



THE GALVESTON NATIONAL LABORATORY (GNL) is one of the two national biocontainment laboratories established in response to the growing need for study and development of countermeasures to combat emerging pathogens and biological agents that could become a health threat to individuals in the United States. These facilities are also part of the national plan involving multiple government agencies in preparing our country to counteract the threat of bioterrorism.

The aerosol dissemination of infectious agents is universally considered the means of greatest threat to exposing large numbers of civilian and military personnel to biological agents. In the GNL, we have established two Aerobiology Services Division laboratories that operate at either BSL-3 or BSL-4 so that researchers can test new therapeutics and vaccines against a wide array of the most dangerous infectious agents. The number of research facilities worldwide with this capability is very limited. This capability within the GNL is essential to safely developing and evaluating new products for biodefense, and facilitating the efficacy testing of new therapeutics and vaccines for eventual review by the U.S. Food and Drug Administration (FDA).

Function of the Division

The function of the Aerobiology Services Division is to offer state-of-the-art facilities for aerosol science and inhalational exposure to support researchers who would like to develop, test or evaluate therapeutics/vaccines against aerosolized infectious agents either at BSL-3 or BSL-4.

Description of the Division

The Aerobiology Services Division will focus on testing therapeutics against a variety of biological agents. The trained staff has expertise in the operation of the aerosol equipment and knowledge of infectious disease agents that enables them to work safely with other trained personnel on any infectious agent considered a biothreat. In addition, the Aerobiology Services Division is developing the



capability to test drugs, vaccines and diagnostics in compliance with FDA's Good Laboratory Practices (GLP) guidelines.

The capabilities of the division include: animal model development for various infectious agents, drug efficacy studies, immunogenicity testing, LD50 determinations, vaccine efficacy testing, quality control testing, and regulatory support for FDA submissions.

We currently offer the following for each study initiated in the facility:

- Fully trained personnel
- Standardized SOPs
- Forms and checklist documentation that is quality controlled and approved
- Deviation reporting
- Data security
- Equipment qualification, preventative maintenance, calibration and performance verification
- Protocol approval
- Interim and final reporting
- Document control
- Environmental monitoring