Sources Sought Notice for RFP #N02-CO31001-27

RFP#: _ N02-CO31001-27_____
Title: "STORAGE AND DISTRIBUTION OF CLINICAL AGENTS"
Solicitation Number: HHS-NIH-NCI-SS-ETSB-31001-27
Notice Type: Sources Sought Notice

This is a 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 all qualified sources to perform the potential requirement;(2) your availability and capability if you are a qualified small business source (3) whether you are the following type of small business; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; woman-owned small businesses; or small disadvantaged businesses; and (4) your 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. This requirement is assigned a code of 493190 in the North American Industry Classification System (NAICS), and the size standard for such requirements is $7 million. Statements should also include an indication of current certified business status; this indication should be clearly marked on the first page of your capability statement as well as the eligible business concern's name, point of contact, address and DUNS number.

**Background**

The Pharmaceutical Management Branch (PMB), Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI), is charged with providing pharmaceutical support for clinical trials sponsored and/or funded by the National Cancer Institute. The DCTD sponsors intramural and extramural research for the clinical evaluation and development of potentially effective cancer treatments. CTEP administers, coordinates, and funds these clinical trials, as well as supports other clinical research initiatives. The program fosters collaborations within the cancer research community and works extensively with the pharmaceutical and biotechnology industries.

The Pharmaceutical Management Branch (PMB), CTEP, in providing pharmaceutical support for cancer clinical trials sponsored and funded by the DCTD, NCI, manages the Contractor who provides a facility and project team to receive, store, distribute and account for the final disposition of clinical agents for open-label and double-blind placebo-controlled clinical trials and maintains necessary records of all aspects of the process. This contract also supports agent distribution services for clinical trials of other NCI Divisions and Programs, preclinical drug development research of NCI grantees, academic institutions, Cooperative Groups, and Cancer Centers, and a compassionate-use distribution program that provides promising new agents to physicians whose patients could benefit. The NCI Clinical Repository is currently open and

accessible during regular business hours (8:30 AM - 5:00 PM, Eastern Time), Monday through Friday, except for official Federal Government holidays. An occasional evening, night, or weekend emergency shipment has been necessary.

The Contractor maintains and operates the Clinical Repository for the Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI. This contract is responsible for the receipt, storage, distribution and final disposition of hundreds of clinical investigational agents. The Contractor must also maintain special expertise in the management, labelling and distribution of clinical supplies for double-blind placebo-controlled trials. The Contractor receives and inspects agents according to applicable regulations as they are received from manufacturers and suppliers throughout the world. Agents are inventoried and stored in a secured, monitored, fire-protected warehouse under specified environmental and controlled temperature conditions. Computerized record keeping accompanies each step of the receipt, storage, distribution, and final disposition of each unit of agent using the PMB computerized inventory system.

**Purpose and Objectives**

The Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI), is soliciting contractors to perform storage and distribution of clinical agents. The contractor shall receive, store, and distribute commercial and investigational agents consisting of chemotherapeutic agents, biologic products (e.g., cytokines, monoclonal antibodies, oncolytic viruses, gene therapy, and vaccines), small-molecule targeted agents and other therapeutic anticancer agents. The Contractor shall receive and inspect agents from manufacturers and suppliers throughout the world. Agents shall be relabeled or supplemental labels applied as necessary to meet U.S. Food and Drug Administration (FDA) and NCI guidelines for completeness and clarity of labeling. The contractor shall store agents in a secure, monitored, fire protected warehouse under specified controlled temperature conditions (room temperature, refrigerated, and frozen at both -20°C and -70°C). An average of 600,000 units (vials, ampules, bottles of tablets, etc.) is maintained in storage at any one time, but can vary greatly depending on the activities of the Program. This contract requires handling, storage, shipping, and disposal of hazardous and biological materials.

**Project requirements**

The following mandatory qualification criteria will apply:

A. The contractor must possess and maintain an Environmental Protection Agency (EPA) Generator of Hazardous Waste permit and any state and local permits (if necessary) for its facility, for generation and transportation of Hazardous Waste and Medical Pathological Waste for disposal, and storing toxic/hazardous substances.

Contractor must have at least one individual with an up-to-date U.S. DOT Hazmat training on the premises at all times during all hours the repository is open. The contractor must possess and maintain any state and local permits or licenses (if necessary) for its facility for storing and distributing investigational drugs for the life of the contract.

B. All pharmacists performing work under the contract shall have a current active license, in the state (or District of Columbia) in which the repository is located.

C. Contractor shall have at least one individual with an up-to-date IATA Dangerous Goods Certification of Training on the premises at all times during all hours the repository is open and on call after hours for emergency shipments.

**Anticipated Period of Performance**

The anticipated period of performance for this requirement is one year, with four one-year options.

**Capability statement/information sought**

Interested qualified business organizations should submit a tailored capability statement for this requirement, not to exceed 20 single-sided pages (including all attachments, resumes, charts, etc.) presented in a single-space format using 12-point font size minimum. To be deemed capable of providing the current need for the project, the offeror must submit a written capability statement. Organizations that submit capability statements in response to this notice will be evaluated against the following technical areas of experience and expertise:

A. **Personnel**

- Suitability and adequacy of the education, training, and relevant experience of personnel.
    a. Principal Investigator
    b. Supervisory Personnel
    c. Pharmacist Personnel
    d. Technical Personnel
    e. All Other Personnel
- Availability of personnel to the contract.
- Description of qualifications sought for individuals not currently employed by offeror.

B. **Facilities and Equipment**

- Availability and adequacy of proposed facilities, space, equipment, security, and monitoring to perform all of the necessary functions of this contract as described in the Statement of Work, Technical Proposal Instructions and in compliance with Current Good Manufacturing Practice Guidelines.
- Adequacy of the offeror's proposed plans for accommodating changing needs of storage space, at individual storage conditions, due to the dynamic storage space needs on this contract.

C. **Understanding of the Project and Proposed Technical Approach**

- Adequacy of the offeror's procedures for safely receiving, storing, inventorying, packaging, and shipping investigational agents to investigators throughout the world.
- Adequacy of the understanding of Current Good Manufacturing Practice Guidelines and approach for inventory control, packaging and labeling of clinical investigational agents for clinical trials.
- Adequacy of the offeror's approach for inventory control, packaging and labeling of blinded medications for clinical trials.
- Adequacy of the offeror's approach to packaging and shipping of clinical investigational agents to ensure the safe, intact, and timely arrival of the contents of each package shipped.
- Awareness and understanding of problems involved shipping, receiving, storage, distribution, final disposition, and record keeping for perishable pharmaceuticals, biologics, and hazardous substances.
- Adequacy of the project management plan to ensure that all required activities described in the statement of work will be performed, including plans for backup coverage for the proposed project team, staff training programs and professional development programs.
- Adequacy of the proposed security arrangements and monitoring procedures to protect inventory and equipment.
- Adequacy of the approach and understanding of safe storage, handling, and disposal of Hazardous Waste and Medical Pathological Waste and the organization's general safety program.
- Adequacy of the plan for the timely and complete transition from current facility that ensures uninterrupted service with no loss of inventory.

D. **Organizational Support and Experience**

- Demonstrated experience in the storage and distribution of pharmaceuticals,

biologicals, perishable agents, and toxic materials.

- Demonstrated program for quality assurance in labeling and distributing both open-label and blinded study medications, as well as in assuring proper storage conditions for inventory.
- Demonstrated organizational experience in providing security to safeguard valuable and/or sensitive items.
- Demonstrated knowledge of current methods of maintenance and quality assurance of all equipment to be used on the contract.
- Organizational awareness of and conformance with relevant and applicable regulations and guidelines and licensing requirements.
- Organizational awareness and knowledge of necessary licenses and permits and the procedures that must be followed in order to obtain them.
- Demonstrated lines of authority relevant to this project and plans for organizational support of the Principal Investigator.
- Demonstrated safety program for handling toxic materials, including appropriate employee training.

**Information Submission Instructions**

All capability Statements sent in response to this SOURCES SOUGHT notice must be submitted electronically (via email) to Charlotte McCormack, Contract Specialist, at mccormackc@mail.nih.gov in MS Word or Adobe Portable Document Format (PDF) by December 16, 2011. No collect calls or facsimile transmissions will be accepted. All responses must be received by the specified due date and time in order to 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 organization's 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 synopsis and solicitation 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).

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