Lyophilization TECHNOLOGY Inc.

Prefilled Cartridge Processing

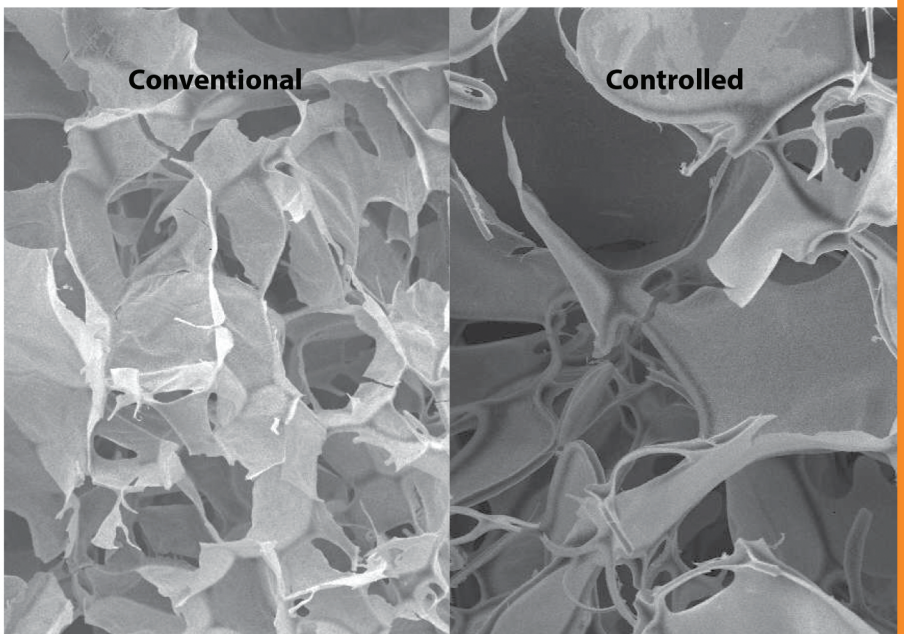
Product Development

Clinical Manufacturing

Customized Solutions

Biologics, Cytotoxins & HPCs

ControLyo™ Controlled Nucleation Technology

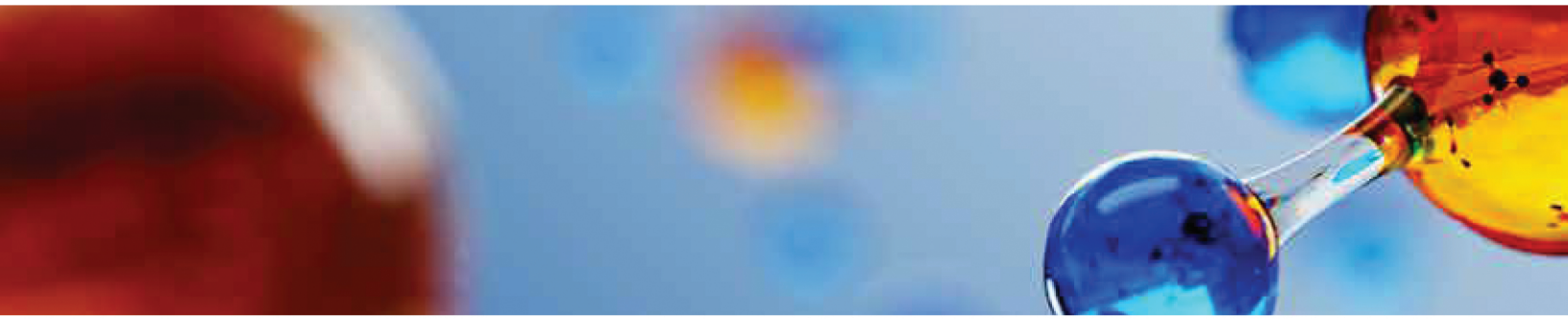


Improved Uniformity

Enhanced Process Control

Predictable Scalability

Greater Efficiency



COMPREHENSIVE SERVICES FOCUSED ON LYOPHILIZATION

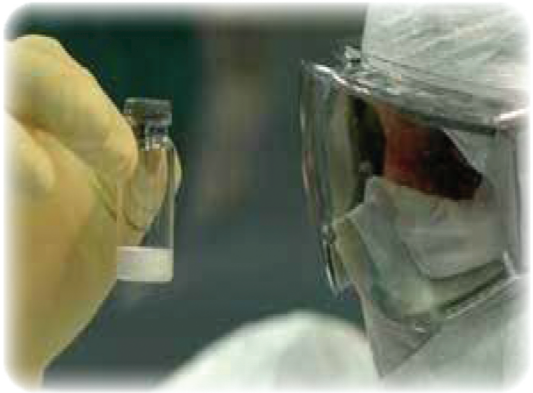
Lyophilization Technology, Inc. (LTI) is a Contract Development & Manufacturing Organization (CDMO) focused on all aspects of lyophilization for preparation of health care products.

Clients leverage our abilities for bringing new products to the clinic and implementing improvements for current products. LTI is recognized as an industry leader with unparalleled capabilities in product development, process engineering, clinical manufacturing, and technical support.

To the benefit of our clients, LTI has provided Development and Clinical Trial Material Manufacturing services to more than 500 biotechnology and pharmaceutical organizations spanning virtual companies to large multi-national corporations for over 25 years. Our proven track record of performance comes from successfully developing formulations, manufacturing processes, and prepared material for clinical trials for over 900 diverse products.

A talented and dedicated staff, skilled with over 300 years of combined experience, enjoys the reputation of providing innovative solutions, achieving desired results, and exceeding client expectations. Gain the benefits of our experience and capabilities for creating solutions for the unique needs of your lyophilized product.

DEVELOPMENT SCIENCES



Development services are conducted with a GMP mindset and a focus on product manufacturability and quality. This entails considering product administration, stability, and processing requirements from the start. Clients and project sponsors realize numerous benefits from the focus on lyophilization, with access to a comprehensive range of services available from a single source.

Following applicable GMP principles, the development and process laboratories are well equipped for conducting a diverse range of experiments encompassing formulation development, cycle design, 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. 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 Technical Services

Clinical Manufacturing

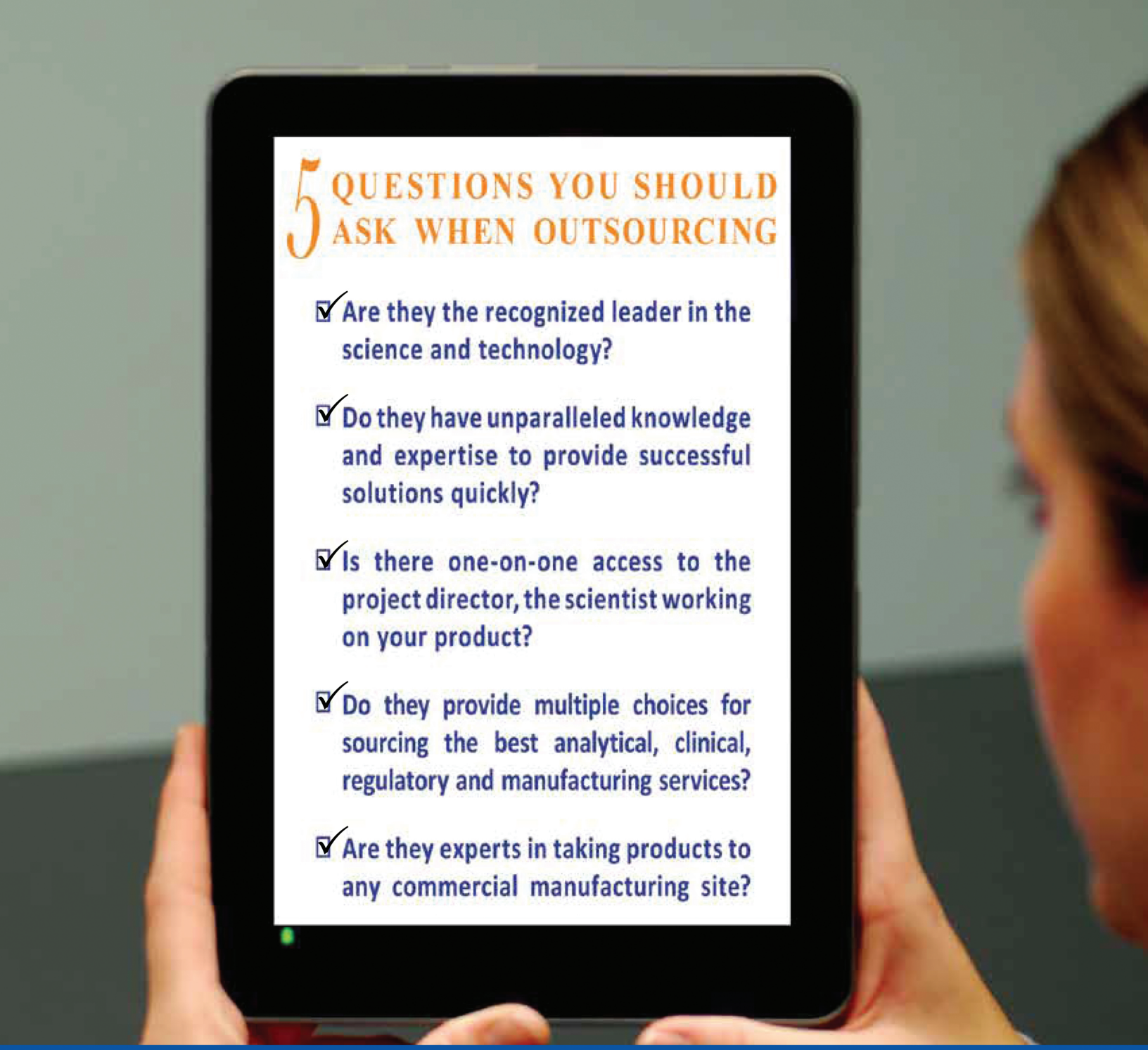
Lyophilization Technology, Inc. has experience with a wide variety of products, from vaccines to IV therapy presentations. We provide aseptic filling of preclinical and clinical (Phase I and II) materials. The Clinical Trial Materials we produce are of the highest quality and purity, meeting US and EU requirements. Our Clinical Manufacturing Area (CMA) is fully cGMP compliant. We are able to capitalize on our distinct flexibility to meet or exceed your expectations while adhering to aggressive project timelines. We have developed procedures to minimize production losses and maximize yield which is critical when producing small batches with valuable API.

- Clinical Trial Manufacturing
- Toxicology Material Processing
- Aseptic Vial Filling
- Aseptic Cartridge Filling
- Small-batch Manufacturing
- Specialized Flexible Capabilities
- ControLyo™, Nucleation On Demand

Our CMA includes separate controlled areas for warehousing, preparing materials, compounding, filling, and inspecting. The operation has been inspected and approved to handle BSL-2 materials and qualified for containment and aseptic processing. Stringent environmental controls within our facility allow for a superior level of purity in your finished product.

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.



Talk with the people who can provide you the right answers

Development Sciences Clinical Manufacturing Technical Services

Lyophilization TECHNOLOGY Inc.

30 Indian Drive | Ivyland, PA 18974 | USA
+1-215-396-8373 | inquiry@lyo-t.com
lyotechnology.com