RFI on DNA Plasmid Development Services - Sources Sought Notice – Mod. 1
April 15, 2009

General Information:

This Sources Sought Notice (SS) is for information and planning purposes only, and shall not be construed as a solicitation or as an obligation on the part of SAIC-Frederick, Inc. (SAIC-F) or the National Cancer Institute at Frederick (NCI-F). SAIC-F does not intend to award a contract on the basis of responses to this Sources Sought Notice, nor otherwise pay for the preparation of any information submitted. As a result of this Sources Sought Notice, SAIC-F may issue a Request for Proposal (RFP) in the future. THERE IS NO SOLICITATION SCHEDULED AT THE PRESENT TIME. THIS IS STRICTLY MARKET RESEARCH. However, should such a requirement materialize for a formal RFP, no basis for claims against SAIC-F shall arise as a result of a response to this Sources Sought Notice or SAIC-F's use of such information as either part of our evaluation process or in the developing specifications for any subsequent requirement. Any questions concerning this solicitation must be directed through the SAIC-F Point of Contact (SAIC-F POC)

Sources Sought Notice Number: S09-117

Posted Date: March 24, 2009

Response Date: On or before May 22, 2009 by 4:00PM Eastern

Archive date: June 22, 2009

Classification Code: A – Research and Development NAICS: 541711

Set Aside: N/A

Contracting office address: SAIC-Frederick, Inc.
National Cancer Institute at Frederick
92 Thomas Johnson Drive, Suite 250
Frederick, MD 21702-1201

Summary:

A contract manufacturing organization or supplier with the ability to develop a process, and perform manufacturing for DNA plasmids for therapeutics and vaccines, using an established cell line, such as *E. coli* DH 5 alpha with productivity of not less than 800mg/liter of purified plasmid DNA in fermentation broth. It is also required to demonstrate that high quality of plasmid product including but not limited greater than 90% of supercoiled DNA can be purified from the broth.

Service Requirement:

Potential Offerors are to provide detailed description of technical approaches and experience, as well as estimated costs in performing the activities detailed below:

Standard Plasmid Construct – Assume a gene insert would be provided to the Offeror for the purposes of responding to this Request for Information/Sources-Sought Notice:

1) Plasmid contains several basic components including but not limited to promoter(s) to allow gene expression in a mammalian cells and/or tissues; with bacterial replication capability in either high or low copy number, and with no beta-lactmase resistance marker.

2) Plasmid with size of less than 12Kb.

3) Plasmid carries at least one protein coding sequence for expression in mammalian cells and/or tissues.

Production System and Productivity

1) *E. coli* DH 5 alpha or equivalent FDA accepted *E. coli* strain that can be employed as host cell for production of a plasmid.

2) The *E. coli* cells used for production meet FDA requirements for GMP manufacturing. The Offeror is to provide standard listing of procedures to establish and characterize Master Cell Bank.

3) It is required to demonstrate that the productivity is 800mg/liter or higher of fermentation broth at 10 liter or larger fermentation scale. The Offeror is requested to provide experience with specific data.

4) It is required to demonstrate at small scale that the plasmid can be purified from the fermentation broth at reasonable purification yield. The Offeror is requested to provide experience with specific data.

Product Characterization and Quality Requirements

1) A full length plasmid DNA sequence is required; the Offeror is to provide methods used and identify any subcontract relationships, if applicable

2) It is required to demonstrate that the purified plasmid is acceptable in quality including but not limited to higher than 90% of supercoiled plasmid.

cGMP Production

1) The Offeror is to provide facility and operational description for production of purified plasmid DNA under GLP and/or cGMP conditions. Examples of previous experience are requested.

2) It is requested that production be demonstrated for at least 5 g purified plasmid DNA per batch. The Offeror is requested to provide information on experience for large scale DNA plasmid production.

Documentation Requirement

1) A documented history of plasmid construction is required; Table of Contents or format for a standard Offeror report is requested.

2) A full length plasmid sequencing result is required and sequence information is in standard electronic formats.

3) Process development and technology transfer reports are required. Table of Contents or format for a standard Offeror report is requested; information would normally include: small scale production in shake flask and 10L fermentor; fermentation procedure and fermentation medium composition; small scale purification procedures; and methods or analysis and assay data.

4) Master File or examples of CMC documentation provided to support clinical materials manufacturing.

Offeror Instructions:

Offerors must submit a capability statement (30 page limitation, excluding resumes) describing their organization's experience and abilities to provide the materials and services as described which includes: (1) a summary of list of past performance with references; (2) a brief description of the professional qualifications and experience of key staff who may be assigned in the production of the materials and delivery of services (CV's may be provided); (3) listing of any/all current and relevant certifications from a qualified neutral third-party and contact information; (4) a general description of the facilities and other resources needed to provide the materials and services; (5) demonstrated ability to produce the materials & services; and (6) an estimated cost broken down in a Time and Material (T & M) format of defined materials and services.

Each response should include the following Business Information in addition to capability statement:

1) Sources Sought Number
2) DUNS number
3) Company Name
4) Company Address
5) Company Point of Contact, Phone, FAX, and Email Address. POC's should include individual(s) who is(are) duly authorized in managing any/all technical issues and/or questions, and individual(s) who is(are) authorized in managing any/all contractual issues and/or questions.
6) Type of Company (i.e. small business, 8(a), woman-owned, veteran-owned, etc.) as validated by the Central Contractor Registration (CCR). All responders must register on the CCR, located at http://www.ccr.gov/index.asp.

The final date to submit questions for this RFI is 12 noon on May 1, 2009

The last date to submit final responses to this RFI is 3:00 PM, May 22, 2009

Point of Contact

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