

LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

June 25, 2008

E-MAIL DOCUMENT 6/25/08
umesh.ba@acunovalife.com

Mr. Umesh B.A.
Chief Quality Officer
Manipal AcuNova Limited
Mobius Towers, SJR i-Park
Whitefield, EPIP Zone
Bangalore – 560 066 INDIA

Dear Mr. Umesh:

Per your request, may this letter serve as our certification that Lachman Consultants Services, Inc. (LCS) had performed a general quality system and USFDA inspection readiness audit of your Clinical Research Centers located in Manipal and Mangalore. This audit was conducted from June 11-15, 2007, by senior LCS auditors / GCP, GLP subject matter experts, Mr. Carl Chancey, RPh., M.P.H. and Mr. Steven Lum, B.S., M.S.

Both Mr. Chancey and Mr. Lum are highly qualified GCP, GLP subject matter experts and have many years of combined U.S. FDA, industry and consulting experiences. Prior to joining LCS, Mr. Chancey was a former U.S. FDA CBER Director, Office of Compliance and Mr. Lum held various senior quality management positions in major U.S. Pharma companies.

The LCS audit covered the BE/BA bioanalytical laboratory, clinical operation, central laboratory and the related supporting computer systems. A formal audit report was provided to the firm on July 5, 2007, with a list of observations and recommendations. Based on the results of this audit, it was the LCS auditors' opinion that the firm was generally in good control, and could be considered in substantial compliance with GCP and GLP requirements if the firm could satisfactorily address all critical observations and make the proper corrective / enhancement actions in a timely manner.

While LCS has not performed a follow-up audit to verify the corrective / enhancement actions taken, it is our understanding that subsequent to the LCS audit, the firm had made many system enhancements and was able to pass several regulatory inspections, including an FDA pre-approval inspection in September 2007.

Please feel free to contact me if further clarification is required.

Regards.

Sincerely,



Frank Chow, Ph.D.
Senior Vice President, Science and Technology

FC/lu

A75F8177