



Selection and use of GLP test sites located outside the UK.

There is an expectation that test sites used to perform a phase of a GLP study are located in a country that is a signatory to the OECD's mutual acceptance of data agreement (MAD). Additionally there is an expectation that these test sites are subject to periodic inspections by their national GLP monitoring authority in order to verify the site is operating in accordance with the OECD principles of GLP. There is no obligation on signatories to the OECD MAD agreement, to accept data from GLP facilities/sites that have not been subject to periodic GLP inspections by their national monitoring authority.

Study directors are expected to confirm, prior to making a claim of compliance for their study, the GLP compliance status of all test sites used and if they have been inspected by the national GLP monitoring authority of the country where the test site is located. Study directors should also confirm that the test site is located in a country that is a full signatory to the MAD agreement.

For a number of countries it is possible to check the compliance status of a GLP facility/site on the website of the relevant monitoring authority. If this information is not available enquiries should be sent to the GLP mail box (glp@mhra.gsi.gov.uk).

If a test site is not included in its national GLP monitoring programme or has not been subject to periodic GLP inspections by its monitoring authority, this should be clearly documented in the study director statement of compliance for the study, and no claim of compliance for that phase of the work can be made.

In some countries, the national monitoring authority may not require a facility/site to be inspected before they make a claim of GLP compliance for the work they perform. In the UK it would be a criminal offence to make a claim of GLP compliance for a phase of a study that was conducted at a facility that was not a member of their national GLP compliance monitoring programme or had not been subject to a monitoring authority inspection.

The UK GLPMA has a mechanism for a test facility's GLP compliance to be extended to non GLP test sites under exceptional circumstances (see MHRA website for guidance on the use of non GLP facilities).