

### **Request for Information**

This is a Request for Information (RFI) to conduct market research to determine the availability of vendors capable of providing the requirement listed below. This RFI does not guarantee the issuance of an RFQ. However, if an RFQ is issued, VA will follow the Contracting Order of Priority in accordance with Veterans Affairs Acquisition Regulation (VAAR) Part 819.7004. Based on responses to this RFI, if multiple small businesses are determined to be capable of providing the full requirement, VA will issue an RFQ as a set-aside to the applicable category. If interested in responding to a future RFQ for this requirement, please provide a brief capabilities statement or unofficial pricing information.

### **Requirement/Background**

The VA is interested in receiving input with regard to a potential requirement for services IAW the attached PWS to perform an audit of the Sustainment of Blood Bank Maintenance Project Quality System used to create and support medical device software thereby meeting Food and Drug Administration Title 21 CFR Part 11, 803, 806, 820, and 821 regulations. The vendor conducting the service must be a Certified Auditor with the International Register of Certificated Auditors (IRCA) or a Certified Quality Auditor with American Society for Quality (ASQ). The audit will include a desk audit of documentation and a site visit of two to three days for additional review, interviews, and discussion. The preferred audit window is June 11, 2018 to June 29, 2018 but must be completed no later than July 13, 2018. A report summarizing the findings and recommendations is a required work product.

### **RFI Questions (Please provide a response to the following questions)**

#### **RFI RESPONSE IS LIMITED TO 5 PAGES**

Describe your firm's work experiences supporting U.S. Food and Drug Administration Title 21, Code of Federal Regulations CFR Part 11, 803, 806, 820, and 821

Describe your past performance (within last 3 years) on similar projects with regard to the scope detailed in Performance Work Statement.

- Customer Name
- Commercial or Government
- Project Title
- Name and Type of Deliverables Submitted
- Project Location
- Project Period of Performance

- Project Dollar Amount
- Describe how you would access or obtain “Certified Auditor” staff
- Identify key partners/team members you anticipate working with you on this project.
- Socio-Economic Group

## **RESPONSE SUBMISSION**

Please submit responses via email to [Kendra.Bell@va.gov](mailto:Kendra.Bell@va.gov) by 3:00 PM EST, May 22, 2018. Responses should also include a contact name, point of contact, phone number, DUNS number, CAGE code, email address, as well as any contract vehicles you are using such as GSA or SEWP. VA reserves the right not to respond to any or all emails or materials submitted.

This RFI is issued solely for information and planning purposes - it does not constitute a RFQ or a promise to issue a RFP in the future. This request does not commit the Government to contract for any supply or service whatsoever. The Department of Veterans Affairs (VA) is not, at this time, seeking quotes and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested vendor's expense. Not responding to this RFI does not preclude participation in any future RFP, if any is issued. Any information submitted by respondents to this RFI is strictly voluntary. All submissions become Government property and will not be returned.