Request for Proposal for Medical Device Alliance Regulatory Strategy Services (RFP #2019-0001)

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. Each profile will 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 the 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, manufacturing, reimbursement and funding.

This work is supported by the Economic Development Administration's Regional Innovation Strategies i6 program.

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 five early-stage medical devices. 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 devices are in the fields of neonatal feeding, orthopedic fractures, bioink for tissue engineering, and breast tumor biopsy and are expected to be Class II and III devices.

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

- Proposed intended use and potential indications for use
- Impact of functionality/claims on regulatory pathway
- Recommended regulatory classification, device class, product code/predicate devices (if applicable), and submission type
- Timeline to marketing authorization and associated FDA fees

The final work product for each assessment will be a high-level regulatory evaluation presented in the form of a Microsoft Word document. Please note that there are separate RFPs for the reimbursement strategy, design for manufacturability evaluation, commercial/market assessment, and patent landscape analysis, so those components are excluded from the scope of this RFP.

In addition to the final report, the service provider will be required to participate in a two-hour phone call in late June or early July. The service providers for each component of the project profile will participate in the call to summarize their findings for the MDCAP and answer questions from the panel.

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

III. Bidding and Delivery Timeline

Bid proposals are due by 5:00 PM on Friday, May 10th. The winning proposals will be notified on Monday, May 13th. Contracts will be put in place the week of May 13th. The final work product is to be delivered no later than June 7th, 2019. Submit all bid proposals to academicprograms@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 assessment to be completed, with a minimum of four assessments 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.

V. Contract Terms and Conditions

The service provider must agree to a non-disclosure/confidentiality provision. Any resultant reward 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.