



## **GUIDANCE ON COMPLETION OF THE FORM USED TO NOTIFY THE GLPMA OF CHANGES WITHIN THE GLP TEST FACILITY**

### **Background**

In order to comply with the recommendations of the Hampton Report the MHRA has adopted regulatory strategies that minimise the burden on the regulated industry whilst maintaining the required levels of public safety. Regulatory effort will be focused on those organisations or activities that pose the greatest threat to public safety. As part of this initiative, the regulatory activities of the UK Good Laboratory Practice Monitoring Authority (GLPMA) are based upon a risk assessment process whereby the risk of failure to comply with the GLP Regulations (and the specific requirements of the GLP Principles) and the potential hazard to public safety resulting from non-compliance are considered. The consideration of risk and potential hazard are taken into account when determining the frequency, duration and scope of GLP compliance monitoring inspections.

The information required to conduct the required risk assessment is, to a large extent, gathered by GLPMA Inspectors during on site monitoring inspections. Following completion of an inspection the Inspector will, based on the outcome of the inspection and other pertinent information, recommend the date, duration and scope of the next monitoring inspection. This recommendation will be based on information available to the Inspector at that time. Any significant changes that have occurred within the GLP test facility, or which are planned, should be notified to the GLPMA. The information provided in the change form is used to inform the risk assessment process operated by the GPLMA, and could lead to a revision in the date, duration or scope of future compliance monitoring inspections.

*NOTE: The test facility name and address should be the name and address under which the test facility undertakes GLP work – i.e. the name and address that appear on study plans (protocols) and final reports. This will also be the name and address that appear on the Statement of GLP Compliance issued by the GPLMA.*

### **Changes that need to be notified**

#### Types of GLP activities (Test types)

The type of GLP studies undertaken within the test facility will impact on the possible hazard to the public should invalid studies be produced as a result of serious GLP non-compliance. The GLPMA should be notified of any intention to conduct studies that are outside the scope of the test types currently stated on the statement of compliance for the test facility.

#### Facilities and Equipment

The GLPMA should be notified of any additional facilities that are now being used for the conduct or support of GLP studies. We do not need to be informed of minor refurbishments.

Any significant changes to the equipment (including major computerised systems) that are used for the conduct of GLP studies should be identified. It is difficult to provide guidance on what would be considered significant in the many different GLP test facilities that exist, but in general, any new equipment that allows additional types of assays to be performed, or new study types to be undertaken should be identified.

The GLPMA should also be informed at the earliest opportunity about plans to relocate to a new facility or of facility closure.

Any facilities that are no longer used for GLP work do not need to be prospectively notified, but should be included in the list of changes submitted as part of the pre-inspection information request.

#### Personnel aspects

This information allows the GLPMA to monitor any changes in personnel that might impact on the conduct of GLP work. Any significant increase, or decrease, in staffing levels should be noted. Any changes in “key personnel” should also be noted. Who constitute “key personnel” within a test facility will vary with the size and



organisation of the test facility concerned. For example, the loss and replacement of the only QA auditor at a small test facility would be significant, but the replacement of one QA auditor in a large QA Unit would not. It is therefore a matter of judgement as to whether individual members of staff are “key personnel” or not, but in general terms staff changes within small test facilities are of greater significance.

Other changes

- Any changes in company ownership

Contact Name

The name and position of the person submitting the change form should be identified. They should provide contact details as any subsequent queries will be addressed to this person.

**UK GOOD LABORATORY PRACTICE MONITORING AUTHORITY**  
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