Contact: Christine Palus
Telephone: (603) 668-5763
Email: info@lyophilization.com

FOR IMMEDIATE RELEASE

LYOPHILIZATION SERVICES OF NEW ENGLAND COMPLETES SUCCESSFUL FDA PRE-APPROVAL INSPECTION FOR STERILE DRUG PRODUCT

Bedford, NH – Lyophilization Services of New England, Inc. (LSNE) announced today that they have completed a successful Pre-Approval Inspection (PAI) and General GMP Inspection in April 2015. This inspection clears the way for the 25 Commerce Drive manufacturing site, located in Bedford, NH, to manufacture commercial drug product for US distribution. The inspection concluded with a recommendation for approval and the Establishment Inspection Report (EIR) has been received. This is the second PAI at the Commerce Drive facility, the first inspection was for a bulk drug intermediate lyophilized in LSNE's 260 square foot lyophilizer.

Shawn Cain, Chief Operating Officer of LSNE stated, "The completion of this inspection is a critical milestone for LSNE as it is the first PAI for a sterile product at the 25 Commerce Road facility. This is also our second site to now be successfully inspected by the FDA to produce commercial products in the past few months. This demonstrates LSNE's commitment to meeting all applicable regulatory standards for the production of commercial medical devices, bulk intermediates and sterile injectable drugs. It is only through the talent and dedication of our staff that we have been able to achieve and maintain this level of compliance."

LSNE has also added additional capabilities across their three sites and they plan to continue expanding in the coming year(s). The 2015 master plan includes expansion of QC analytical testing capabilities, ICH stability chambers, additional complex formulation capabilities, as well as adding increased manufacturing capacity. LSNE continues its path towards becoming the premier turn-key CMO for its clinical and commercial clients and its commitment to reduce the time and cost of bringing client projects from bench to market.

About LSNE Contract Manufacturing

LSNE Contract Manufacturing is a privately held company with three GMP manufacturing facilities located in New England. LSNE has been providing contract lyophilization services to the pharmaceutical, biotechnology and medical device industries since 1997, specializing in a wide range of services including cycle development, cGMP fill/finish of liquid and lyophilized products. Through the thoughtful integration of three processing facilities, qualified staffing, and an extensive manufacturing history, LSNE is strategically positioned to provide uninterrupted manufacturing for clinical through commercial supply for medical devices and pharmaceuticals to a multi-national market.
###

Media Contact
Christine Palus

Vice President of Sales & Marketing
(603) 668-5763
info@lyophilization.com
www.lyophilization.com