Adenoviral Reference Material Working Group
Canji & SPRI Group 9.0 Bid Submission Form
Participation in Assignment of Infectious Titer

Please complete the following fields: This is a group submission; Beth Hutchins is the group coordinator.

Contact Information – RFP 9.0

*Contact Individual:	Dr. Beth Hutchins
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Email Address:	beth.hutchins@canji.com

***If laboratories are submitting a proposal as a group, a main contact should be provided along with contact information for each participating laboratory (attach additional copies of this form).**

Please indicate if your institution is also submitting proposals for the other activities:

- [X] Determination of Particle Concentration
- [ ] Short-term/Field Stability Studies
- [X] Long-term Stability Study
- [X] Other Characterization
- [ ] Donation of Supplies/Other Services for Characterization Phase

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*Contact Individual:	Dr. Michael Grace
Institution:	Schering Plough Research Institute (SPRI)
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Email Address:	michael.grace@spcorp.com

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Group Submission

Canji, Inc. is a wholly owned subsidiary of Schering Plough Corp., specializing in adenoviral vector gene therapy including pharmacology, analytical method, and process development. Canji's Process Sciences' personnel have a well-established reputation for expertise in adenoviral vector technology, evidenced by publications and issued patents related to production and characterization methods. The BioAnalytical Group in Biotechnology Development Operations at Schering Plough Research Institute (SPRI) is the group receiving methods from Canji to support clinical development of adenoviral gene therapy products

Both the BioAnalytical/QC Group in Process Sciences and the SPRI BioAnalytical Group would perform the infectious titer assay under the leadership of Dr. Barry Sugarman and Paul Shabram and Dr. Michael Grace (SPRI). The HEK-293 Test Cell Bank vial would be expanded by the Cell Core group, headed by Dr. Wendy Hancock. Dr. Hancock has more than 8 years of experience working with HEK-293 cells. Canji's work in examining the role of diffusion in underestimating infectious titers was developed by Paul Shabram and Daniel Giroux, and incorporated into a collaboration with Dr. Estuardo Aguilar-Cordova and published in C. Nyberg-Hoffman, P. Shabram, W. Li, D. Giroux, and E. Aguilar-Cordova, "Sensitivity and reproducibility in adenoviral infectious titer determination," (1997) *Nature Medicine 3:* 808-811. The equation used to incorporate a correction for diffusion into the Working Group's Infectious Titer SOP was developed by Canji scientists.

Equipment to be used is part of Canji's and SPRI's calibration and preventive maintenance program. At Canji micropipettes are calibrated and laminar flow hoods are certified / incubators calibrated on a 3 and 6 month schedule, respectively. In addition incubators are monitored for temperature on a daily basis.

Canji and SPRI will be able to initiate infectious titer testing within 3 to 4 weeks of receiving the Ad5 WT Reference Material vials and one vial per group (2 vials total) of the 293 Test Cell Bank. Canji and SPRI anticipate reporting data back to the Working Group within 3 weeks of initiating the analysis.