

## NOTICE TO THE PUBLIC

(1) Closed Filtration Pump for Sterility Testing the Pacific Southwest Medical Products Laboratory (PSMPL) for the Food and Drug Administration, (FDA-1256059)

This is a combined synopsis/solicitation for commercial items prepared in accordance with the format in FAR 12.6. This announcement constitutes the only solicitation, and a written solicitation will not be issued.

This requirement is “Subject to the Availability of Funds” The Following FAR Clause applies: AVAILABILITY OF FUNDS (52.232-18) (APR 1984)

This synopsis, NAICS code 334516, identified as REQ#1257125 is to notify contractors that the government intends to issue a Purchase Order in accordance with FAR Part 13.106 for the following specifications, under the simplified acquisition procedures.

### **Background**

The Food and Drug Administration (FDA), Pacific Southwest Medical Products Laboratory (PSMPL) performs microbiological testing on various pharmaceutical dosage forms some of which require testing to determine if the product is sterile. To perform sterility testing using membrane filtration the microbiology section at PSMPL requires a closed filtration pump to be used within a laminar air flow hood in order to perform sterility testing.

### **Purpose/Objective**

The closed filtration pump will be used to perform sterility testing in a laminar flow hood. PSMPL uses a membrane filtration method to determine if pharmaceutical regulatory products are sterile as required by FDA regulations for certain dosage forms.

### **Scope**

PSMPL requires one (1) Closed Filtration Pump for Sterility Testing that meets or exceeds the requirements below:

### **Requirements**

The Contractor shall provide a Millipore Sigma Steritest Symbio LFH Pump or equivalent. The instrument shall meet or exceed the following requirements:

- The instrument shall consist of a peristaltic pump compatible with Steritest canister devices.
- The pump shall be of a compact design suitable for use in a laminar flow hood.
- The pump head must be capable of automatic opening and closing.

- The pump housing is to be constructed of 316L stainless steel.
- The peristaltic pump must have an adjustable speed with a maximum speed of at least 200 rpm.
- Pump shall be equipped with a keypad for selecting instrument settings.
- Pump shall be equipped with a timer function.
- Pump shall be equipped with a pressure control system.
- Pump shall be equipped with a color LCD user interface screen.
- Pump shall have the ability to store at least 200 filtration protocols.
- The pump body must not exceed the following measurements: 14 inches in width, 15 inches in depth and 11 inches in height.

### **Trade and Service Specifications**

1. The instrument must be a newly manufactured unit, not used and refurbished or previously used for demonstration.
2. FOB Point destination to include inside delivery.
3. The entire system must be warranted for parts and labor for 12 months from the date of formal government acceptance. The vendor must also be capable of servicing the instrument through the covered warranty period. The system must include at least a one (1) year warranty and shall include at a minimum: coverage on all non-consumable items and parts supplied including base instrument, factory-certified replacement parts, engineer labor and travel costs. Any equipment repair and maintenance work shall be performed by an OEM-trained engineer. This factory-trained engineer shall have (verified by the OEM) the following: 1) access to OEM factory telephone support; 2) access to the most current OEM factory training for both hardware and software components; and 3) access to all current OEM factory parts, not build-to-order parts. The OEM-trained service engineer shall not use salvaged parts from other instruments for performing maintenance and repairs. All parts used in PM and repairs must be guaranteed, factory-tested, OEM quality parts.

### **Records and Reports**

The Contractor shall, commensurate with the completion of each service call (inclusive of warranty service), provide the end-user of the equipment with a copy of a field service report/ticket identifying the equipment name, manufacturer, model number, and serial number of the equipment being serviced/repared and detailing the reason for the service call, a detailed description of the work performed, the test instruments or other equipment used to affect the repair or otherwise perform the service, the name(s) and contact information of the technician who performed the repair/service, and for information purposes, the on-site hours expended and parts/components replaced.

**Deliverables**

One Closed Filtration Pump for Sterility Testing for PSMPL, Irvine, CA. meeting or exceeding the requirements stated above will be delivered, inside delivery required, to the address found in the Delivery Location of this document.

	Description of Deliverable	Qty	Due Date
1	Closed Filtration Device for Sterility Testing	1	Delivery within 90 days after award.
2	Manufacturer’s warranty of equipment, parts and operational services.	1	Begins with the delivery of the equipment through one year.

**Delivery Location**

POC: To be determined at time of award  
FDA/PSMPL  
19701 Fairchild  
Irvine, CA 92612

Delivery will be accepted during regular business hours (Monday-Friday) during the times of 8:00 AM – 4:00 PM local Time.

**Period of Performance**

The period of performance shall be 12- month from the date of award which includes a 12- month warranty period.

**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. **NOTE: If significant damage is observed, such as a hole going through the container and packing to reach the enclosure itself, it will be rejected.**

### **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](mailto: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.

January (New Year's Day)

January (Martin Luther King Day)

February (President's Day)

May (Memorial Day)

June (Juneteenth)

July (Independence Day)

September (Labor Day)

October (Columbus Day)

November (Veterans Day)

November (Thanksgiving Day)

December (Christmas Day)

## **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](mailto:Maryrose.nicol@fdahhs.gov) and be received by 5:00 PM (1700) on , July 12, 2022 to the attention of Mary Rose A. Nicol, [maryrose.nicol@fda.hhs.gov](mailto:maryrose.nicol@fda.hhs.gov). Offerors shall ensure the RFQ number is visible in the header of the email.

**ALL QUESTIONS REGARDING THIS SYNOPSIS/SOLICITATION MUST BE SUBMITTED IN WRITING NO LATER THAN 5:00 PM (1700) EST July 8, 2022. FAX QUOTES SHALL NOT BE ACCEPTED.**

