

STRATEGIC

ACQUISITION CENTER



Biologics Industry Day Contract Overview

Ms. LeShanna Calahan

VA



**U.S. Department
of Veterans Affairs**

All concepts, dates and figures introduced
here are notional and are subject to change

Acquisitions and Contractual Authority Disclaimer

Acquisitions and contractual commitments can only be made by Government officials having expressed authority to enter into such agreements on behalf of the United States Government. The only Government officials with such authority are Warranted Contracting Officers. Any discussions of procurement requirements do not constitute contractual direction or authorization of any kind. Future contractual directions, if any, shall only come from the cognizant Department of Veterans Affairs Warranted Contracting Officer and released in a final solicitation. All concepts, dates and figures introduced here are notional and are subject to change.

RULES OF ENGAGEMENT

Our goals are to maintain an atmosphere of politeness and fairness throughout this industry day presentation.

- Light refreshments are provided.
- Restrooms are located in front of (women's) and behind the elevators (men's). Women's rest room requires a combination for entry.
- No one-on-one meetings will be granted.
- During the presentation we will accept written comments and questions on the index cards provided.
- Responses will only be provided during the Question and Answer session.

POINT OF CONTACTS

SAC Contracting Officer: LeShanna Calahan

SAC Contract Specialists: Hector Hernandez
Dawn Montgomery
Michael Schrantz
Lawrence Toperoff
Shemika Wray

VHA Project Manager: Joyce Edmondson

COR: Audrey Ezell-Upchurch

BIOLOGICAL IMPLANTS

The intended use of biological implants is any human cell, tissue, cellular or tissue-based product or animal product inserted or grafted into the body for prosthetic and therapeutic purposes. Biological implants are comprised of allografts and xenografts. Contractors must meet the industry labeling requirements of the International Standard for Blood and Transplant (ISBT) 128 labeling requirement, which is the global standard for the identification, labeling, and information transfer of medical products. Biological implants must be tracked from human donor or animal source at each step of distribution to implantation so that all patients who receive a biological implant by the VA can be notified of a recall subject to the evaluation by appropriate medical personnel.

- Competition: Sole Source
 - Other Than Full and Open, 38 U.S.C 8123
 - Target: Capture 80% of VA spend through the establishment of enterprise-wide strategic contracts for Biological Implants
- Contract Type: Indefinite Delivery Indefinite Quantity (Firm Fixed Price)
- NAICS Code: 339113 Surgical Appliance and Supplies Manufacturing
- Contract Length: To Be Determined (TBD)
- Contract Ceiling amount: TBD

TIMELINE (estimated)

Solicitation Release Date: 4th FY17

Proposal Due Date: 60 days after the release of the solicitation

Award Date: 1st Quarter FY18

EVALUATION CRITERIA

- Technical
- Socio Economic Consideration
- Subcontracting Plan (if applicable)
- Price

TECHNICAL PROPOSAL

- The contractor shall not propose any products that are projected to become obsolete during base year of performance.
- The Government will not consider new product additions during the base period of performance.

TECHNICAL PROPOSAL

- Provide listing to display location of vendor representatives and demonstrate how national coverage will be provided
- Provide qualifications and certifications of vendor representatives
- Provide an outline showing the ability and commitment to train operating room and hospital personnel over the life of the contract
- Describe procedures and policies tracking trends and failures on products offered to VA and how its communicated to the VA

TECHNICAL PROPOSAL

- Provide Food and Drug Administration (FDA) registration certification
- Provide Proof of Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendment certificate (if applicable)
- Provide a copy of the American Association of Tissue Banks accreditation or Eye Bank Association of America accreditation or equivalent accreditation body (if applicable)

TECHNICAL PROPOSAL

- Provide copy of the FDA 3356 for supplier facility
- Must hold and provide a copy of State license
- Provide verification statement to meet Industry labeling requirements (ISBT 128), for Human Tissue (Allograft Biological Implants) by effective date of contract
- Distributors are required to submit a letter of supply from the manufacturer/s of the offered biological implant guaranteeing a source of supply for the term of the contract, including option periods. This letter must be from the manufacturer and on the manufacturer's stationary.
- A Subcontracting plan is required (not applicable if a small business)

TECHNICAL PROPOSAL

- Provide descriptive product literature that demonstrates the breadth and depth of each product line.
 - “Descriptive literature,” means information (e.g., cuts, illustrations, drawings, and brochures) that is submitted as part of an offer. Descriptive literature is required to establish, for the purpose of evaluation and award, and pertain to significant elements such as: (1) design; (2) materials; (3) components; (4) performance characteristics; and (5) methods of manufacture, assembly, construction, or operation.

PRICE PROPOSAL

- Provide a complete price/cost excel worksheet (catalog of products).
 - Include commercial catalog price, best customer price, average VA historical price (if applicable), discount, and proposal price for each contract line item.

QUESTIONS