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FOR IMMEDIATE RELEASE
February 2011

Lyophilization Services of New England, Inc. (LSNE) Passes Comprehensive FDA Inspection

Manchester, NH – LSNE, a premier contract manufacturer specializing in aseptic fill/finish and lyophilization of both drug and medical device products, recently completed a week-long, comprehensive Food and Drug Administration (FDA) audit of its medical device manufacturing facility. The successful completion of this audit for which no 483 citations were issued, demonstrates LSNE's continued commitment in offering its clients quality cGMP manufacturing services.

LSNE has undergone six FDA inspections since 1999 and has manufactured approximately 6,000 lots of medical device product material following its last inspection in 2006. Matthew Halvorsen, President of LSNE, states that "the recent audit results, which did not involve any 483's being issued, are an enormous accomplishment considering the numerous lots that have been processed in our Manchester facility in the 4 years since the last FDA inspection. This is certainly an accomplishment that we can and should take pride in as a company."

Since its founding and initial offering of medical device contract manufacturing in 1997, LSNE has made the successful transition into also providing aseptic fill/finish contract drug manufacturing through the acquisition of state-of-the-art equipment, recruitment of qualified key personnel and continued expansion of what now includes three integrated cGMP manufacturing facilities. LSNE has sustained positive corporate growth while maintaining the regulatory standards for both medical device and drug manufacturing; including the recent completion of an FDA Pre-Approval Inspection (PAI) and Compliance audit for an Abbreviated New Drug Application (ANDA) for a sterile-injectable drug product at its Bedford, NH fill/finish facility.

Lyophilization Services of New England, Inc. (LSNE) provides development, manufacturing and support contract manufacturing services to the biotechnology, pharmaceutical and medical device industries. For additional information or a sample copy, Contact: Claudio Tracanna, 25 Commerce Drive, Bedford, NH 03101, 603-668-5763 x241, ctracanna@lyophilization.com

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