

TO MEET THE NEEDS OF THE NIH/NIAID as well as other government and industry organizations, the Galveston National Laboratory (GNL) at the University of Texas Medical Branch (UTMB) is developing the capability to support studies at A/BSL-3 and A/BSL-4 for product development in compliance with the Good Laboratory Practice (GLP) regulations, as defined by 21 CFR Part 58. The preparations for support of preclinical product testing and development in the GNL are being coordinated through the GNL's Regulatory Services Core. This core has been established as a small group of subject matter experts and supporting staff who are working with GNL Administration, GNL Core and Service Division Directors and their staff, and individual research investigators on the design and implementation of required GLP quality system elements covering general building and core facility operations, and GLP study-specific compliance activities.

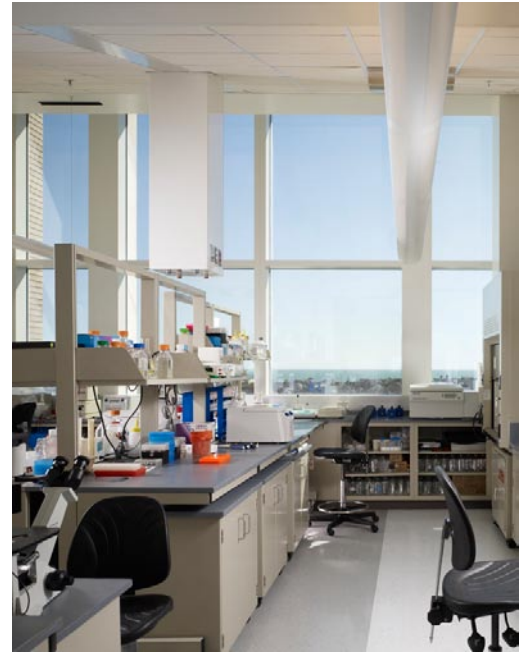
The UTMB possesses the critical components necessary to support GLP studies, including a GLP program office at the institutional level that provides the infrastructure for the highest level of testing facility management, an independent Quality Assurance Unit (QAU), and an archivist. The institutional GLP program office has established standardized procedures that describe a universal approach to developing and approving standard operating procedures (SOPs), establishing training files, collecting and retaining study data, and performing equipment validation for all GLP studies performed at the UTMB. All preparations for GLP compliant research in the GNL are occurring within the framework established at the UTMB institutional level.



THE PRIMARY AIMS OF THE GNL REGULATORY SERVICES CORE ARE:

- (1) Develop policies and procedures pertaining to GLP compliant research within the GNL, including review and risk assessment of existing UTMB policies and procedures that may impact regulated research activities;
- (2) Provide oversight and coordination for all research functions within the GNL that require compliance with regulatory guidelines for the purpose of supporting product licensure, promoting the accuracy and integrity of any data generated in such studies;
- (3) Provide advice and oversight for laboratory and capital equipment procurement, installation, operation, maintenance, calibration and testing to ensure appropriate consideration is given to the potential requirements of regulated studies;
- (4) In conjunction with staff from the UTMB GLP program office, develop and carry out general and job specific GLP compliance training programs for GNL core and service division directors, key staff and investigators;
- (5) Serve as a central point for communications amongst individual GNL investigators, laboratories (both within and outside the GNL), UTMB's Institutional GLP Program Office, the NIH, the FDA, and industry to facilitate GLP compliance where required to improve the quality and integrity of all basic and developmental research conducted in the GNL.

THE GNL REGULATORY SERVICES CORE does not participate directly in the conduct of GLP studies or function in a GLP quality assurance role. However, core staff provides their specialist expertise to assist other GNL staff and investigators with study preparations, including SOP and protocol development, evaluation of facilities and equipment for appropriateness to the requirements of the study, general and job-specific GLP training, and the development of interim and final reports to sponsors and the FDA where necessary.



Key enabling capabilities currently under development for support of GLP studies in the GNL include:

- o A restricted access BSL-2 “clean prep” laboratory managed by the Regulatory Services Core which will be available to researchers conducting GLP studies and provide a suite of basic lab equipment, including -20C° and -80C° freezers, a 4C° refrigerator, a biological safety cabinet, a chemical fume hood, balances, and water baths for storage and handling of critical non-infectious reagents (e.g. test articles and controls). Equipment in this laboratory will be validated, calibrated and maintained according to an established set of general operational parameters, or study specific requirements where those differ from the general operations of the laboratory, in accordance with the UTMB GLP program’s validation master plan.
- o Basic quality system elements in all GNL scientific and supporting divisions, including the definition of facility management roles and responsibilities at multiple levels, establishment of documented facility and core-specific training programs, and development of SOPs, accompanied by periodic audits through the UTMB GLP QAU with reporting to UTMB GLP program management and GNL management for corrective actions where necessary.
- o A centrally coordinated program for calibration and maintenance of all laboratory equipment housed in the GNL, under the direction of the GNL’s Associate Director for Research, with input from Regulatory Services Core staff.



For additional information, please contact GNL Regulatory Services Core Director David Beasley, Ph.D. at 409-266-6914 or GNL Regulatory Services Coordinator Vicki Crutchfield 409-266-6915.
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