Request for Proposal for Medical Device Alliance Regulatory Analysis (RFP #2020-0003)

SCRA
SOUTH CAROLINA MEDICAL DEVICE ALLIANCE

I. Background

Chartered as a 501(c)3 by the state of South Carolina in 1983, South Carolina Research Authority (SCRA) is a public, non-profit corporation that fuels South Carolina's innovation economy.

The South Carolina Medical Device Alliance (MDA) is transforming how the state is inventing, advancing and commercializing medical devices to address unmet clinical needs. This multi-stakeholder partnership is the foundation of a regional innovation cluster to grow the economic impact through job creation and startup formation, as well as to attract international businesses. The MDA will advance technologies to market with multidisciplinary teams and launch startups that have been rigorously evaluated by seasoned industry experts.

Having evaluated and selected the most promising early-stage technologies, the current phase of the MDA process involves building project profiles to address aspects of medical device development that are key to commercialization. Profiles may include a regulatory assessment, reimbursement strategy, commercial/market assessment, design for manufacturability evaluation, and patent landscape analysis. Please view our other RFPs if you are interested in submitting a bid proposal for other components of the project profiles.

The project profiles will be compiled and provided to the innovator and their affiliated institution(s). The primary audience for the project profiles, however, is the Medical Device Commercialization Advisory Panel (MDCAP). The MDCAP was formed by SCRA to provide industry insight to academic innovators and technology transfer offices, prioritize technologies to advance through the MDA, and recommend the next commercially relevant steps in development. The MDCAP consists of seasoned medical device executives across disciplines, including regulatory affairs, R&D, product development, manufacturing, reimbursement and funding.

This work is supported by the Economic Development Administration's Regional Innovation Strategies i6 program, SCRA, Clemson University, and Medical University of South Carolina.

II. Scope of Solicitation

SCRA is soliciting fixed price bids for professional consulting services to determine the regulatory pathway for U.S. Food and Drug Administration (FDA) clearance/approval for up to eight early-stage medical devices. Please refer to the chart below and address your experience in each of these specialties.

Technology	Specialty
External Device for Postoperative Ileus	GI
Annulus Fibrosis Repair Patch	Neurosurgery/Ortho
Surgical Guides for Dental Implants	Dental
Device to Guide PD Medication Titration	Neurology
Pediatric Concussion Assessment Device	Neurology
Localized High Frequency Stimulation (LHFS) for Myocardial Infarction Remodeling	Cardiology
Wound Dressing	Multiple
Minimally Invasive Subdural Evacuation System	Neurosurgery

Such regulatory evaluations typically include identification of potential pathways through the FDA and into the U.S. market based on (1) what types of marketing claims will be made to patients and providers regarding the intended use of the product and (2) what types of technologies will be integrated prior to marketing.

The strategic regulatory assessment for each technology will include the following components:

- Recommended regulatory classification, device class, product code/predicate devices (if applicable), and submission type
- Determination of predicates to the invention or other similar products that have been cleared
- Review the need for clinical trials, either to secure initial clearances or approvals, as compared to similar products, and how large and long those comparable trials took to complete
- Identify the breadth or limitations for an initial proposed intended use and potential indications for use labeling claims that might secure earliest commercialization
- Impact of proposed claims on regulatory pathway and timing
- Timeline to marketing authorization, inclusive of any required clinical trials, and associated FDA fees

All final work product will be presented in the form of a Microsoft Word document and, if appropriate, Microsoft Excel spreadsheet. In addition to the final report, the service provider will be required to virtually participate in a technology review session in July to summarize their findings for the MDCAP and answer questions from the panel.

For questions regarding the scope of work, please contact academicinnovations@scra.org.

III. Bidding and Delivery Timeline

Bid proposals are due by 5:00 PM on Wednesday, May 20th, 2020. The winning proposals will be notified on Wednesday, May 27th. The due date for the final work product is dependent on other analyses but is expected to fall in late-June. Submit all bid proposals to academicinnovations@scra.org. No proposals will be accepted by mail or hand delivery.

IV. Bid Package

Bid proposals must include a sample report, redacted as needed to protect confidentiality, that will be emulated by the service provider for the reports to be provided to SCRA. Bid proposals may also outline work, in addition to the scope of work in Section I, which the service provider views as crucial to execution of the project. The bid proposal must specify the cost per report to be completed in the time frame outlined in section III – Bidding and Delivery Timeline.

Service providers may submit bid proposals for multiple SCRA RFPs. Please submit a bid under each RFP separately, but indicate if there will be pricing discounts available if selected to provide services under more than one RFP.

Due to the U.S. federal funding associated with this project, all work must be completed by U.S.-based personnel from U.S.-based entities. Please explicitly state in the bid package if the company and personnel

meet these criteria.

V. Contract Terms and Conditions

The service provider must agree to a non-disclosure/confidentiality provision. Any resultant contract will include all clauses that are required under the Economic Development Administration's Regional Innovation Strategies i6 program, all clauses required by law on the date of contract execution, other mutually agreeable clauses, provisions, and terms and conditions.

This is a solicitation and does not commit SCRA to pay any cost incurred in the preparation and submission of any offer in any form or to produce or subcontract for said work. Any resultant agreement between SCRA will be subject to the provisions and Terms and Conditions of the Solicitation as well as SCRA's Standard Terms and Conditions. If you have any questions of a contractual nature, please feel free to contact sheila.riley@scra.org.