STATEMENT OF WORK

Purchase of one (1) Automated High-Throughput Tissue Homogenizer

Background
The regulatory laboratories of the Food and Drug Administration (FDA), conduct a range of chemical analyses on pharmaceutical products to determine if they meet regulatory requirements. A homogenizer laboratory grinder is necessary to complete United States Pharmacopeia analyses on pharmaceutical regulatory samples.

Purpose/Objective
Purchase of one (1) Automated High-Throughput Tissue Homogenizer to be used to grind and homogenize regulatory samples to include dried plant material, seeds and dried organic materials for the production of sample extractions to be used in analytical testing at the Pacific Southwest Medical Products Laboratory (PSMPL), Irvine, CA.

Scope
PSMPL requires one (1) SPEX SamplePrep 2010 Geno/Grinder or equivalent that meets or exceeds the requirements below.

Minimum Requirements
The contractor shall provide a SPEX SamplePrep 2010 Geno/Grinder or equivalent. The homogenizer unit shall meet or exceed the following requirements:

- LCD screen display for full timer settings (minutes and seconds).
- Functionality which allows an operator to set the run time and the vertical grinding speed.
- Grinding speed shall be precisely controlled between 500 and 1750 strokes per minute.
- System will include safety interlocks and pneumatic cylinder stabilizer lid for safe operation.
- The system will be equipped with clamping mechanism latch with secondary locking tabs to secure the sample during homogenization.
- The unit shall be capable of an up and down grinding/pulverizing action.
- The system must have the ability to process sample tubes with a size range of 0.6ml up to 50ml and be able to process at least two deep-well titer plates.
- Unit dimensions need to be sized appropriately for compact bench top usage. (No more than 27”H x 22”D x 17”W)
- Standard US 115V, 60hz electrical requirement.

- The unit motor horsepower shall be 0.33 or greater.

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.

4. All standard information on the equipment, including but not limited to User Manuals, Operation and Maintenance (O&M) Manuals, Safety Data Sheets (SDS), troubleshooting guides, and any other applicable documentation, shall be provided upon with the delivery of the system.

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/repaired 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 or Delivery Schedule

One (1) automated high-throughput tissue homogenizer for PSMPL, Irvine, CA. meeting or exceeding the requirements stated above will be delivered, inside delivery required, in accordance with the following:

	Description of Deliverable	Qty	Due Date
1	Homogenizer/Grinding mill	1	Delivery within 90 days after award.
2	Manufacturer's warranty of equipment, parts and operational services.	1	Begins at the delivery and government acceptance through one year.

Inspection and Acceptance

Upon arrival, the shipping container(s) will be inspected for damage. If significant damage is observed, such as a hole going through the container and packing to reach the enclosure itself, it will be rejected. All equipment shall be new, not used or refurbished.

Delivery Location and Place of Performance

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

Period of Performance

The period of performance begins the date of contract award. All requirements shall be completed no later than 90 days after contract award.

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

Quotation Instructions

All quotes are due by e-mail to Nina Montgomery, Nina.Montgomery@fda.hhs.gov on or before July 8, 2022 at 10:00 am (Eastern Standard Time).