

1. Title: United States Pharmacopeia (USP) 797 Viable Sampling Services

2. Purpose: The Michael E. Debakey Veteran Affairs Medical Center (MEDVAMC) hereby issues the following Sources Sought Notice as a Request for Information (RFI). This RFI is being used for **Market Research purposes only** to seek contractors with the capability to provide the Central Arkansas Veterans Healthcare System (CAVHS) with all labor, personnel, equipment, supplies, transportation, materials, supervision and other related services necessary to provide USP 797 Viable Sampling Services.

3. Place of Performance:

A. John L. McClellan Memorial Veterans Hospital
4300 West 7th Street
Little Rock, AR 72205

B. Eugene J. Towbin Healthcare Center
2200 Fort Roots Drive
North Little Rock, AR 72114

NOTE: All Questions shall be answered in Section 4 in order for the government to consider whether the contractor has the capability to meet the government requirement.

4. Responses Requested: The MEDVAMC requires the following questions answered in this RFI: Questions that are not provided shall be considered non-responsive to the Request for Information.

a. Does the Contractor possess Controlled Environment Testing Association (CETA) and/or National Sanitation Foundation (NSF) certified technicians who are accredited, or have at least three (3) years of field experience under an accredited technician

Contractor shall attach documentation of this accreditation/certification to be viewed by the government to be considered as part of the Market Research and responsiveness to this Sources Sought notice.

b. Are personnel CETA certified in accordance with the most current version of CETA Application Guide CAG-009-2011?

Contractor shall attach documentation of this accreditation/certification to be viewed by the government to be considered as part of the Market Research and responsiveness to this Sources Sought notice.

c. Prospective contractors shall provide their point(s) of contact name, address, telephone number, and email address. In addition, contractors shall provide the company's business size, and Data Universal Numbering System (DUNS) Number.

d. Is your company a small business, SDBs, HUBZone, or 8A concern? NAICS Code: 561990, PSC Code: R614, Support Administrative: Paper Shredding.

Please provide proof of qualifications.

e. Provide in your capability statement a list of active contracts for commercial, federal, state, and local governments. List Contracts shall provide communication on the government requirement illustrating the capability for comparison.

f. Is your company available under any Government Wide Agency Contract (GWAC), General Services Administration Schedules (GSA), Indefinite Delivery Indefinite Quantity (IDIQ), and/or Blanket Purchase Agreement (BPA)? **If so, please list the contract number and a brief summary of the products and services provided.**

g. Provide a brief summary of your potential approach to this type of contract and meeting the specific requirements per the draft Performance Work Statement; along with your experience managing similar contracts with similar requirements.

h. Will you be performing services as a prime contractor or subcontracting services out?

i. What is your company's recent experience, be it US Federal contracted service or a service performed external to US Federal government?

5. **Opportunity:** The MEDVAMC is seeking information from potential contractors on their ability to provide this service. **THIS IS A REQUEST FOR INFORMATION (RFI) ONLY.** Small Business Concerns are encouraged to provide responses to this RFI to assist the MEDVAMC in determining potential levels of competition available in the industry.

Contractor shall possess the capability to provide all requirements and objectives.

6. **Instructions and Response Guidelines:** RFI responses are due by July 11, 2018 at 11:00 am (CST); size is limited to 8.5 x 11 inches, 12-point font, with 1-inch margins in Microsoft Word format via email to john.walker15@va.gov **All Questions shall be submitted by July 5, 2018 2:00pm(CST) via email to john.walker15@va.gov** Telephone requests or inquiries will not be accepted.

The subject line shall read: 36C25618Q9697 USP 797 Viable Sampling Services

NO SOLICITATION EXISTS AT THIS TIME. There is no page limitation on subparagraphs 4(a) - 4(i). All **Questions shall be answered** to be considered as part of the Market Research for capable contractors to meet the government requirements.

Please provide additional information you deem relevant in order to respond to the specific inquiries of the RFI. Information provided will be used solely by MEDVAMC as "market research" and will not be released outside of the MEDVAMC Purchasing and Contract Team.

DISCLAIMER: This RFI does not constitute a Request for Proposal (RFP), Invitation for Bid (IFB), or Request for Quotation (RFQ), and it is not to be construed as a commitment by the Government to enter into a contract, nor will the Government pay for the information submitted in response to this request. All information contained in this RFI is preliminary as well as subject to modification and is in no way binding on the Government. In accordance with FAR 15.201(e), responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract. If a solicitation is released, it is will be synopsisized in the Federal Business Opportunities (FedBizOpps) website or GSA. It is the responsibility of the interested parties to monitor these sites for additional information pertaining to this RFI, or future RFP.

7. Contact Information:

Contract Specialist, John Walker

Email address: john.walker15@va.gov

Your responses to this notice is appreciated.

DRAFT PERFORMANCE WORK STATEMENT

USP 797 Viable Sampling Services

A. GENERAL:

1. The contractor shall provide all labor, personnel, equipment, supplies, transportation, materials, supervision and other related services necessary to perform periodic viable particle sampling services and both primary and secondary engineering controls according to the most current version of CAG-009-2011 to ensure compliance with USP 797. The contractor shall provide field certifiers who are CETA and/or National Sanitation Foundation (NSF) certified technicians overseen by an accredited technician, or have at least 3 years of field experience under an accredited technician. Documentation of this accreditation and training must be provided to the facility. Vendor must use an appropriate, independent, accredited laboratory for analysis of all viable samples collected.

B. REQUIREMENT:

1. Viable Air Particle Sampling:

Viable Air Particle Sampling shall be done to detect the presence of bacterial and fungal colonies within the cleanroom areas quarterly

Air sampling of viable particles shall include (7) ISO 5 classified areas within the direct compounding area of the PEC listed below:

QTY	EQUIPMENT
2	Horizontal Laminar Flow Hoods (Baker/Model: EG-4252)
3	Vertical Laminar Flow Hoods (Germfree/Model: BVBI-3SSRX)
2	Biological Safety Cabinets (Germfree Class II, Type A1/Model: BBF-3)

Air sampling of viable particles shall include (4) ISO 7 and (4) ISO 8 classified areas within the SEC as listed below:

QTY	CLASSIFICATION
4	ISO Class 8
4	ISO Class 7

Air sampling of viable particles shall include (2) unclassified areas.

QTY	LOCATION
2	Pass Through Box

The pharmacy cleanrooms are in 3 different locations within the facility. Those locations include John L McClellan Memorial Hospital (JLM) Room GC-189, JLM Mobile Pharmacy Cleanroom Trailer, and Eugene Towbin Healthcare Center Building 170 Room 2F-111.

2. **Viable Surface Particle Sampling:**

Viable Surface Particle Sampling shall be done to detect the presence of bacterial and fungal colonies within the cleanroom areas quarterly

Surface sampling of viable particles shall include (7) ISO 5 classified areas within the direct compounding area of the PEC listed below:

QTY	EQUIPMENT
2	Horizontal Laminar Flow Hoods (Baker/Model: EG-4252)
3	Vertical Laminar Flow Hoods (Germfree/Model: BVBI-3SSRX)
2	Biological Safety Cabinets (Germfree Class II, Type A1/Model: BBF-3)

Surface sampling of viable particles shall include (4) ISO 7 and (4) ISO 8 classified areas within the SEC as listed below:

QTY	CLASSIFICATION
4	ISO Class 8
4	ISO Class 7

Surface sampling of viable particles shall include (2) unclassified areas.

QTY	LOCATION
2	Pass Through Box

The pharmacy cleanrooms are in 3 different locations within the facility. Those locations include John L McClellan Memorial Hospital (JLM) Room GC-189, JLM Mobile Pharmacy Cleanroom Trailer, and Eugene Towbin Healthcare Center Building 170 Room 2F-111.

3. **Gloved Fingertip Sampling:**

The contractor shall provide Gloved Fingertip (GFT) sampling for all inpatient staff members quarterly. Due to the large number and various schedules within pharmacy service (approximately 72 employees), the vendor will be expected to provide a complete viable GFT sampling on at least 24 employees monthly. This will total 288 samples annually. The sampling procedure will have no less than three (3) viable GFT samplings per employee per USP 797 guidelines for initial testing and one (1) viable GFT sampling for each subsequent testing. The contractor shall provide results from an accredited environmental testing laboratory of the viable GFT sampling in a written report. This report will serve as documented test results within 2-3 weeks of completion of each sample. If any samples have microbial growth the samples are to be cultured and identified for bacterial/fungal species contaminate and findings reported back to the facility. Certificate of analysis for growth and sterility controls must be provided to the facility as well.

4. Media-Fill Test:

The contractor shall complete a Media-Fill Test (MFT) on at least 24 employees monthly. This will also total 288 samples annually. All pharmacists are required to take a medium risk MFT (approximately 42 employees) and all technicians are required to take the low-risk MFT (approximately 30 employees). The contractor shall provide results from an accredited environmental testing laboratory of the viable MFT in a written report. This report will serve as documented test results within 2-3 weeks of completion of each sample. If any samples have microbial growth the samples are to be cultured and identified for bacterial/fungal species contaminate and findings reported back to the facility. Certificate of analysis for growth and sterility controls must be provided to the facility as well.

The contractor shall provide all necessary items to perform sampling as noted. The contract is between CAVHS, as a healthcare provider, and the contractor. For the purpose of reimbursement, the contractor has a set price for providing GFT and MFT testing.

C. OPERATIONAL COVERAGE:

1. Normal Work Hours: 8:00 a.m. to 4:30pm, Monday-Friday (excluding weekends and federal holidays). Exception: work may be performed outside of regular administrative working hours when deemed necessary. The contractor shall receive prior approval from the Contracting Officer Representative (COR) for irregular testing hours.
2. National Holidays: The ten (10) holidays observed by the Federal Government are: New Year's Day, Martin Luther King's Birthday, President's Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veteran's Day, Thanksgiving Day and Christmas Day, in addition to any other day specifically declared by the President of the United States to be a national holiday.

D. DELIVERABLES:

The contractor shall provide the CAVHS Pharmacy Management a written report within 2-3 weeks of completion of testing.

E. PLACE OF PERFORMANCE:

1. John L. McClellan Memorial Veterans Hospital
4300 West 7th Street
Little Rock, AR 72205
2. Eugene J. Towbin Healthcare Center
2200 Fort Roots Drive
North Little Rock, AR 72114