Most academic institutions and small biotechnology companies outsource GMP manufacturing to contract manufacturing organizations, which can be very costly and time consuming. The cGMP Core at Houston Methodist is designed to provide not only the infrastructure and equipment for cGMP manufacturing and release, but also the expertise to guide and implement GMP manufacturing protocols for investigators.

cGMP Core
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The cGMP Core at Houston Methodist is designed to provide internal investigators and external academic or industry partners with a cGMP compliant and cost-effective route to translating novel therapeutics and devices to the clinic. This state-of-the-art facility manufactures therapeutics and novel devices for first-in-human clinical trials. These therapeutics and devices are produced under tightly controlled and regulated conditions, critical for the translation of novel discoveries from the bench to the clinic.

Manufacturing

The facility houses four isolated, independent production rooms, which provide versatility in the manufacturing of a variety of therapeutic drugs (mRNA, nanomaterials and nanoparticles) and devices. Additionally, it houses a dedicated room for aseptic fill/finish and packaging, prior to transfer of manufactured drugs and devices for release testing, pre-clinical and clinical use.

Quality Control

Our on-site quality control laboratory, located on the 11th floor of the Houston Methodist Research Institute, provides testing and release for manufactured products with strict adherence to FDA requirements. These tests confirm the quality, identity, purity and strength of the manufactured drugs in order to ensure that we deliver safe and effective products to our patients.

Features

- ISO 7 certified manufacturing suites to produce therapeutic drugs and devices for both preclinical toxicology studies and phase I/II clinical trials.
- Continuous power (generator) for all critical equipment.
- Continuous monitoring of critical parameters: temperature, differential pressure and humidity.
- Validated monitoring of all equipment, including HVAC.
- Provisions for nitrogen and other gases.
- In-house pH neutralization system to process wet bench waste streams.
- Key-card-restricted access.