies and procedures being complied with?
  {Part I, 1.-(2)(e)}

<u>Who can perform the inspection of QA?</u>

To avoid any potential conflict of interest, the review of QA should be undertaken by staff that are independent of any of the functions or activities that are being reviewed. It is for test facility management to determine how this may best be achieved. However iinspections should be undertaken by persons who are suitably trained and experienced and are familiar with the test facility's QA processes and procedures, this may be an external consultant or an existing member of facility staff. Since the GLP Regulations state that 'the quality assurance programme should be carried out by an individual or individuals designated by and directly responsible to management' it would not be appropriate to consider inspections by either the GLPMA or a sponsor to solely meet the requirement. However, departures from GLP identified during such inspections should be considered by test facility management and may contribute to the overall assessment of QA.

The GLPMA recognises that in small test facilities it may be more difficult to identify suitably trained or experienced staff that would be able to conduct a truly independent review of quality assurance activities. In these cases the GLPMA will take a pragmatic view of the procedures employed by test facility management to assure themselves that the quality assurance function is operating effectively. Records of these review activities should be retained.

Where the quality assurance function is provided by a contractor, it is particularly important that test facility management assures itself that the service provided meets the requirements laid down in the GLP principles and the operational needs of the test facility. Test facility management should ensure that external consultants are suitably trained and experienced. There should be a formal agreement between test facility management and the consultant(s). The test facility should retain documentary evidence to support the appointment of the consultant. The GLPMA has published separate guidance on the use of a contract quality assurance service. *("GLPMA Expectations when Using a Contract Quality Assurance Service")*

Summary

Test facility management should establish a mechanism to confirm that their quality assurance programme complies with the requirements of GLP, and that the quality assurance function is complying with established policies and procedures.

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