

## Why has Quality Assistance implemented Good Clinical Laboratory Practice (GCLP)?

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As a provider of analytics for the pharmaceutical industry, our company works in a very strict normative context, governed essentially by **Good Manufacturing Practice (GMP)** and **Good Laboratory Practice (GLP)**. Throughout our involvement in development programs for medicinal products destined for the international market, we also have to follow regulations specifically decreed by authorities such as the *WHO*, *FDA*, *EMA* or *Pmda*.

GMP and GLP are applicable as soon as analytical data are generated for **a registration file** or for **batch release**. GMP applies mainly in the context of the testing of active ingredients and drug products and the development of the CMC parts (module 3) of the CTD. GLP is applicable for the analysis of samples coming from non-clinical safety studies.

There has, however, always been a gap at the level of regulations assuring the **reliability and integrity of raw data** generated by **analytical laboratories** from **clinical studies samples**. In fact, these analyses are not within the scope of either GMP or GLP principles.

In 2003 the *British Association of Research Quality Assurance (BARQA)* therefore drew up a guidance concerning **Good Clinical Laboratory Practice (GCLP)**, thus filling this regulatory gap. This initiative was approved by the *World Health Organisation*, as it took up the principles in a publication in 2009 (1).

In general, these principles include almost all the points of GLP. Some terms, however, are different, e.g. the term *Analytical Project Manager* is used instead of *Study Director*. They also integrate the idea of confidentiality as in GCP, in order to protect patients involved in the study. Finally, the term multi-site study is not used in GCLP, as the analytical laboratory works independently of the site where sampling is done and always reports directly to the Sponsor of the study.

We have already adapted **our quality system** in order to meet the requirements of Sponsors who would like their studies to be done in accordance with GCLP.

We would also like to use this occasion to remind you that, given our wide experience in this area, our specialists can help you choose the most appropriate GxP to follow for your studies.

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### Reference:

- (1) Good Clinical Laboratory Practice, ISBN 978 92 4 159785 2