

## **STATEMENT OF WORK**

Contractor will provide a mobile compounding pharmacy (Odulair Model: HD2-NHD1 - USP 800 Mobile Trailer Facility.) (minimum features seen below) in a trailer at 53' in length including transportation to the location and commissioning, setup and training included. The trailer will provide two areas with dual pharmacy compounding hoods and layout that meet or exceed United States Pharmacopeia USP-800 and USP-797 for handling hazardous drugs in healthcare settings and sterile preparations for pharmaceutical compounding. Current compounding areas are required to be modified to meet the new standards and this trailer will provide the necessary services and equipment to meet the new standard while construction brings the existing pharmacy into compliance. Services shall be provided for the Department of Veterans Affairs Northern California Health Care System, Sacramento VA Medical Center, 10535 Hospital Way, Mather, CA 95655. All services shall be provided in accordance with the specifications, terms and conditions contained herein.

### **DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

#### **1. SERVICES:**

Contractor will provide a mobile compounding pharmacy (Odulair Model: HD2-NHD1 - USP 800 Mobile Trailer Facility.) (minimum features seen below) in a trailer at 53' in length including transportation to the location and commissioning, setup and training included.

Company is to design and build a 53' semi-trailer with one large ante room, one hazardous buffer room and one non-hazardous buffer room that meets USP 800 and USP 797 code compliance.

Drawings will be provided with the below characteristics. The Drawings/Semi-trailer will have the following features listed below:

#### **USP 800 Hazardous Drug & USP 797 Non-Hazardous Drug Pharmaceutical Compounding Pharmacy Trailer**

##### **ROOMS & AREAS**

- Ante Room ISO 7
- Sterile Hazardous Drug Buffer Room ISO 7
- Sterile Non-Hazardous Drug Buffer Room ISO 7
- Sterile Hazardous Drug Storage Area
- Self-Supporting Modular Design inclusive of walls, roof / ceiling, flooring, lighting, electrical & filtering equipment
- Modular clean room must fit within our trailer or within your designated space
- Modular Clean Room seismic integrity provisions where necessary
- Finishes - Non-porous and cleanable surfaces, ceilings, walls, and floors subject to wet cleaning

##### **ANTE ROOM**

- 2 Scrub sinks with eye wash station positioned at least 3' from the Sterile HD Buffer Room door
- Clean Personal Protective Equipment (PPE) Storage Bin

- Soiled PPE Waste Bin
- Staff Changing Bench
- Environmental Services Closet

#### **STERILE HAZARDOUS DRUG BUFFER ROOM Equipment**

- 2 ISO 5 Class II Type B2 Biological Safety Cabinets (BSC) with 100% Outside Air Supply and Exhaust - 3ft each
- Interlocking HEPA filtered Pass-Thru Chamber from Ante Room
- Stainless Steel Workstation
- RFID Refrigerator for inventory control
- Soiled PPE Waste Bin
- Storage Cabinet for sterile hazardous drugs

#### **STERILE NON-HAZARDOUS DRUG BUFFER ROOM Equipment**

- ISO 5 Horizontal Laminar Airflow Workbench (LAFW) - 4ft
- Interlocking HEPA Filtered Pass-Thru Chamber from Ante Room
- Stainless Steel Workstation
- USP 797 Compliant Refrigerator
- Soiled PPE Waste Bin
- Non-Hazardous Drug Storage Cabinet

#### **MECHANICAL ROOM**

- Back-up Generator With Automatic Transfer Switch
- Water Storage Tanks (Fresh & Gray)
- Data Connection Package - Interior Video Intercom System

#### **UTILITY REQUIREMENTS**

- Electrical: 208V 3-Phase 200 Amps
- Water: 1" Potable Water Line
- Sewer: 4" Standard Sewer Line

#### **WHEELCHAIR RAMP**

- ADA Compliant
- Aluminum ramp with guardrails, landing, and stairs
- Width: 4'
- Installation on site

#### **ENVIRONMENTAL CONTROLS**

- All Facility & Engineering Controls Compliant with new USP 800 and USP 797
- Physically separated Ante Room and Sterile Hazardous Drug Buffer Room and Sterile Non Hazardous Drug Buffer Room
- C-PEC Containment Primary Environmental Control: (BSC or LAFW) LControls)
  - ISO 5 Biological Safety Cabinet (BSC) located in the Sterile HD Buffer Room

- ISO 5 LAFW located in Sterile Nonhazardous Buffer Room
- C-SEC Containment Secondary Environmental Controls (Room Controls)
  - ISO 7 Ante Room Environmental Controls:
    - Positive pressure
    - Minimum of 30 Air Exchanges Per Hour (ACPH) compliant with USP 800
    - High Efficiency Particulate Air (HEPA) filtered supply air
    - 24/7 Real-time Environmental Room Monitor providing:
      - ❖ Temperature
      - ❖ Humidity
      - ❖ Differential pressure
      - ❖ Airborne particle count
  - ISO 7 Sterile HD Buffer Room Environmental Controls:
    - Negative pressure between 0.01" to 0.03" WC
    - Minimum of 30 Air Exchanges Per Hour (ACPH) compliant with USP 800
    - 100% Outside Supply Air (into room)
    - High Efficiency Particulate Air (HEPA) filtered supply air
      - Externally Vented 100% of Air Exhausted Directly Outside
      - Zero recirculation of HD Buffer Room air
      - 24/7 Real-time Environmental Room Monitor providing:
        - ❖ Temperature
        - ❖ Humidity
        - ❖ Differential pressure
        - ❖ Airborne particle count
      - 24/7 Real-time Monitoring of RFID Refrigerator interior temperature to ensure drug safety
    - ISO 7 Sterile Non-HD Buffer Room Environmental Controls:
      - Positive pressure
      - Minimum of 30 Air Exchanges Per Hour (ACPH) compliant with USP 800
      - High Efficiency Particulate Air (HEPA) filtered supply air
      - 24/7 Real-time Environmental Room Monitor providing:
        - ❖ Temperature
        - ❖ Humidity
        - ❖ Differential pressure
        - ❖ Airborne particle count
        - ❖ 24/7 Real-time Monitoring of RFID Refrigerator interior temperature to ensure drug safety

## **COMMISSIONING & CERTIFICATION**

- Delivery
- Set-up
- On-site Test & Balance Certification
- Certification Supervision
- On-site Training

## **2. DEFINITIONS/ACRONYMS:**

A. Biomedical Engineering - Supervisor or designee, Phone Number (916-366-5481).

B. CO - Contracting Officer.

C. COR - Contracting Officer's Technical Representative.

D. PM - Preventive Maintenance Inspection. Services which are periodic in nature and are required to maintain the equipment in such condition that it may be operated in accordance with its intended design and functional capacity with minimal incidence of malfunction or operative conditions. Service shall consist of calibration and testing in accordance with the manufacturer's latest established service procedures to ensure operation of equipment within manufacturer's or VA's performance specifications, whichever is the most rigorous. PM includes cleaning, inspecting lubricating and testing all equipment. All equipment shall be operated at least one complete operating cycle at the end of each PM.

E. FSE - Field Service Engineer. A person who is authorized by the contractor to perform maintenance (corrective and/or preventive) services on the VA Outpatient Clinic premises.

F. ESR - Vendor Engineering Service Report. A documentation of the services rendered for each incidence of work performance under the terms and conditions of the contract.

G. Acceptance Signature - VAOPC employee who indicates FSE demonstrated service conclusion/status and user has accepted work as complete/pending as stated in ESR.

H. Authorization Signature - COR's signature; indicates COR accepts work status as stated in ESR.

I. NFPA - National Fire Protection Association.

J. CDRH - Center for Devices and Radiological Health.

K. VAOPC - Department of Veterans Affairs Outpatient Clinic.

L. OEM - Original Equipment Manufacturer

### **3. CONFORMANCE STANDARDS:**

Contractor shall provide services and material to ensure that the equipment functions in conformance with the latest requirements of NFPA-99, JCAHO, NEC, OSHA, CAP, Federal and VA specifications and requirements as applicable. The equipment shall be maintained such that it meets or exceeds the performance specifications as established in the OEM's technical specifications. Additional performance specifications that exceed the OEM specifications shall be specified in writing by the VA.

### **4. PREVENTIVE MAINTENANCE (PM):**

A. Contractor shall ensure that the system has current PMs performed by the OEM and is meeting the manufacturer's specifications during the warranty period

- B. The contractor shall furnish documentation, including all measurement and calibration data to certify that the system is performing in accordance with the performance specifications.

## **5. EMERGENCY MAINTENANCE:**

The contractor will maintain that a 95% uptime of the system is met and that there are provisions for emergency service during normal business hours. All maintenance will be performed by a contract agreement with the OEM during warranty periods.

## **6. PARTS:**

The contractor shall furnish and replace parts at **no cost** to the Government during warranty. The contractor shall have ready access to unique and/or high mortality replacement parts. All parts supplied shall be OEM and fully compatible with existing equipment. The contract shall include all parts with the exception of consumable or expendable items. The contractor shall use new or rebuilt parts. Used parts, those removed from another system, shall not be installed without approval by Engineering.

## **7. REPORTING REQUIREMENTS:**

The contractor shall contact Engineering prior to performance of work under this contract. This check-in is mandatory and can be accomplished in person or by phone contact. When the service(s) is/are completed, the FSE shall document the services rendered on a legible ESR(s).

## **9. ADDITIONAL CHARGES:**

There will be no additional charge for time spent at the site during, or after the normal hours of coverage awaiting the arrival of additional FSE and/or delivery of parts.

## **10. REPORTING REQUIRED SERVICES BEYOND THE CONTRACT SCOPE:**

The Contractor shall immediately, but no later than 24 consecutive hours after discovery, notify engineering, (in writing), of the existence or the development of any defects in, or repairs required to the scheduled equipment which the Contractor considers he/she is not responsible for under the terms of the contract. The contractor shall furnish the CO and COR with a written estimate of the cost to make necessary repairs.

## **11. CONDITION OF EQUIPMENT:**

The contractor accepts responsibility for the equipment described in Section B, in "as is" condition. Failure to inspect the equipment prior to contract award will not relieve the contractor from performance of the requirements of this contract.

## **12. COMPETENCY OF PERSONNEL SERVICING EQUIPMENT:**

A. Each respondent must have an established business, with an office and full-time staff. The staff includes a "fully qualified" FSE and a "fully qualified" FSE who will serve as the backup.

B. "Fully Qualified" is based upon training and on experience in the field. For training, the FSE(s) shall have successfully completed a formalized training program, for the equipment identified in Section B. For field experience, the FSE(s) shall have a minimum of two years of experience, with respect to scheduled and unscheduled preventive and remedial maintenance on equipment identified in Section B.

C. The FSE(s) shall be authorized by the contractor to perform the maintenance services as required. All work shall be performed by "Fully Qualified" competent FSEs. The contractor shall provide written assurance of the competency of their personnel and a list of credentials of approved FSEs for each make and model the contractor services at the VAOPC. The CO may authenticate the training requirements, request copies of training certificates or credentials from the contractor at any time for any personnel who are servicing or installing any VAOPC equipment. The CO and/or the COR specifically reserve the right to reject any of the contractor's personnel and refuse them permission to work on the VAOPC equipment.

### **13. TEST EQUIPMENT:**

Prior to commencement of work on this contract, the contractor shall make available if requested a copy of the current calibration certification of all test equipment that is to be used by the contractor in performing work under the contract. This certification shall also be provided on a periodic basis when requested by the VAOPC. Test equipment calibration shall be traceable to a national standard.

### **14. IDENTIFICATION, PARKING, SMOKING, CELLULAR PHONE USE AND VA REGULATIONS:**

The contractor's FSE shall wear visible identification at all times while on the premises of the VAOPC. It is the responsibility of the contractor to park in the appropriate designated parking areas. Information on parking is available from the VA Police-Security Service. The VAOPC will not invalidate or make reimbursement for parking violations of the contractor under any conditions. Smoking is prohibited inside any buildings at the VAOPC. Cellular phones and two-way radios are not to be used within six feet of any medical equipment. Possession of weapons is prohibited. Enclosed containers, including tool kits, shall be subject to search. Violations of VA regulations may result in a citation answerable in the United States (Federal) District Court, not a local district state, or municipal court.

### **15. COMPLIANCE WITH OSHA BLOODBORNE PATHOGENS STANDARD:**

The contractor shall comply with the Federal/California OSHA Bloodborne Pathogens Standard. The contractor shall:

- A. Have methods by which all employees are educated as to risks associated with bloodborne pathogens.
- B. Have policies and procedures that reduce the risk of employee exposure to bloodborne pathogens.
- C. Have mechanisms for employee counseling and treatment following exposure to bloodborne pathogens.
- D. Provide appropriate personal protective equipment/clothing such as gloves, gowns, masks, protective eyewear, mouthpieces for the employee during performance of the contract.

#### Records Management Language

The following standard items relate to records generated in executing the contract and should be included in a typical Electronic Information Systems (EIS) procurement contract:

1. Citations to pertinent laws, codes and regulations such as 44 U.S.C chapters 21, 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
2. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
3. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government IT equipment and/or Government records.
4. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
6. The Government Agency owns the rights to all data/records produced as part of this contract.
7. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.

8. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].
9. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.
10. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.