LYOPHILIZATION TECHNOLOGY, INC.

Integrating Science and Technology

Development Sciences Clinical Manufacturing Technical Services

Comprehensive Services Focused on Lyophilization

Lyophilization Technology, Inc. (LTI) was formed in 1992 to provide an extensive range of scientific services and technical support in freezing and freeze drying. As a Contract Development and Manufacturing Organization (CDMO), our services range from product and process development and integration of a new product and process into commercial manufacturing operations through clinical trial material preparation. With our expertise, you realize the benefit from development, clinical material manufacturing, technical support, consulting services, improved quality, efficiency, and compliance for new and commercial lyophilized products.

- Development Studies
- Pilot Plant Scale-up
- Design Space Studies
- Clinical Trial Material
- Consulting
- On-site Training

As an industry leader, LTI has experience in a wide spectrum of products from anti-infectives to vaccines, nanoparticles to large molecules and biological preparations. Working synergistically, emerging companies and multi-national corporations throughout the world have engaged our support in successful collaborations for a variety of projects. These projects span initial product and process development for new entities right out of drug discovery, preparing Phase I and II clinical material, technology transfer to commercial manufacturing and gaining regulatory approval. As a client, you gain the benefits of unparalleled expertise, outstanding quality and exceptional service, minimizing time from discovery to the clinic.

Development Sciences

- Low Temperature Thermal Analysis
- Product Development
- Cycle Design / Refinement
- Vials / Cartridges
- Finished Product Testing
- Isolation / Containment
- Aqueous / Organic Solvents

Our development laboratories are well equipped for conducting a diverse range of experiments. These encompass formulation development, cycle design and process refinement, as well as evaluating finished product. Ease of scale-up is accomplished by completing process development studies within a pilot scale manufacturing environment. This now includes use of Praxair® ControLyo™ technology in process engineering studies. Critical areas for fill/finish are all within a certified HEPA environment, emulating aseptic operations for sterile product. Our comprehensive development reports readily support your regulatory submissions.

Clinical Manufacturing

Toxicological and clinical parenteral products are prepared in the Clinical Manufacturing Area (CMA), a unique aseptic fill/finish facility with isolation and containment capabilities using disposable and dedicated equipment. This area allows processing of BSL-2 biologicals, controlled substances, highly potent compounds and oncolytics. Stringent environmental controls within this unique facility allow for a superior level of purity in the finished product.

- Aseptic Processing
- Isolation / Containment
- Disposable / Dedicated Equipment
- Qualified / Validated
- US and EU Compliant

Preparation of clinical material accompanying the extensive activities performed in the development laboratory and pilot plant provides a single source for an expedient and effective pathway into clinical studies. Batch preparation, aseptic processing and lyophilization are completed in a unique aseptic containment environment that provides quality and purity, in addition to safety and security for product and personnel. This is achieved by a high level of control throughout the operation, supported by the facility layout, processing equipment, and environmental controls.

- Sterile Bulk and Drug Product
- 2 to 160cc presentations
- 13 to 28mm closures
- Temperature controlled compounding and filling
- Praxair ControLyo technology
- Aqueous / Organic Solvents
- 8 to 48 ft^2 (0.7 to 4.4 m^2) Lyophilizers

Experience with a variety of products, from vaccines to IV therapy presentations, capitalizes on our unique flexibility in preparation of parenteral products. Clinical Trial Material, with control for high yield and minimal loss, is of the highest quality and purity, meeting US and EU requirements.

Technical Services

Complementing development sciences and clinical manufacturing, technical services include consultation on equipment specifications, scale-up, quality control, validation, and compliance auditing. On-site training is available in the fundamentals of lyophilization and validation.

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