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FOR IMMEDIATE RELEASE

LYOPHILIZATION SERVICES OF NEW ENGLAND COMPLETES FDA INSPECTION

Manchester, NH – Lyophilization Services of New England (LSNE), a New Hampshire based contract manufacturing organization is pleased to announce that the Food and Drug Administration (FDA) recently completed an inspection of their Manchester manufacturing facility. This is the sixth successful inspection of the site, which is currently functioning as a multiproduct medical device manufacturing facility. The November 2013 inspection was a combination FDA general GMP and Pre-approval inspection. The inspection resulted in no Form 483 being issued, as there were no observations noted by FDA.

Matthew Halvorsen, President and Chief Executive Officer of LSNE stated, “We are very pleased with the result of the latest FDA inspection, which adds to our successful regulatory history. LSNE is committed to maintaining the highest level of quality across our three manufacturing sites so that we can remain a reliable partner to our clients.”

This FDA inspection follows a successful MHRA inspection of the LSNE 25 Commerce Drive, Bedford NH contract pharmaceutical manufacturing facility in which LSNE received a Certificate of GMP Compliance from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to manufacture aseptic lyophilized drug products for use in the European Union.

About LSNE Contract Manufacturing

LSNE Contract Manufacturing is a privately held company with three GMP 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, and lyophilization. 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 device and pharmaceuticals to a multi-national market.

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