Annex F. Good Laboratory Practice

Good Laboratory Practice (GLP) was developed in the 1970s in response to fraudulent scientific safety studies that were submitted to receiving authorities in support of applications for the regulatory registration/approval of drugs to the US FDA. Subsequently the principles of GLP were developed by the OECD to ensure data reliability and reconstructability of safety studies. The principles apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing chemical products of various kinds. The principles have been published in 1981 as an annex to the OECD Council Decision on Mutual Acceptance of Data (MAD)[1]. The decision states that 'data generated in the testing of chemicals in an OECD Member Country in accordance with the OECD Test Guidelines (Annex I of this decision) and OECD Principles of Good Laboratory Practice (Annex II of this decision) shall be accepted in other member countries for purposes of assessment and other uses relating to the protection of man and the environment'. Since 1981 a number of additional guidance, consensus and advisory documents have been published in the OECD Series on Principles of GLP[2], including an Advisory Document of the OECD Working Group on GLP n° 14 which specifically addresses *in vitro* Studies (OECD, 2004[1]).

In the EU, the principles of GLP are included in Directive 2004/10/EC, while the compliance monitoring procedures are included in Directive 2004/9/EC. GLP provisions are included in legislation for chemicals, human medicinal products, veterinary products, detergents, feed additives, food additives, genetically modified food or feed, pesticides, biocides and cosmetics (Coecke et al., 2016[2]), as well as for medical devices. Where applicable, conformity with the provisions of Directive 2004/10/EC of the European Parliament and of the Council shall be demonstrated. The US FDA requires GLP in the context of safety testing on medical devices.

Notes

1. See: http://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm
2. See: http://www.oecd.org/chemicalsafety/testing/oecdseriesonprinciplesofgoodlaboratorypracticeglpandcompliancemonitoring.htm

References

Coecke, S. et al. (2016), "Practical Aspects of Designing and Conducting Validation Studies Involving Multi-study Trials", in *Advances in Experimental Medicine and Biology, Validation of Alternative Methods for Toxicity Testing*, Springer International Publishing, Cham, http://dx.doi.org/10.1007/978-3-319-33826-2_5. [2]

OECD (2004), *The Application of the Principles of GLP to in vitro Studies*, OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, No. 14, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264084971-en. [1]