GLP: GOOD LABORATORY PRACTICES

WHAT IT IS AND WHAT IT IS NOT

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NC State University Office of Sponsored Programs
Good Laboratory Practice (GLP) is a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
GLP: WHAT IT IS

• It is an FDA (Food and Drug Administration) Regulation
• GLP applies to practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products.
GLP: WHAT IT IS, CONT.

- It is intended to assure the quality and integrity of the safety data filed with the FDA. GLP, a data quality system.

- It should not be confused with standards for laboratory safety - appropriate gloves, glasses & clothing to handle lab materials safely.
FOR FDA GLP: EXAMPLES - WHAT IT IS AND WHAT IT IS NOT

• It is not only good analytical practice, but a regulation.

• The regulations do not aim to evaluate the scientific or technical conduct of studies.

• The laboratory must have a specific organizational structure and procedures to perform and document laboratory work.

• The objective is not only quality of data but also traceability and integrity of data.

• But the biggest difference between GLP and Non-GLP work is the type and amount of documentation.
No. Per 21 CFR 58.3(d), “nonclinical laboratory study” does not include “basic exploratory studies carried out to determine whether a test article has any potential utility . . . .” Therefore, basic exploratory studies carried out to determine whether a device has any potential utility, or to determine physical or chemical characteristics of a device, are not subject to the GLP regulations (21 CFR 58.3(d)).
GLP: SUBAWARDS

Are subrecipients / subcontractor labs covered by GLP?

Yes, to the extent that they contribute to a study that is subject to the GLP.
<Insert Link> Go here for PINS help
PINS HELP: WHAT TO DO WITH THE GLP QUESTION

Where you find the GLP question
The GLP question

*Will this project require facilities that are certified for Good Laboratory Practices (GLP) in accord with FDA regulations?
GLP – HOW DO I ANSWER IN PINS?

• If it is not an FDA–regulated project, the answer is No.

• If it does not fit the definition, the answer is No.

• If it is not part of a regulation, the answer is No.

Remember – it is not about good lab standards!

Don’t check the box in PINS unless it fits the criteria and definition.
RESOURCES & CITATIONS

• Good Laboratory Practice Regulations Tutorial
• SPARCS GLP Help (link inserted later)
• FDA GLP Questions and Answers
• Practice (GLP) Regulations and the OECD Principles of GLP
• GLP: Good Laboratory Practice presentation

Other Resources – Note: EPA-regulated GLP studies are not subject to the FDA’s investigation

• Comparison Chart of FDA and EPA Good Laboratory
GLP: WHERE TO GET HELP

Contact SPARCS if you have any questions about whether your project will involve GLP

• Call: 919.515.2444

• Email: sps@ncsu.edu