

GLP vs. Non-GLP Studies: Which level of compliance is appropriate for your study?

Study Components	Good Laboratory Practice (GLP) Studies	Non-GLP Studies
Stages of Drug Development	Non-Clinical Safety studies (Toxicology & Safety) and Preclinical Development	Basic Research, Disease Discovery, Drug Discovery
FDA Regulations	21 CFR Part 58	Not FDA Regulated
Point of Contact for Study	Study Director/Principal Investigator	Scientist
Operating Procedures	Standard Operating Procedures (SOPs), Protocols and Controlled Methods	Protocol or Methods
Equipment	Calibrated and Qualified for Use	Maintained by Scientist
Master Schedule	An Index of all studies is maintained by the Quality Assurance Unit (QAU)	Master Schedule is not Addressed
Final Reporting	Audited by Quality Assurance Unit (QAU), proper signatures on all procedures, preparations, calibrations along with dates completed.	Reviewed by Scientist
Federal Agency Inspections	FDA will Audit/Inspect	FDA does not Audit/Inspect

*** This Infographic highlights a set of differences between GLP and Non-GLP studies. Additional considerations may be taken into account when making a decision to complete GLP or non-GLP studies.



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