Lyophilization Technology, Inc.

Corporate Description
A dedicated staff supports clients bringing new products to patients and improving existing products and operations. Clients gain with successful development and clinical manufacturing, bridging discovery through product approval and commercial manufacturing. Support services span product development, process engineering, clinical manufacturing and technical service. Internationally recognized as an industry leader, clients have fostered our reputation for providing innovative solutions, achieving desired results, and exceeding expectations. This reputation is demonstrated by successful collaborative relationships with clients for over 23 years.

Major Products/Services
LTI successfully developed formulations, processes or prepared clinical material for over 851 diverse products:
• Anti-infectives
• Human/Recombinant Biologics
• Vaccines
• Nanoparticles/emulsions
• Oncolytics/HPCs
• Small Molecules/Therapeutics
• Diagnostics
• Bioengineered materials

Capabilities
• Pre-clinical through Phase III Clinical Materials, lyophilized/liquid products
• Containment for cytotoxic/high potent products
• Dedicated/disposable equipment
• Vials: 2 to 160 mL: novel delivery systems
• Cartridges/syringes: 1 to 50 mL
• Lyophilizers: 0.2 m² to 4.5 m²
• Praxair ControlLyo™
• Bulk Lyophilization
• Batch sizes: up to 75L
• Drug and Device Registration/DEA license
• US/EU compliant

Development Sciences lab focuses on formulation through product characterization. The Process Lab provides capacity for small/medium scale lyophilization. Filtration, filling, stoppering and loading qualified pilot-scale lyophilizers are in certified Class A/100 environments, emulating aseptic manufacturing conditions.
• Thermal Analysis
• Product Design
• Formulation Development
• Product/Process Feasibility
• Cycle Design/Refinement
• Product Characterization
• Toxicology Material
• Stability Batches

Clinical Manufacturing Area (CMA) for preparation of clinical material is for processing a wide range of products, including unique requirements. The CMA includes an aseptic suite featuring unique disposable negative pressure isolators for containment/isolation technology, inspected and approved for handling BSL-2, cytotoxic and highly potent material.
• Aseptic compounding
• Pre-clinical through Phase III
• Small to medium batch sizes
• Liquid/diluents

Technical services are available providing support for all aspects of lyophilization.
• Customized Training
• Qualification/Validation Support
• Investigations
• Quality/Compliance

Major Markets
LTI provides Development and Clinical Trial Material Manufacturing to more than 436 biopharmaceutical companies spanning virtual, small, large and multinational companies. Gaining an international reputation, projects are with clients in US, Canada, Mexico, Eastern and Western Europe, Australia and Japan.