GLP in clinical trials

In accordance with EU Directives 1,2,3,4,5, applicants are reminded that all pivotal non-clinical studies (for example those studies identified in ICH guidelines as needing to be carried out in accordance with the principles of good laboratory practice) conducted to support submissions for Marketing Authorisation Applications (MAA) and Clinical Trial Applications (CTA) must be conducted in, or inspected by, a country that has implemented the OECD Mutual Acceptance of Data (MAD) system. Studies conducted at a facility located in a non-MAD adherent country may be accepted if the facility has been subject to a full monitoring inspection conducted in the last three years by a monitoring authority from a country which is a signatory to the MAD agreement. However, if the study is considered to be pivotal to the application, there is a possibility that a study audit will be required by some regulatory receiving authorities at the time of a MAA.

As applications for CTAs do not include individual study reports, Sponsors should include a statement confirming the OECD GLP status, either within the Investigator's Brochure (IB) or within the covering letter.

References

2. EU Directive 2004/10/EC - on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version)