Small Business Sources Sought Notice
HHS-NIH-NCI-SBSS-TSB-77001-98

This is a small business sources sought notice. This is **NOT** a solicitation for proposals, proposal abstracts, or quotations. The purpose of this notice is to obtain information regarding: (1) the availability and capability of qualified small business sources; (2) whether there are small businesses; HUBZone small businesses; service-disabled sources, veteran-owned small businesses; 8(a) small businesses; veteran owned small businesses; woman-owned small businesses; or small disadvantaged business; and (3) their size classification relative to the North American Industry Classification System (NAICS) code for the proposed acquisition. Your responses to the information requested will assist the Government in determining the appropriate acquisition method, including whether a set-aside is possible. An organization that is not considered a small business under the applicable NAICS code should not submit a response to this notice.

A determination by the Government not to compete this requirement as a set-aside based upon responses to this notice is solely within the discretion of the Government. Interested parties are expected to review this notice and the draft statement of work to familiarize themselves with the requirements of this project; failure to do so will be at your firm's own risk.

Background:

The Developmental Therapeutics Program (DTP) in the Division of Cancer Treatment and Diagnosis (DCTD) at the National Cancer Institute (NCI)/National Institutes of Health (NIH) supports the NCI's Experimental Therapeutics (NExT) to facilitate the transition of novel drug discoveries into clinical trials of new cancer therapeutic agents. One of the essential parts of the program involves the manufacture and supply of bulk chemicals/drugs that are prepared under the current Good Manufacturing Practice (cGMP). The bulk materials will be used to support pre-clinical studies and to prepare clinical products that are necessary to support human clinical trials under the NCI sponsorship or investigator initiated investigational new drug (IND) applications.

Purpose and Objectives:

The purpose of this small business sources sought notice is to identify qualified small business concerns including HUBZone small businesses; service disabled, veteran-owned small businesses; 8(a) small businesses; women-owned small businesses; or small disadvantaged businesses that are interested in and capable of performing the work described herein. The NCI does not intend to award a contract on the basis of responses received nor otherwise pay for the preparation of any information received.

The Pharmaceutical Resources Branch (PRB) DTP/DCTD/NCI/NIH is seeking contractors that will provide services, personnel, equipment, and facilities as required to perform process development and synthesis of bulk materials under cGMP conditions. The quantity of a given material to be synthesized may range from multi-grams to multi-kilograms. The materials are required to be highly pure and well characterized. They are intended for use in formulation development, pharmacology, toxicology and clinical trials.

Major aspects of the contract work scope will include:

1. cGMP process development to transform laboratory-scale procedures to large-scale process;
2. Synthesis of bulk chemicals/drugs on multi-grams to multi-kilograms scale as needed;
3. Analysis for ensuring the purity, identity and quality of the prepared compounds including QA/QC for the GMP batches;
4. Additional studies such as solubility/stability as needed. Technical reports submitted by the contractor may be used to support the filing of IND applications to the Food and Drug Administration (FDA).

As a result of this notice, the NCI may issue a Request for Proposal (RFP). There is no solicitation available at this time. However, should such a requirement materialize, no basis for claims against the NCI shall arise as a result of a response to this notice or the NCI's use of such information as either part of our evaluation process or in developing specifications for any subsequent requirement.

If a RFP is issued, the NCI anticipates one (1) award may result from the issuance of the RFP.

Project Requirements:

The contractor shall furnish all of necessary services, qualified personnel, materials, equipment, laboratory supplies, and facilities for scale-up manufacturing and analysis of cGMP bulk materials. Specifically, the contractor shall be able to perform all areas in the draft statement of work provided. This draft statement of work is subject to revisions.

Anticipated Period of Performance:

It is anticipated that the award from this solicitation will be a cost-plus-fixed-fee (CPFF) contract. The duration of the contract will be five (5) years, consisting of a one (1) year base period with four (4) one-year option. The anticipated start date is on or about August 2017.

NAICS Code and Size Standard:

In the event an RFP is issued, the NAICS code is 325412 with a size standard of 1,250 employees.

Capability Statement/Information Sought:

Tailored capability statements shall demonstrate a clear understanding of all tasks specified in the draft statement of work (SOW), to include document understanding of the multi-step preparation sequences as outlined in the draft SOW. Tailored capability statements for this requirement shall also address the following areas:

1. Provide and operate material preparation facilities for:

    a. Synthesis of varying amounts of materials under laboratory and cGMP conditions in the quantity and/or quality needed. The target materials will involve a wide variety of well-characterized small molecules, including small peptides and oligomers. The Contracting Officer's Representative (COR) will assign priorities for preparation, standards of purity and quality specifications. The quantity of any assigned preparation ranges from several grams to multi-kilogram.

    b. Development of existing synthetic processes for scale-up or optimization of the processes. Procedures of synthesis or literature citations will be available for many but not all assignments. Development of new and/or existing synthetic procedures and process development for scale up to large size lots will be frequently required.

    c. Occasional assignment of preparation of gram quantities of research grade compounds of interest to the DTP.

2. Provide pertinent analytical data to adequately assess purity, quality and identity of all materials prepared or purchased. The data should include elemental analysis, proton/carbon-NMR, MS, IR, UV, melting point, solubility, HPLC purity, residual solvents, etc. as requested by the COR.

3. Retain and/or provide samples of synthetic intermediates prepared during the manufacture of target compounds in the amounts required by the COR.

4. Prepare data sheets and description of preparative methods for all materials. The preparative methods shall be sufficiently detailed for filing with the FDA as bulk manufacturing procedures. This includes details of sources, purities and lot numbers of all raw materials and solvents used, their acceptance data and quantities used. Detailed methodology including the reaction conditions, the isolation and purification procedures used for all intermediates and the target compound, and the acceptance criteria used for each should be provided.

5. Provide itemized costs of process development and preparation for each target material.

6. Deliver the materials, data sheets, preparative methods, and cost information in accordance with the instructions of the COR. Material Safety Data Sheet (MSDS) for the material should be prepared and included with all shipments to the Government's repositories or other facilities as instructed by the COR.

7. Additionally, upon specific instructions from the COR, the contractor shall:

    a. Procure, purify (if necessary) and characterize substances from commercially available sources.

    b. Perform preliminary stability, solubility and characterizations of materials produced or procured by the contractor or by the Government.

    c. Conduct preliminary stability or safety studies in the handling and storing of substance accepted as an assignment. The contractor shall provide the necessary data as a guide for the proper handling and storage of such substances.

    d. Prepare analytical reference standards if requested by the COR.

8. Comply with cGMP regulations for bulk drug production and Government health and safety regulations:

    a. FDA requirements:

        i. The contractor shall be registered with the FDA as a manufacturer of bulk drugs. Facilities shall meet FDA standards in accordance with cGMP regulations. If inspections by the FDA during the term of the contract cite deficiencies which are not addressed satisfactorily to the FDA in timely manner, such citations could be the basis for termination of the contract.

    b. Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), and Department of Transportation (DOT) regulations:

        i. The contractor shall comply with all OSHA and DOT regulations. The contractor shall comply with all EPA regulations regarding the discharge of water and air pollutants and assure that disposal of all chemical residues meet current EPA regulations.

9. The chemicals and drugs to be prepared or handled under this contract are to be regarded as proprietary in nature. Under no circumstances are chemicals or drugs or any information associated with these chemicals or drugs to be released or divulged to the public without prior written approval of the COR.

10. Under certain conditions, the contractor may be eligible for filing for patent protection to protect any

inventions that they may have made during the course of their contract performance. When the drug comes from an external collaboration with the NCI, the collaborator's original discovery needs to be protected.

11. All data provided to the contractor and developed by the contract under this contract must be treated confidentially. When compounds are assigned to the contractor, "discreet" compounds will be identified by the letter "D" as a prefix to the compound's NSC number. Under no circumstances are chemicals or drugs or any information associated with these chemicals or drugs, including data generated under this contract can be released to the public without prior written approval of the COR.

Information Submission Instructions:

1. Page Limitations: Interested, qualified small business organizations should submit a tailored capability statement for this requirement not to exceed twenty-four (24) single-sided pages including all attachments, resumes, charts, etc. (single spaced, 12 point font minimum) that clearly details the firm's ability to perform the aspects of the notice described above and in the draft SOW. Tailored capability statements should also include an indication of current certified small business status. This indication should be clearly marked on the first page of your capability statement (preferably placed under the eligible small business concern's name and address) as well as the eligible small business concern's name, point of contact, address and DUNS number. All pages must be numbered including attachments, resumes, charts, etc.

2. Delivery Point:

    a. All capability statements sent in response to this sources sought notice must be submitted electronically (via email) to Mr. Stephen Shaffer, Contract Specialist at Stephen.Shaffer@nih.gov in Microsoft Word or Adobe Portable Document Format (PDF). The subject line must specify HHS-NIH-NCI-SBSS-TSB-77001-98. Facsimile responses will not be accepted.

3. Common Cut-Off Date:

    a. Electronically submitted tailor capability statements are due no later than 3:00 PM EST on November 9, 2016. Capability statements received after this date and time will not be considered.

DISCLAIMER AND IMPORTANT NOTES:

This notice does not obligate the Government to award a contract or otherwise pay for the information provided in response. The Government reserves the right to use information provided by respondents for any purpose deemed necessary and legally appropriate. Any organization responding to this notice should ensure that its response is complete and sufficiently detailed to allow the Government to determine the organizations qualifications to perform the work. Respondents are advised that the Government is under no obligation to acknowledge receipt of the information received or provide feedback to respondents with respect to any information submitted. After a review of the responses received, a pre-solicitation notice may be published in Federal Business Opportunities. However, responses to this notice will not be considered adequate responses to a solicitation.

Confidentiality: No proprietary, classified, confidential, or sensitive information should be included in your response. The Government reserves the right to use any non-proprietary technical information in any resultant solicitation(s).