

Lyophilization Technology, Inc.

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DATE FOUNDED
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OUTSOURCING and Consulting Services



Lyophilization Technology, Inc.

Corporate Description

A Contract Development and Manufacturing Organization focused on all aspects of Lyophilization. A talented and dedicated staff, skilled through experience, is coupled with in-house capabilities in product development, process engineering, clinical manufacturing and technical support.

Major Products/Services

LTI has successfully developed formulations, manufacturing processes and prepared material for clinical trials for over 384 diverse products.

- Anti-infectives
- Oncolytics/HPCs
- Human/Recombinant Biologics
- Small Molecules/Therapeutics
- Vaccines
- Diagnostics

Capabilities

- Pre-clinical to Phase II Clinical Materials, lyophilized and liquid products
- Dedicated/disposable product contact items/equipment
- Containment capabilities for handling cytotoxic/high potent APIs
- Lyophilizers ranging from 0.2 m² to 4.5 m²
- Praxair ControlLyo™, Nucleation On Demand **New**
- Vials from 2 to 160 mL and novel delivery systems
- Cartridges/syringes from 1 to 50 mL **New**
- Bulk Lyophilization or Drying
- Batch sizes to 75L
- Drug and Device Registration/DEA license
- US/EU complaint

Development Sciences

Distinct development and process laboratories provide ample capacity for small- to medium-scale formulating through fill and finish activities. Filling, stoppering, and loading the qualified pilot-scale lyophilizers are completed in certified Class 100 clean rooms to emulate aseptic manufacturing conditions.

- Thermal Analysis
- Cycle Design/Refinement
- Product Design
- Product Characterization
- Formulation
- Toxicology Material Development



Clinical Manufacturing

The Clinical Manufacturing Area (CMA) is flexible for preparation of products with unique requirements, adheres to aggressive project timelines, and is fully cGMP compliant. The dedicated CMA includes separate controlled areas for warehousing, preparing materials, compounding, fill/finish, and inspection. The aseptic processing suite features containment and isolation technology. The operation has been inspected and approved for handling BSL-2 material.

- Pre-clinical
- Phase I
- Phase II
- Liquid Fills

Technical Services

Technical services are available providing support for all aspects of lyophilization:

- Customized Training
- Validation
- Investigations
- Quality/Compliance

Major Markets

LTI has provided lyophilization-focused Development and Clinical Trial Material Manufacturing services to more than 296 biotechnology and pharmaceutical clients spanning from virtual, small to large multinational companies over 20 years.

