

Statement of Work

Cryogen liquids for NMR Installation for the Food and Drug Administration, (FDA) 125358

Background

Nuclear magnetic resonance (NMR) is one of the most advanced structural characterization techniques used to deduce chemical structures of new drug molecules and any new drug impurities (degradation or process related). NMR technique can therefore be used to conduct regulatory testing and research to address product quality issues. The research conducted by NMR instrument therefore supports CDER Research Governance Council (RGC) goal #4 and Objective b (Advance analytical characterization and predictive in vitro methods to support bioequivalence and pharmaceutical equivalence for generic drug products with complex active ingredients, formulations, or dosage forms) and Objective c (Improve bioequivalence evaluation methods for generic drug products with complex routes of delivery such as locally-acting products) and Objective e (Improve quantitative tools and methodologies for evaluating bioequivalence and substitutability of generic drugs). The Division of Product Quality Research (DPQR) recently purchased a 400 MHz NMR instrument and is delivered and waiting for installation. The installation of this instrument requires cryogen liquids (liquid helium and liquid nitrogen) since the magnet used in the NMR is cryogen magnet and is required to be cooled at very low temperatures of liquid helium and liquid nitrogen.

Objective

The Division of Product Quality Research (DPQR) is requesting a cryogen package (including liquids nitrogen and liquid helium). The cryogenic liquids purchased will be used to install a 400 MHz nuclear magnetic resonance (NMR) instrument. The NMR instrument is used to support several regulatory research testing projects to support the FDA regulatory mission.

Scope The contractor shall be able to provide 400 liters of liquid nitrogen and 400 liters of liquid helium for use in our 400 MHz NMR instrument.

The cryogenic liquids should be delivered in highly insulated Dewar's/tanks to minimize loss of cryogenic liquid during transport and storage. The required features of the cryogen package are:

Item 1: Liquid nitrogen

- 400 liters of liquid nitrogen

Item 2: Liquid helium

- 500 liters of liquid helium

Deliverable: The contractor shall provide the following Deliverables.... list them all

- Liquid Nitrogen for NMR: 400 liters in insulated Dewar/tank
- Liquid Helium for NMR: 500 liters in insulated Dewar/tank

Item 3: Delivery

The vendor will cover all costs associated with the following:

- Shipping and delivery.

Items should be shipped within 2 weeks from time of award due to urgent need.

The government will have 30 days from receipt of shipment to confirm quality of items.

Delivered

FDA Campus Point of Entry Address:

Food And Drug Administration
White Oak Campus
Attn: [ADIL MOHAMMAD]
WO Building 62; Loading Dock
Silver Spring, MD 20993

Equipment Installation/Service Performance Location:

Food And Drug Administration
White Oak Campus
Attn: [ADIL MOHAMMAD]
WO Building 64; Room [1013]
Silver Spring, MD 20993

POC: Adil Mohammad, adil.mohammad@fda.hhs.gov, 301-796-4728

Period of Performance: 12 months from date of award.

Inspection and Acceptance

The COR and/or COR designee will perform inspection and acceptance of equipment.

A final inspection and acceptance of all deliverables will be performed by the COR and/or COR designee to ensure the products provided meet the requirements of the Statement of Work (SOW).

Inspection and acceptance will occur at the place of performance and take place within five (5) business days of task being completed. The Government will provide written notification of acceptance or rejection within five (5) business days. Inspection will include review of the deliverables to ensure adequacy.

The Government will accept goods, reports, and services only if they conform to all terms and conditions of the SOW, and satisfy the performance standards developed under this SOW.

The Government will reject non-conforming products and services. The Contractor shall correct any deficiencies within fifteen (15) business days of when the Government issues the rejection notice. If the Contractor cannot correct the deficiencies within this period, the Contractor shall immediately notify the COR of the reason for the delay and provide a proposed corrective action plan within five business days.

Contracting Officer Authority

The Contracting Officer (CO) is the sole person authorized to make or approve any changes in any of the requirements of this order and notwithstanding any provisions contained elsewhere in the order, the said authority remains solely with the CO. In the event the Contractor makes any changes at the direction of any person other than the CO, the change shall be considered to have been made without authority and no adjustment will be made in the delivery order terms and conditions, including price. The CO shall be the only individual authorized to accept nonconforming work, waive any requirement of the order and modify any term or condition of the order. The CO is the only individual who can legally obligate Government funds.

The Contracting Officer's Representative (COR) or Project Officer is not authorized to make any commitments or otherwise obligate the Government or authorize any changes which affect the order price, terms or conditions. The COR/Project Officer is responsible for the technical aspects of the project and serves as technical liaison with the contractor and is responsible for the final inspection and acceptance, and such other responsibilities as may be specified in the order.

Contract Type

Firm-Fixed-Price (FFP). All deliverables shall be clearly identified, complete with clear descriptions; due dates, and at a predetermined, agreed-upon price.

Government Contacts

Contracting Officer: (CO):

Office of Acquisitions Grants and Services

Mary Rose A. Nicol, CO

Phone: 240-402-7606

Email: Maryrose.nicol@fda.hhs.gov

Contracting Office Representative (COR): TBD

Government Holidays

Unless otherwise specified, the Contractor shall perform work Monday through Friday (excluding Federal Holidays) between the hours of 8:00 a.m. and 4:30 p.m. EST. Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day. Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

- New Year's Day
- Martin Luther King Day
- President's Day
- Memorial Day
- Juneteenth National Independence Day
- Independence Day
- Labor Day
- Columbus Day
- Veteran 's Day
- Thanksgiving Day
- Christmas Day

Pricing

Total Price \$ _____

Basis of Award

The Government will award a contract resulting from this solicitation to the responsible quoter as a fixed-price contract on the lowest price technically acceptable (LPTA) evaluation method. Award will be made on the basis of the lowest evaluated price meeting or exceeding the non-cost factor (technical conformance to the requirements of the solicitation). The Quoter's initial quotation shall contain the Quoter's best terms from a price standpoint. Failure to demonstrate meeting any of the requirements will result in a rating of technically unacceptable and will not be considered for award.

In order to facilitate the award process, ALL quotes shall include a statement regarding the terms and conditions herein. Additionally, all quotes shall include price (s); FOB point; a poc (name and telephone number); a statement from the offeror verifying that they are Registered in SAM.gov under NAICS code; 334516_delivery date (delivery date is of the utmost importance); business size; and payment terms. Delivery shall be to FDA.

FDA intends to make an award soon after the response date of this notice and all quotes

must be submitted via email to Maryrose.nicol@fdahhs.gov and be received by 5:00 PM (1700) on August 4 , 2022 to the attention of Mary Rose A. Nicol, maryrose.nicol@fda.hhs.gov. Offerors shall ensure the RFQ number is visible in the header of the email.

ALL QUESTIONS REGARDING THIS SYNOPSIS/SOLICIATION MUST BE SUBMITTED IN WRITING NO LATER THAN 5:00 PM (1700) EST August 1, 2022. FAX QUOTES SHALL NOT BE ACCEPTED.