NAMSA®

NAMSA's GLP and GMP Guide

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Table of Contents

Testing performed on FDA-regulated products may be performed under different regulations, including Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP) and Quality System Regulations (QSR). This guide outlines the differences between the GLP, Pharmaceutical GMP lot release, medical device QSR GMP lot release and GMP in-process testing regulations to help identify when these regulations are applicable.

The FDA GMPs for human medical products are defined in the following sections of 21 CFR:

- Drugs – Parts 210 through 211
- Biologics and blood products – Parts 600 through 680
- Medical devices – Part 820
- HCT/P – Part 1271

The GLPs are a set of principles and requirements within which preclinical laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the safety of medical devices, pharmaceuticals, biologics, combination products, etc. is determined. Testing under GLPs help assure regulatory authorities that the data submitted in research or marketing applications are a true reflection of the results obtained during studies and can therefore be relied upon when making risk/safety assessments. For the purposes of this guide, references to GLP requirements refer to those applicable to FDA-regulated products only. Tests/studies not specifically performed to determine product safety and that do not utilize an animal, plant or microorganism (or subpart) test system do not need to be performed under GLPs. The FDA GLPs are defined in 21 CFR Part 58.

	GLP	Pharmaceutical GMP Lot Release	Medical Device QSR GMP Lot Release	GMP In-Process Testing	Other
Type of Testing	Safety testing intended for submission to FDA as a component of research application (e.g., IND, IDE) or marketing application (e.g., NDA, BLA, PMA, 510k).	Determination of whether or not each product lot to be released to market meets specifications listed in marketing application; may also be performed on lots to be used in clinical trials and/or stability studies.	Determination of whether or not each product lot to be released to market meets specifications listed in marketing application; may also be performed on lots to be used in clinical trials and/or stability studies.	In-process testing which supports FDA regulated product manufacturing.	Testing that is not subject to GMP or GLP regulatory surveillance.
Test Article or Product	Usually a product in development; should be identical/ similar to product to be marketed. Must be fully characterized, but usually does not have approved product specifications. Responsibility for characterization (Sponsor or Test Facility) is defined in study protocol.	Marketed product lots or lots used in clinical trials or stability studies, or components used in the manufacture of finished products. Generally has requirements (specifications).	Marketed product lots or lots used in clinical trials or stability studies, or components used in the manufacture of finished products. Generally has requirements (specifications).	In-process or finished pharmaceutical or medical device which may or may not have specifications.	Does not have to be characterized in advance of safety studies; approved product specifications are not required. May be a product or material in development.
Examples of NAMSA's Test Offerings	Cytotoxicity, Toxicity Studies, Intracutaneous, Muscle Implantation and many more.	Particulate Testing, Endotoxin (LAL) Testing, Sterility Tests and many more.	Particulate Testing, Endotoxin (LAL) Testing, Sterility Tests and many more.	Bioburden, Microbial ID and Environmental Monitoring.	Custom Microbiology studies, Antimicrobial Testing, Chemical Characterization and many more.
Personnel and Training	Personnel executing or managing each study must have appropriate education, training and experience to be able to perform assigned tasks. Training documented in a controlled system.	Personnel executing and supporting testing must have appropriate education, training and experience to be able to perform assigned tasks. Training documented in a controlled system.	Personnel executing and supporting testing must have appropriate education, training and experience to be able to perform assigned tasks. Training documented in a controlled system.	Personnel executing and supporting testing must have appropriate education, training and experience to be able to perform assigned tasks. Training documented in a controlled system.	At NAMSA, personnel executing and supporting testing have appropriate education, training and experience to be able to perform assigned tasks. Training documented in a controlled system.

	GLP	Pharmaceutical GMP Lot Release	Medical Device QSR GMP Lot Release	GMP In-Process Testing	Other
Study Director	Each GLP study must assign a Study Director responsible for technical conduct of the study, interpretation, analysis, documentation and reporting of results. The "single point of study control", primary responsibility for study quality lies with the Study Director, with involvement from the Quality Assurance Unit.	Not required. Responsibility for quality of testing lies with laboratory management, with oversight by the Quality Unit.	Not required. Responsibility for quality of testing lies with laboratory management, with oversight by the Quality Unit.	Not required. Responsibility for quality of testing lies with laboratory management, with oversight by the Quality Unit.	Not required. Responsibility for quality of testing lies with laboratory management, with oversight by the Quality Unit.
Quality Unit Responsibilities	The Quality Unit monitors each study to ensure GLPs are adhered to, and that the integrity of the study is maintained. Performs in-life, data and report inspections.	Performs and reports Quality Audits as well as a secondary review of all test data and reports to ensure technicians followed the relevant test method(s) and SOPs.	Performs and reports Quality Audits as well as a secondary review of all test data to ensure technicians followed the relevant test method(s) and SOPs.	Performs and reports Quality Audits as well as a secondary review of all test data to ensure technicians followed the relevant test method(s) and SOPs.	At NAMSA, responsibilities are to perform and report Quality Audits as well as a secondary review of all test data to ensure technicians followed the relevant test method(s) and SOPs.
Equipment	Test equipment calibrated, qualified and maintained according to SOPs. Computer systems used for tests must be validated.	Test equipment calibrated, qualified and maintained according to SOPs. Computer systems used for tests must be validated.	Test equipment calibrated, qualified and maintained according to SOPs. Computer systems used for tests must be validated.	Test equipment calibrated, qualified and maintained according to SOPs. Computer systems used for tests must be validated.	At NAMSA, the same equipment is used as in GLP and GMP testing.
Audits	Real-time, study-specific inspections are conducted by Quality Unit during critical phases of each study. Process or systems-based audits may also be performed to verify GLP compliance.	Process or systems-based audits are conducted by Quality Assurance; specific tests may be audited after test completion as a component of audits. GMP compliance and the effectiveness of the quality system is assessed through audits and trend analysis.	Process or systems-based audits conducted by Quality Assurance; specific tests may be audited after test completion as a component of audits. GMP compliance and the effectiveness of the quality system is assessed through audits and trend analysis.	Process or systems-based audits conducted by Quality Assurance; specific tests may be audited after test completion as a component of audits. GMP compliance and the effectiveness of the quality system is assessed through audits and trend analysis.	Process or systems-based audits conducted by Quality Assurance; specific tests may be audited after test completion as a component of audits. The effectiveness of the quality system is assessed through audits.

	GLP	Pharmaceutical GMP Lot Release	Medical Device QSR GMP Lot Release	GMP In-Process Testing	Other
Documents	**Protocol** – Each study requires a protocol, approved by the Sponsor and Study Director prior to initiation. **SOPs** – Drafted by technically competent personnel, approved by Quality Unit. **Specifications** – Generally not in place/not applicable. **Study Data** – Documented on worksheets, in LIMS or in notebook. Reviewed by lab and Study Director, and audited by Quality Assurance. Good documentation practices used. **Reports** – Detailed report describing study methodology, test system, statistical analysis, data summary, calculations, analysis and conclusions; signed by Study Director, and certified by Quality Unit. **Archival** – Records maintained for at least two years following FDA approval of research or marketing application, or at least five years after submittal to FDA.	**Test Methods** – Approved by Laboratory Management and Quality Unit. Test method is validated or qualified, as applicable. **SOPs** – Drafted by technically competent personnel, and approved by Quality Unit. **Specifications** – Product specifications are provided by the Sponsor. **Test Data** – Documented on worksheets, in LIMS or in notebook. Reviewed by lab and Quality Assurance. Good documentation practices used. **Reports** – May be in the form of a Certificate of Analysis or a more detailed report; approved by technical reviewer and Quality Unit. **Archival** – Records are maintained for at least one year following expiry date for lot.	**Test Methods** – Approved by Laboratory Management and Quality Unit. Test method is validated or qualified, as applicable. **SOPs** - Drafted by technically competent personnel, and approved by Quality Unit. **Specifications** – Product specifications are provided by the Sponsor. **Test Data** – Documented on worksheets, in LIMS or in notebook. Reviewed by lab and Quality Assurance. Good documentation practices used. **Reports** – May be in the form of a Certificate of Analysis or a more detailed report; approved by technical reviewer. **Archival** – Records are maintained for at least one year following expiry date for lot.	**Test Methods** – Approved by Laboratory Management and Quality Unit. Test method is validated or qualified, as applicable. **SOPs** – Drafted by technically competent personnel, and approved by Quality Unit. **Specifications** – Product specifications are provided by the Sponsor. **Test Data** – Documented on worksheets, in LIMS or in notebook. Reviewed by lab and Quality Assurance. Good documentation practices used. **Reports** – May be in the form of a Certificate of Analysis or a more detailed report; approved by technical reviewer. **Archival** – Records are maintained for at least one year following expiry date for lot.	**Test Methods or Protocol** – May be utilized for this testing scope. Protocols would be approved by the Sponsor and laboratory management prior to initiation. "Standard" test methods do not require a protocol or client approval. **SOPs** – Drafted by technically competent personnel, and approved by Quality Unit. **Specifications** – Product specifications are generally not in place/not applicable. **Test Data** – Documented on worksheets, in LIMS or in notebook. A secondary review is conducted. Good documentation practices used. **Reports** – May be a brief or detailed report, depending on the complexity of the study. Report approved by technical reviewer. **Archival** – Records maintained as per standard NAMSA retention policy.
Test/Study Deviations	Deviations from protocol or SOPs are managed by Study Director. Foreseen deviations are managed as amendments; unplanned deviations are assessed and documented. All deviations that may have affected the quality or integrity of the study are included in the study report.	Test deviations are documented and investigated as appropriate. Out of Specification (OOS) results are investigated per FDA guidance. Quality Unit facilitates and oversees investigation process. Client typically approves final OOS investigation report.	Test deviations are documented and investigated as appropriate. OOS results are investigated per FDA guidance. Quality Unit facilitates and oversees investigation process. Client typically approves final OOS investigation report.	Test deviations are documented and investigated as appropriate. Quality Unit facilitates and oversees investigation process.	Test deviations are documented and investigated as appropriate. Quality Unit facilitates and oversees investigation process, if applicable.

Notes

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