Lyophilization TECHNOLOGY Inc.

Development Sciences Clinical Manufacturing Technical Services

Lyophilization Technology was formed in January, 1992 as an organization to offer an extensive range of scientific services and technical support in freezing and freeze drying. Since its inception, the company has grown to provide a wide variety of services in diverse applications of the technology. These involve development of new products for clinical studies of novel therapies, transferring marketed products to multiple manufacturing sites, and streamlining operations coupled with improving regulatory compliance stature.

The mandates for the organization are to provide a source of services to industry that comprise development of new products, streamline manufacturing operations, and improve compliance with current regulations. The practical application of experience and expertise is coupled with interests in applied research and advancing the technology. This combination of research and commercial enterprise offers the industry a unique source of comprehensive expertise that spans from bringing a new product to market to increasing the productivity of existing operations.

SERVICES AND TECHNICAL SUPPORT

Lyophilization Technology provides scientific services and technical support for the health care and related industries involved in producing pharmaceuticals, biologics, diagnostics, biopharmaceuticals, medical devices and fine chemicals. Scientific services consist of development, clinical material preparation, optimization and troubleshooting lyophilized products and processing. Such services may be provided using our laboratory facilities and when appropriate, on-site visits. Technical support includes consultation on equipment specifications, scale-up, validation, and compliance auditing. In-house training in fundamentals of the technology and validation are also available.

Successful collaborations involve small start-up companies to multi-national corporations. Projects span initial product and process development, technology transfer, gaining regulatory approval and commercial manufacturing. Clients and project sponsors realize numerous benefits from the focus on a comprehensive range of services in the technology.

Capabilities for preparation, processing, as well as finished product testing are now available for biologicals, including a range of vaccines, oncology products, and highly potent compounds, in addition to a range of antibiotics, biopharmaceuticals, liposomes, peptides and proteins. Development as well as preparation of clinical materials in this expanded facility complement the extensive activities currently performed in a well-equipped development laboratory and pilot plant.

Expertise in product design and process development for a wide variety of products

Biologic and viral vaccines
Cells and cell cultures
Fibrous and globular natural and recombinant proteins
Monoclonal antibodies
Polypeptides
Small molecules

Experience and capabilities of unique products with extraordinary requirements

Aqueous and organic solvents
Light and oxygen sensitivities
Physical structure and specific morphology

Success with projects focused on targeted objectives and aggressive schedules

Novel therapies and routes of administration
Dosage form design for initial dose ranging studies
Overseeing small scale production of later phase clinical materials
Product transfer and process scale-up to commercial manufacturing

Access to unique processing capabilities for aseptic preparation of clinical trial material Capability for a wide variety of products, spanning small molecules to biologicals Disposable product contact equipment dedicated to assure quality and purity
High level containment with dedicated equipment and soft-wall isolators
Flexibility in operations for aseptic processing

Increase productivity for commercial products and manufacturing processes Robust processes with increased control, productivity and yield Improvements in process reproducibility and product consistency Assessments of application of industry practices and regulatory compliance

Improved level of quality and compliance

Resolution to equipment malfunctions and process excursions
Evaluation of process deviations and product failures
Support for preparing submissions and responses to regulatory observations
Method development for moisture testing and physical inspection standards

Greater in-house expertise through on-site training programs Customized for departmental groups and multidisciplinary staff Principles and practical aspects of the science and technology Workshops in product/process development and situation responses
Approaches and techniques for equipment qualification and process validation

Staff Qualifications and Experience

These specially trained individuals, with more than 330 years combined experience, utilize their formal education in basic and applied sciences to meet the challenges presented in product and process development and troubleshooting. These talented scientists and technicians form a cumulative multi-disciplinary background in the Sciences. Experience of the staff spans the pharmaceutical and medical device industries, as well as direct clinical settings. The staff also receives routine and extensive training in specialized areas that encompass analytical methods such as Thermal Analysis techniques, preparation of pharmaceutical and diagnostic products, with heavy emphasis on the science and technology of freeze drying.

Analyitical, Development and Process Laboratories

Housed in a 10,000 square foot facility, these laboratories are well equipped for conducting a diverse range of experiments for product development, process engineering, as well as evaluating finished product. The behavior during freezing and drying characterized using a uniquely designed freeze drying microscope and electrokinetic analysis. Capability for multiple methods of finished product testing include Coulometric Karl Fischer and Thermogravimetric moisture analysis.

Ease of scale-up is accomplished by completing process development studies within simulated manufacturing environment in the Process Lab. This small manufacturing lab can accommodate formulation, filtration, filling, lyophilization and packaging operations. A Qualified facility, with systems and equipment maintained within GMP compliance, is suitable for both development studies and preparing material for stability studies. Routine inspections by both study sponsors and independent auditors assure continually meeting a high level of compliance.

Aseptic Preparation of Clinical Material in a Containment Facility

Capabilities for preparation, processing, and finished product testing are now available for biologicals, oncology products, and highly potent compounds. Preparation of clinical materials, as well as toxicology material, in this expanded facility complement the extensive activities currently performed in the conventional development laboratory and pilot plant. Batch preparation, aseptic processing and lyophilization are completed in a unique environment that provides 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 used in batch preparation, and environmental controls.

Scientific Presentations

Numerous courses, papers, publications and poster sessions have been presented for societies and professional organizations, both within the United States and internationally. These presentations can be found on our website and requested at www.lyotechnology.com.