Statement of Work (SOW)

1. INTRODUCTION:

The Winchester Engineering and Analytical Center (WEAC) has a critical need for Sputter Coater for Scanning Electron Microscope (SEM) sample preparation to accomplish mission critical regulatory analyses and research & development projects for FDA. A SEM can be used to image nano-structural features of various samples such as metals and alloys, polymers, ceramics, and biological specimens. To ensure obtaining high quality images via SEM, some samples first need to be sputter coated with an ultra-thin layer of highly conductive metal coating (ex. Gold). Sputter coating is required for poorly conductive or non-conductive specimens to inhibit the charging of the sample and prevent the microscopic beam damage. Sample Sputter Coater will be required for sample preparation for several critical projects at WEAC including but not limited to, analytical test protocols development and optimization for identifying and detection emission of particulate matter from respiratory devices using SEM, antibiofilm research development and material evaluation projects (CARTS #IR01848 and #IR01538) aim to develop technologies for eliminating medical device associated bacterial biofilms. To complete these mission critical regulatory and research projects successfully, we will need a sample Sputter Coater for the SEM.

Without this equipment, the FDA will not benefit from the capacity increase and rapid and accurate analytical imaging capability brought with this equipment for preparing samples for regulatory testing and research and development efforts at WEAC.

2. BACKGROUND:

A Sputter Coater is necessary for assessing safety medical devices by imaging and detecting possible emissions of particulate matters from these machines in in terms sample preparation in support of regulatory testing program of FDA. Sputter Coater will readily support regulatory analysis of engineering samples done by WEAC. In addition, several OCS research project that study and develop antimicrobial-free biofilm elimination strategies for medical devices will be highly benefited through this equipment for sample preparation for Scanning Electron Microscopy in house as it will further help advance the research and development activities that support the FDA's public health mission at WEAC.

3. SCOPE:

Winchester Engineering and Analytical Center (WEAC) requires a sample Sputter Coater to support the development of analytical test protocol for SEM for detecting emission of particulate matter from Respironics ventilators for assessing the safety of these devices, regulatory analysis of engineering samples as well as microbial biofilm and surface characterization projects.

4. REQUIREMENTS:

Minimum Technical Requirements:

A sputter coater should have the following specifications:

- Should have ability to deposit a broad range of coating materials including but not limited to gold, platinum, and iridium by both Sputtering/evaporation modes.

- An adjustable rotating and tilting plate/stage should be present to ensure uniform coating and provide excellent coverage, even on specimens with asymmetrical surfaces.
- System should be fully automated with several operational modes including automatic, semi-automatic and manual operational modes with ability to run sputtering using pre-set protocols
- System should include a glass/stainless steel process chamber with at lease with 6 inches in diameter and 6 inches in height and with both top and bottom sealing gaskets
- System should include a programmable logic controller that is convenient to use during entire deposition process.
- Direct drive mechanical pump and a Turbo pump should present to evacuate the chamber with higher vacuum capabilities, quickly changeable sputter source head, gas inlet with needle valve control and positive shutoff valve should be present.
- Electrical Utility requirement should match the following specification: 120VAC, 10Amp, 1 phase, 50/60Hz
- Options to use either Argon or Nitrogen as the Process gas for the sputtering
- Unit should be compact and should be able to install in a small bench space.
- Safety features such as automatic interlocks during operations and emergency stop button to safeguard both the machine and the user should be present.
- Manual/instructional documentation for operation should be included
- The components and/or equipment shall be a newly manufactured, not used, and refurbished, or previously used for demonstration.
- The entire system shall be warranted for parts and labor for a minimum of 12 months from date of formal government acceptance. The warranty must include unlimited telephone/e-mail support for questions regarding operation.

5. DELIVERABLES:

Description	Quantity	Delivery Date
Sputter coater with Tilting/Rotating Standard Plate with full range vacuum gauge and oil vane mechanical pump	1	Within 6 month of contract award date

6. DELIVERY POINT:

ORA/Winchester Engineering and Analytical Center
Attn: Jayaleka J. Amarasinghe
109 Holton St.
Winchester, MA, 01890
Jayaleka.amarasinghe@fda.hhs.gov
781-756-9721