

Lyophilization Technology, Inc.

30 Indian Drive
Ivyland, PA 18974-1431

TELEPHONE
215.396.8373

FAX
215.396.8375

E-MAIL
inquiry@lyo-t.com

WEBSITE
www.lyotechnology.com

DATE FOUNDED
1992

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 is coupled with in-house capabilities in product development, process engineering, clinical material preparation and technical support.

Major Products/Services

LTI has successfully developed formulations, manufacturing processes and prepared material for clinical trials for a wide variety of products.

- Anti-infectives
- Oncolytics / HPCs
- Biologics / Vaccines
- Small Molecules / Therapeutics

Development Sciences

Development services are conducted with product quality and a manufacturing mindset from the start, considering product administration, stability and processing requirements. Development and process laboratories provide ample capacity for small to medium scale formulating, fill and finish activities. Distinct processing areas are comprised of ISO 5 clean rooms directly linked to pilot-scale lyophilizers.

- Thermal Analysis
- Process Engineering
- Product Design
- Design Space Studies
- Formulation
- Product Development
- Characterization



Clinical Manufacturing

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, inspection, and packaging. The aseptic processing suite features HEPA unidirectional air supply and returns, containment, and isolation technology. The operation has been inspected and approved for handling BSL-2 material and qualified for containment and aseptic processing.

- Pre-clinical to Phase II Clinical Material
- Dedicated / disposable product contact items/equipment
- Product dedicated / disposable containment system
- Combined aseptic processing with product containment
- Vials 2 to 100 mL and novel delivery systems
- Batch sizes to 75 L
- US / EU compliant

Technical Services

The broad range of experience in a wide variety of products provides a specialized expertise from which you can capitalize.

- Investigations
- Validation
- Quality / Compliance
- Training

Markets Served

LTI has provided lyophilization-focused Development and CTM Manufacturing services to more than 280 biotechnology and pharmaceutical clients spanning from virtual, small to large multi-national companies.