

THE UNIVERSITY OF RHODE ISLAND

Solicitation Information July 2, 2020

RFP# 100910

TITLE: QA, COMPLIANCE AND VALIDATION SERVICES

Submission Deadline: July 30, 2020 at 2:00PM (Eastern Time)

PRE-BID/ PROPOSAL CONFERENCE: No

MANDATORY:

If YES, any Vendor who intends to submit a bid proposal in response to this solicitation must have its designated representative attend the mandatory Pre-Bid/ Proposal Conference. The representative must register at the Pre-Bid/ Proposal Conference and disclose the identity of the vendor whom he/she represents. A vendor's failure to attend and register at the mandatory Pre-Bid/ Proposal Conference shall result in disqualification of the vendor's bid proposals as non-responsive to the solicitation.

DATE: n/a

LOCATION: n/a

Questions concerning this solicitation must be received by the URI Purchasing Department at URIPurchasing@uri.edu no later than July 14, 2020 at 12:00PM (EST). Questions should be submitted in a *Microsoft Word attachment*. Please reference the RFP# on all correspondence. Questions received, if any, will be posted on the Division of Purchases' website as an addendum to this solicitation. It is the responsibility of all interested parties to download this information.

BID SURETY BOND REQUIRED: No

PAYMENT AND PERFORMANCE BOND REQUIRED: No

Ryan Pincince - Assistant Director
DZ

Note to Applicants:

- Applicants should register on-line at the URI Controller's Website at <https://web.uri.edu/controller/accounts-payable/suppliers/>
- Proposals received without a completed URI Bidder Certification Form may result in disqualification.

University of Rhode Island Bidder Certification Form

ALL OFFERS ARE SUBJECT TO THE REQUIREMENTS, PROVISIONS AND PROCEDURES CONTAINED IN THIS CERTIFICATION FORM. Offerors are expected to read, sign and comply with all requirements. Failure to do so may be grounds for disqualification of the offer contained herein.

Rules for Submitting Offers

This Certification Form must be attached in its entirety to the front of the offer and shall be considered an integral part of each offer made by a vendor to enter into a contract with the University of Rhode Island. As such, submittal of the entire Bidder Certification Form, signed by a duly authorized representative of the offeror attesting that he/she (1) has read and agrees to comply with the requirements set forth herein and (2) to the accuracy of the information provided and the offer extended, is a mandatory part of any contract award.

To assure that offers are considered on time, each offer must be submitted with the specific Bid/RFP/LOI number, date and time of opening marked in the upper left hand corner of the envelope. Each bid/offer must be submitted in separate sealed envelopes.

A complete signed (in ink) offer package must be delivered to the University of Rhode Island Purchasing Office by the time and date specified for the opening of responses in a sealed envelope.

Bid responses must be submitted on the URI bid solicitation forms provided, indicating brand and part numbers of items offered, as appropriate. Bidders must submit detailed cuts and specs on items offered as equivalent to brands requested WITH THE OFFER. Bidders must be able to submit samples if requested.

Documents misdirected to other State or University locations or which are not present in the University of Rhode Island Purchasing Office at the time of opening for whatever cause will be deemed to be late and will not be considered. For the purposes of this requirement, the official time and date shall be that of the time clock in the reception area of the University of Rhode Island Purchasing Office. Postmarks shall not be considered proof of timely submission.

RIVIP SOLICITATIONS. To assure maximum access opportunities for users, public bid solicitations shall be posted on the RIVIP for a minimum of seven days and no amendments shall be made within the last five days before the date an offer is due. Except when access to the Web Site has been severely curtailed and it is determined by the Purchasing Agent that special circumstances preclude extending a solicitation due date, requests to mail or fax hard copies of solicitations will not be honored.

PRICING. Offers are irrevocable for sixty (60) days from the opening date (or such other extended period set forth in the solicitation), and may not be withdrawn, except with the express permission of the University Purchasing Agent. All pricing will be considered to be firm and fixed unless otherwise indicated. The University of Rhode Island is exempt from Federal excise taxes and State Sales and Use Taxes. Such taxes shall not be included in the bid price.

PRICES QUOTED ARE FOB DESTINATION.

DELIVERY and PRODUCT QUALITY. All offers must define delivery dates for all items; if no delivery date is specified, it is assumed that immediate delivery from stock will be made. The contractor will be responsible for delivery of materials in first class condition. Rejected materials will be at the vendor's expense.

PREVAILING WAGE, OSHA SAFETY TRAINING and APPRENTICESHIP REQUIREMENTS. Bidders must comply with the provisions of the Rhode Island labor laws, including R.I. Gen. Laws §§ 37-13-1 et seq. and occupational safety laws, including R.I. Gen. Laws §§ 28-20-1 et seq. These laws mandate for public works construction projects the payment of prevailing wage rates, the implementation and maintenance of occupational safety standards, and for projects with a minimum value of \$1 Million, the employment of apprentices. The successful Bidder must submit certifications of compliance with these laws from each of its subcontractors prior to their commencement of any work. Prevailing wage rates, apprenticeship requirements, and other workforce and safety regulations are accessible at www.dlt.ri.gov.

PUBLIC RECORDS. Offerors are advised that all materials submitted to the University for consideration in response to this solicitation will be considered without exception to be Public Records pursuant to Title 38 Chapter 2 of the Rhode Island General Laws, and will be released for inspection immediately upon request once an award has been made. Offerors are encouraged to attend public bid/RFP openings to obtain information; however, bid/RFP response summaries may be reviewed after award(s) have been made by visiting the Rhode Island Vendor Information Program (RIVIP) at www.purchasing.ri.gov > Solicitation Opportunities > Other Solicitation Opportunities. Telephone requests for results will not be honored. Written requests for results will only be honored if the information is not available on the RIVIP.

Award will be made to the responsive and responsible offeror quoting the lowest net price in accordance with specifications, for any individual item(s), for major groupings of items, or for all items listed, at the University's sole option.

BID SURETY. Where bid surety is required, bidder must furnish a bid bond or certified check for 5% of the bid total with the bid, or for such other amount as may be specified. Bids submitted without a required bid surety will not be considered.

SPECIFICATIONS. Unless specified "no substitute", product offerings equivalent in quality and performance will be considered (at the sole option of the University) on the condition that the offer is accompanied by detailed product specifications. Offers which fail to include alternate specifications may be deemed nonresponsive.

VENDOR AUTHORIZATION TO PROCEED. When a purchase order, change order, contract/agreement or contract/agreement amendment is issued by the University of Rhode Island, no claim for payment for services rendered or goods delivered contrary to or in excess of the contract terms and scope shall be considered valid unless the vendor has obtained a written change order or contract amendment issued by the University of Rhode Island Purchasing Office PRIOR to delivery.

Any offer, whether in response to a solicitation for proposals or bids, or made without a solicitation, which is accepted in the form of an order OR pricing agreement made in writing by the University of Rhode Island Purchasing Office, shall be considered a binding contract.

REGULATIONS, GENERAL TERMS AND CONDITIONS GOVERNING STATE AND THE UNIVERSITY OF RHODE ISLAND CONTRACTS. This solicitation and any contract or purchase order arising from it are issued in accordance with the specific requirements described herein, and the State's Purchasing Laws and Regulations and other applicable State Laws and Regulations, including the Board of Governors for Higher Education Regulations and General Terms and Conditions of Purchase. The Regulations and General Terms and Conditions are incorporated into all University of Rhode Island contracts and can be viewed at: <https://web.uri.edu/purchasing/files/BOGREG.pdf> and www.ridop.ri.gov.

EQUAL EMPLOYMENT OPPORTUNITY. Compliance certificate and agreement procedures will apply to all awards for supplies or services valued at \$10,000 or more. Minority Business Enterprise policies and procedures, including subcontracting opportunities as described in Title 37 Chapter 14.1 of the Rhode Island General Laws also apply.

PERFORMANCE BONDS. Where indicated, successful bidder must furnish a 100% performance bond and labor and payment bond for contracts subject to Title 37 Chapters 12 and 13 of the Rhode Island General Laws. All bonds must be furnished by a surety company authorized to conduct business in the State of Rhode Island. Performance bonds must be submitted within 21 calendar days of the issuance of a tentative notice of award.

DEFAULT and NON-COMPLIANCE Default and/or non-compliance with the requirements and any other aspects of the award may result in withholding of payment(s), contract termination, debarment, suspension, or any other remedy necessary that is in the best interest of the state/University of Rhode Island.

COMPLIANCE Vendor must comply with all applicable federal, state and local laws, regulations and ordinances.

SPRINKLER IMPAIRMENT AND HOT WORK. The Contractor agrees to comply with the practices of the State's Insurance carrier for sprinkler impairment and hot work. Prior to performing any work, the Contractor shall obtain the necessary information for compliance from the Risk Management Office at the Department of Administration or the Risk Management Office at the University of Rhode Island.

Each bid proposal for a *public works project* must include a "public copy" to be available for public inspection upon the opening of bids. **Bid Proposals that do not include a copy for public inspection will be deemed nonresponsive.**

For further information on how to comply with this statutory requirement, see R.I. Gen. Laws §§ 37-2-18(b) and (j). Also see State of Rhode Island Procurement Regulation 5.11 at <https://www.ridop.ri.gov/rules-regulations/>

SECTION 4 - CERTIFICATIONS

Bidders must respond to every statement. Bid proposals submitted without a complete response may be deemed nonresponsive.

Indicate "Y" (Yes) or "N" (No), and if "No," provide details below.

THE VENDOR CERTIFIES THAT:

___1 I/we certify that I/we will immediately disclose, in writing, to the University Purchasing Agent any potential conflict of interest which may occur during the course of the engagement authorized pursuant to this contract.

___2 I/we acknowledge that, in accordance with (1) Chapter §37-2-54(c) of the Rhode Island General Laws "no purchase or contract shall be binding on the state or any agency thereof unless approved by the Department [of Administration] or made under general regulations which the Chief Purchasing Officer may prescribe," and (2) RIGL section §37-2-7(16) which identifies the URI Board of Trustees as a public agency and gives binding contractual authority to the University Purchasing Agent, including change orders and other types of contracts and under State Purchasing Regulation 8.2.B any alleged oral agreement or arrangements made by a bidder or contractor with any agency or an employee of the University of Rhode Island may be disregarded and shall not be binding on the University of Rhode Island.

___3 I/we certify that I or my/our firm possesses all licenses required by Federal and State laws and regulations as they pertain to the requirements of the solicitation and offer made herein and shall maintain such required license(s) during the entire course of the contract resulting from the offer contained herein and, should my/our license lapse or be suspended, I/we shall immediately inform the University of Rhode Island Purchasing Agent in writing of such circumstance.

___4 I/we certify that I/we will maintain required insurance during the entire course of the contract resulting from the offer contained herein and, should my/our insurance lapse or be suspended, I/we shall immediately inform the University of Rhode Island Purchasing Agent in writing of such circumstance.

___5 I/we certify that I/we understand that falsification of any information herein or failure to notify the University of Rhode Island Purchasing Agent as certified herein may be grounds for suspension, debarment and/or prosecution for fraud.

___6 I/we acknowledge that the provisions and procedures set forth in this form apply to any contract arising from this offer.

___7 I/we acknowledge that I/we understand the State's Purchasing Laws (§37-2 of the General Laws of Rhode Island) and Purchasing Regulations and General Terms and Conditions available at the Rhode Island Division of Purchases Website (<https://www.ridop.ri.gov/rules-regulations/>) and the Board of Governors Regulations on the URI Purchasing Website (<https://web.uri.edu/purchasing/files/BOGREG.pdf>) apply as the governing conditions for any contract or purchase order I/we may receive from the University of Rhode Island, including the offer contained herein.

___8 I/we certify that the bidder: (i) is not identified on the General Treasurer's list, created pursuant to R.I. Gen. Laws § 37-2.5-3, as a person or entity engaging in investment activities in Iran described in § 37-2.5-2(b); and (ii) is not engaging in any such investment activities in Iran.

___9 If the product is subject to Department of Commerce Export Administration Regulations (EAR) or International Traffic in Arms Regulations (ITAR), please provide the Export Control Classification Number (ECCN) or the US Munitions List (USML) Category: _____

___10 I/we certify that the above information is correct and complete.

IF YOU ARE UNABLE TO CERTIFY YES TO QUESTIONS #1 – 8 and 10 OF THE FOREGOING, PROVIDE DETAILS/EXPLANATION IN AN ATTACHED STATEMENT. INCOMPLETE CERTIFICATION FORMS SHALL BE GROUNDS FOR DISQUALIFICATION OF OFFER.

Signature below commits vendor to the attached offer and certifies (1) that the offer has taken into account all solicitation amendments where applicable, (2) that the above statements and information are accurate and that vendor understands and has complied with the requirements set forth herein.

Vendor/Company Name; _____

Vendor's Signature: _____ Bid Number: _____ Date: _____
(Person Authorized to enter into contracts; signature must be in ink) (if applicable)

Print Name and Title of Company official signing offer

SECTION 1: INTRODUCTION

The Rhode Island Council on Postsecondary Education/University of Rhode Island is soliciting proposals for URI Pharmaceutical Development Institute (PDI) from qualified OFFERORS to provide Quality Assurance (QA), Compliance and Validation Services in accordance with the terms of this Request for Proposal (“RFP”) and the General Terms and Conditions of Purchase indicated in the attached URI Bidder Certification Form.

The initial contract period will begin approximately August 1, 2020 for one year. Contracts may be renewed for up to four additional 12-month periods based on vendor performance and the availability of funds.

This is a Request for Proposals, not a Request for Quotes. Responses will be evaluated on the basis of the relative merits of the proposal, in addition to cost; there will be no public opening and reading of responses received by the University of Rhode Island Purchasing Department pursuant to this solicitation, other than to name those offerors who have submitted proposals.

Instructions and Notifications to Offerors

1. Potential offerors are advised to review all sections of this RFP carefully and to follow instructions completely, as failure to make a complete submission as described elsewhere herein may result in rejection of the proposal.
2. Alternative approaches and/or methodologies to accomplish the desired or intended results of this RFP are solicited. However, proposals which depart from or materially alter the terms, requirements, or scope of work defined by this RFP may be rejected as being non-responsive.
3. All costs associated with developing or submitting a proposal in response to this RFP or for providing oral or written clarification of its content shall be borne by the vendor. The University assumes no responsibility for these costs even if the RFP is cancelled or continued.
4. Proposals are considered to be irrevocable for a period of not less than 180 days following the opening date, and may not be withdrawn, except with the express written permission of the University of Rhode Island Purchasing Director.
5. All pricing submitted will be considered to be firm and fixed unless otherwise indicated in the proposal.
6. It is intended that an award pursuant to this RFP will be made to a prime vendor, or prime vendors in the various categories, who will assume responsibility for all aspects of the work. Subcontracts are permitted, provided that their use is clearly indicated in the vendor’s proposal, and the subcontractor(s) to be used is identified in the proposal.
7. The purchase of goods and/or services under an award made pursuant to this RFP will be contingent on the availability of appropriated funds.

8. Vendors are advised that all materials submitted to the University of Rhode Island Purchasing Department for consideration in response to this RFP may be considered to be public records, as defined in R. I. Gen. Laws § 38-2-1, *et seq.*, and may be released for inspection upon request, once an award has been made.

Any information submitted in response to this RFP that a vendor believes are trade secrets or commercial or financial information which is of a privileged or confidential nature should be clearly marked as such. The vendor should provide a brief explanation as to why each portion of information that is marked should be withheld from public disclosure. Vendors are advised that the University of Rhode Island Purchasing Department may release records marked confidential by a vendor upon a public records request if the University determines the marked information does not fall within the category of trade secrets or commercial or financial information which is of a privileged or confidential nature.

9. Interested parties are instructed to peruse the Division of Purchases website on a regular basis, as additional information relating to this solicitation may be released in the form of an addendum to this RFP.
10. By submission of proposals in response to this RFP vendors agree to comply with R. I. General Laws § 28-5.1-10 which mandates that contractors/subcontractors doing business with the State of Rhode Island exercise the same commitment to equal opportunity as prevails under Federal contracts controlled by Federal Executive Orders 11246, 11625 and 11375.

Vendors are required to ensure that they, and any subcontractors awarded a subcontract under this RFP, undertake or continue programs to ensure that minority group members, women, and persons with disabilities are afforded equal employment opportunities without discrimination on the basis of race, color, religion, sex, sexual orientation, gender identity or expression, age, national origin, or disability.

Vendors and subcontractors who do more than \$10,000 in government business in one year are prohibited from engaging in employment discrimination on the basis of race, color, religion, sex, sexual orientation, gender identity or expression, age, national origin, or disability, and are required to submit an “Affirmative Action Policy Statement.”

Vendors with 50 or more employees and \$50,000 or more in government contracts must prepare a written “Affirmative Action Plan” prior to issuance of a purchase order.

- a. For these purposes, equal opportunity shall apply in the areas of recruitment, employment, job assignment, promotion, upgrading, demotion, transfer, layoff, termination, and rates of pay or other forms of compensation.
- b. Vendors further agree, where applicable, to complete the “Contract Compliance Report” (<http://odeo.ri.gov/documents/odeo-eeo-contract-compliance-report.pdf>), as well as the “Certificate of Compliance” (<http://odeo.ri.gov/documents/odeo-eeo-certificate-of-compliance.pdf>) and submit both documents, along with their Affirmative Action Plan or an Affirmative Action Policy Statement, prior to issuance of a purchase order. For public works projects vendors and all subcontractors must submit a “Monthly Utilization Report”

(<http://odeo.ri.gov/documents/monthly-employment-utilization-report-form.xlsx>) to the ODEO/State Equal Opportunity Office, which identifies the workforce actually utilized on the project.

For further information, contact the Rhode Island Equal Employment Opportunity Office, at 222-3090 or via e-mail at Krystal.Waters@doa.ri.gov.

11. In accordance with R. I. Gen. Laws § 7-1.2-1401 no foreign corporation has the right to transact business in Rhode Island until it has procured a certificate of authority so to do from the Secretary of State. This is a requirement only of the successful vendor(s). For further information, contact the Secretary of State at (401-222-3040).

12. In accordance with R. I. Gen. Laws §§ 37-14.1-1 and 37-2.2-1 it is the policy of the State to support the fullest possible participation of firms owned and controlled by minorities (MBEs) and women (WBEs) and to support the fullest possible participation of small disadvantaged businesses owned and controlled by persons with disabilities (Disability Business Enterprises a/k/a “DisBE”)(collectively, MBEs, WBEs, and DisBEs are referred to herein as ISBEs) in the performance of State procurements and projects. As part of the evaluation process, vendors will be scored and receive points based upon their proposed ISBE utilization rate in accordance with 150-RICR-90-10-1, “Regulations Governing Participation by Small Business Enterprises in State Purchases of Goods and Services and Public Works Projects”. As a condition of contract award vendors shall agree to meet or exceed their proposed ISBE utilization rate and that the rate shall apply to the total contract price, inclusive of all modifications and amendments. Vendors shall submit their ISBE participation rate on the enclosed form entitled “MBE, WBE and/or DisBE Plan Form”, which shall be submitted in a separate, sealed envelope as part of the proposal. ISBE participation credit will only be granted for ISBEs that are duly certified as MBEs or WBEs by the State of Rhode Island, Department of Administration, Office of Diversity, Equity and Opportunity or firms certified as DisBEs by the Governor’s Commission on Disabilities. The current directory of firms certified as MBEs or WBEs may be accessed at <http://odeo.ri.gov/offices/mbeco/mbe-wbe.php>. Information regarding DisBEs may be accessed at www.gcd.ri.gov.

For further information, visit the Office of Diversity, Equity & Opportunity’s website, at <http://odeo.ri.gov/> and see R.I. Gen. Laws Ch. 37-14.1, R.I. Gen. Laws Ch. 37-2.2, and 150-RICR-90-10-1. The Office of Diversity, Equity & Opportunity may be contacted at, (401) 574-8670 or via email Dorinda.Keene@doa.ri.gov

13.

Restrictions on Communications – No Bidder-initiated contact, other than normal business activities not associated with this procurement, will be allowed after the issuance of this RFP between Bidders and University employees or their agents regarding this solicitation, except with express permission of the University Purchasing Department. Any such other contact may be considered improper and may disqualify a Bidder from further consideration. The appropriate channel to direct

any communications, concerns or questions regarding the RFP is through the email address provided herein.

If a Bidder fails to notify the University of Rhode Island Purchasing Department contact person of an error in this RFP which was known or reasonably should have been known to the Bidder, the Bidder shall submit a response at the Bidder's own risk. If awarded the contract, the Bidder shall not be entitled to additional compensation or performance time by reason of the error or its later correction.

SECTION 2: BACKGROUND

The URI Pharmaceutical Development Institute (PDI) is positioned to be a university-affiliated Good Manufacturing Practices (GMP) and analytical lab that assists academic, government and industry partners with the custom development and manufacture of pharmaceuticals in a GMP certified facility. Services will include contract manufacturing, early clinical trials, custom formulation and proof of concept. The facility is new and is currently under restoration and will be commissioned in the coming months. We seek Quality Assurance (QA) expertise for the quality oversight and review expertise for commissioning, qualification, and validation documentation and activities associated with PDI's Current Good Manufacturing Practices (CGMP) facility. The Food and Drug Administration (FDA) has enforced regulations (Code of Federal Regulations (CFR) 210 & CFR 211) that require that GMP systems ensure that products are consistently produced and controlled according to quality standards. The GMP guidelines and principles are legal codification of quality and purity that must be followed right from intake of raw materials to manufacturing, testing and packaging of active pharmaceutical ingredients, medical devices and other products so that the end user gets product in its safest and purest form. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. GMP helps to ensure the consistent quality and safety of products by focusing attention on five key elements – people, premises, processes, products and procedures. The Quality Assurance role involves the interpretation of GMP and an integration of their requirements into the quality systems being operated within the PDI. The professional is responsible for assuring compliance with these requirements as they are applied by the PDI.

SECTION 3: SCOPE OF WORK AND REQUIREMENTS

General Scope of Work

Provide Quality, Compliance and Validation expertise and review as it relates to Current Good Manufacturing Practices (CGMP) and Phase-Appropriate Quality Management Systems (QMS) for the URI Pharmaceutical Development Institute.

Specific Activities / Tasks

- Quality oversight of commissioning, qualification, and validation documentation and activities associated with PDI's CGMP facility.

- Perform a gap assessment on Policies, Standard Operating Procedures (SOPs), Forms, and other related controlled documents required to support CGMP manufacturing of Phase 1 clinical trial materials (CTMs) at PDI.
- Review and update of a PDI Quality Plan.
- Provide on-going quality oversight and involvement to maintain PDI's CGMP compliance. Activities included but not limited to:
 - Quality system audits – observing personnel in the manufacturing areas and laboratories to assure they are following relevant procedures and working in compliance with GMP
 - Facility audits – to assure the facilities, equipment and systems are fit for purpose and relevant documentation to support processes are in place
 - Review and approval of standard operating procedures; manufacturing and analytical methodology; protocols and reports for the qualification/validation of processes, facilities, equipment and systems
 - Review and approval of changes or deviations that occur in the manufacture, packaging and testing of investigational products
 - Review and release of batches of investigational products to ensure that they have been manufactured, packaged and testing in accordance with GMP and are suitable for use in clinical trials.
- Serve as PDI's Quality Advisor for discussions with potential and future clients as it relates to compliance and PDI's Quality Management System (QMS).
- Provide QA oversight of the following systems, processes and equipment:
 - Purified water
 - Clean compressed air
 - Compressed gases
 - HVAC
 - Solid-dosage (small molecule) equipment
 - Biologicals (large molecule) equipment
- Must be able to respond to time sensitive issues, on site, within 48 hours

SECTION 4: PROPOSAL

A. Technical Proposal

Narrative and format: The proposal should address specifically each of the following elements:

1. **Staff Qualifications** – Provide staff resumes/CV and describe qualifications and experience of key staff who will be involved in this project. Staff must have GMP experience, including International ISO8, FDA, and Gowning Room expertise.
2. **Capability, Capacity, and Qualifications of the Offeror** - Please provide a detailed description of the Vendor's experience. A list of relevant client references must be provided, to include client names, addresses, phone numbers, dates of service and type(s) of service(s) provided.

3. **Work Plan** – The work plan description shall include a detailed proposed project schedule (by task and subtask), a list of tasks, activities, and/or milestones that will be employed to administer the project, the assignment of staff members and concentration of effort for each, and the attributable deliverables for each and will identify and describe what type of methodology will be utilized in the program.
4. **Approach/Methodology** - This section shall describe the offeror’s understanding of the University’s requirements, including the result(s) intended and desired, the approach and/or methodology to be employed and a work plan for accomplishing the results proposed. The description of the approach shall discuss and justify the approach proposed to be taken for each task, and the technical issues that will or maybe confronted at each stage on the project.

B. Cost Proposal

Provide a proposal cost proposal to include the following...Time - One hourly rate for all work performed (see attached cost proposal rate template in Appendix B) ..

C. ISBE Proposal

See Appendix A for information and the MBE, WBE, and/or Disability Business Enterprise Participation Plan form(s). Bidders are required to complete, sign and submit these forms with their overall proposal in a sealed envelope. Please complete separate forms for each MBE, WBE and/or Disability Business Enterprise subcontractor/supplier to be utilized on the solicitation.

SECTION 5: EVALUATION AND SELECTION

Proposals will be reviewed by a Technical Review Committee (“TEC”) comprised of staff from URI/State Agencies. The TEC first shall consider technical proposals.

Technical proposals must receive a minimum of 60 (85.7%) out of a maximum of 70 points to advance to the cost evaluation phase. Any technical proposals scoring less than 60 points shall not have the accompanying cost or ISBE participation proposals opened and evaluated. The proposal will be dropped from further consideration.

Technical proposals scoring 60 points or higher will have the cost proposals evaluated and assigned up to a maximum of 30 points in cost category bringing the total potential evaluation score to 100 points. After total possible evaluation points are determined ISBE proposals shall be evaluated and assigned up to 6 bonus points for ISBE participation.

The University of Rhode Island reserves the right to select the vendor(s) or firm(s) (“vendor”) that it deems to be most qualified to provide the goods and/or services as specified herein; and, conversely, reserves the right to cancel the solicitation in its entirety in its sole discretion.

Proposals shall be reviewed and scored based upon the following criteria:

Criteria	Possible Points
Staff Qualifications	10 Points
Capability, Capacity, and Qualifications of the Offeror	25 Points
Work Plan	30 Points
Approach Proposed	5 Points
Total Possible Technical Points	70 Points
Cost proposal*	30 Points
Total Possible Evaluation Points	100 Points
ISBE Participation**	6 Bonus Points
Total Possible Points	106 Points

*** Cost Proposal Evaluation:**

The vendor with the lowest cost proposal shall receive one hundred percent (100%) of the available points for cost. All other vendors shall be awarded cost points based upon the following formula:

$$(\text{lowest cost proposal} / \text{vendor's cost proposal}) \times \text{available points}$$

For example: If the vendor with the lowest cost proposal (Vendor A) bids \$65,000 and Vendor B bids \$100,000 for monthly costs and service fees and the total points available are thirty (30), Vendor B's cost points are calculated as follows:

$$\$65,000 / \$100,000 \times 30 = 19.5$$

****ISBE Participation Evaluation:**

A. Calculation of ISBE Participation Rate

1. ISBE Participation Rate for Non-ISBE Vendors. The ISBE participation rate for non-ISBE vendors shall be expressed as a percentage and shall be calculated by dividing the

amount of non-ISBE vendor's total contract price that will be subcontracted to ISBEs by the non-ISBE vendor's total contract price. For example if the non-ISBE's total contract price is \$100,000.00 and it subcontracts a total of \$12,000.00 to ISBEs, the non-ISBE's ISBE participation rate would be 12%.

2. ISBE Participation Rate for ISBE Vendors. The ISBE participation rate for ISBE vendors shall be expressed as a percentage and shall be calculated by dividing the amount of the ISBE vendor's total contract price that will be subcontracted to ISBEs and the amount that will be self-performed by the ISBE vendor by the ISBE vendor's total contract price. For example if the ISBE vendor's total contract price is \$100,000.00 and it subcontracts a total of \$12,000.00 to ISBEs and will perform a total of \$8,000.00 of the work itself, the ISBE vendor's ISBE participation rate would be 20%.

B. Points for ISBE Participation Rate:

The vendor with the highest ISBE participation rate shall receive the maximum ISBE participation points. All other vendors shall receive ISBE participation points by applying the following formula:

$$\begin{aligned} & (\text{Vendor's ISBE participation rate} \div \text{Highest ISBE participation rate} \\ & \quad \times \text{Maximum ISBE participation points}) \end{aligned}$$

For example, assuming the weight given by the RFP to ISBE participation is 6 points, if Vendor A has the highest ISBE participation rate at 20% and Vendor B's ISBE participation rate is 12%, Vendor A will receive the maximum 6 points and Vendor B will receive $(12\% \div 20\%) \times 6$ which equals 3.6 points.

General Evaluation:

Points shall be assigned based on the vendor's clear demonstration of the ability to provide the requested goods and/or services. Vendors may be required to submit additional written information or be asked to make an oral presentation before the Technical Review Committee to clarify statements made in the proposal.

SECTION 6: QUESTIONS

Questions concerning this solicitation may be e-mailed to the University of Rhode Island Purchasing Department at URIPurchasing@uri.edu no later than the time and date indicated on page 1 of this solicitation. Please reference the reference **RFP #100910** on all correspondence. Questions should be submitted in a Microsoft Word attachment in a narrative format with no tables. Answers to questions received, if any, shall be posted on the Division of Purchases' website as an addendum to this solicitation. It is the responsibility of all interested parties to monitor the Division of Purchases website for any procurement related postings such as addenda. If technical assistance is required, call the Help Desk at (401) 574-8100.

SECTION 7: PROPOSAL CONTENTS

A. Proposals shall include the following:

1. One completed and signed **URI Bidder Certification Form** (include in the Technical Proposal original copy only). *Do not include in copies of the Technical or Cost proposal.*
2. One completed and signed **URI W-9** (included in the original copy only) downloaded from the URI Controller website at <https://web.uri.edu/controller/files/W-9-Form-Substitute-URI-2019.pdf> *Do not include any copies in the Technical or Cost proposals*
3.  **Technical Proposal** - describing the qualifications and background of the applicant and experience with and for similar projects, and all information described earlier in this solicitation. The technical proposal is limited to six (6) pages (this excludes any appendices and as appropriate, resumes of key staff that will provide services covered by this request). All copies submitted must include the same information.
 - a. One (1) Electronic copy on a CD-R, marked “Technical Proposal - Original”.
 - b. One (1) printed paper copy, marked “Technical Proposal -Original” and signed.
 - c. One (1) printed paper copy
4.  **Cost Proposal** - A separate, signed and sealed cost proposal reflecting the hourly rate, or other fee structure, proposed to complete all the requirements of this project. *Do not include any copies in the Technical proposals.*
 - a. One (1) Electronic copy on a CD-R, marked “Cost Proposal -Original”.
 - b. One (1) printed paper copy, marked “Cost Proposal -Original” and signed.
 - c. One (1) printed paper copy
5.  **ISBE Proposal** - Two (2) completed (original and copy) versions, signed and sealed Appendix A. MBE, WBE, and/or Disability Business Enterprise Participation Plan. Please complete separate forms for each MBE/WBE or Disability Business Enterprise subcontractor/supplier to be utilized on the solicitation. *Do not include any copies in the Technical proposals.*

B. Formatting of proposal response contents should consist of the following:

1. Formatting of CD-Rs – Separate CD-Rs are required for the technical proposal and cost proposal. All CD-Rs submitted must be labeled with:
 - a. Vendor’s name

- b. RFP #
- c. RFP Title
- d. Proposal type (e.g., technical proposal or cost proposal)
- e. If file sizes require more than one CD-R, multiple CD-Rs are acceptable. Each CD-R must include the above labeling and additional labeling of how many CD-Rs should be accounted for (e.g., 3 CD-Rs are submitted for a technical proposal and each CD-R should have additional label of '1 of 3' on first CD-R, '2 of 3' on second CD-R, '3 of 3' on third CD-R).

Vendors are responsible for testing their CD-Rs before submission as the URI Purchasing Department's inability to open or read a CD-R may be grounds for rejection of a Vendor's proposal. All files should be readable and readily accessible on the CD-Rs submitted with no instructions to download files from any external resource(s). If a file is partial, corrupt or unreadable, the URI Purchasing Department may consider it "non-responsive". USB Drives or any other electronic media shall not be accepted. Please note that CD-Rs submitted, shall not be returned.

2. Formatting of written documents and printed copies:

- a. For clarity, the technical proposal shall be typed. These documents shall be single-spaced with 1" margins on white 8.5"x 11" paper using a font of 12 point Calibri or 12 point Times New Roman.
- b. All pages on the technical proposal are to be sequentially numbered in the footer, starting with number 1 on the first page of the narrative (this does not include the cover page or table of contents) through to the end, including all forms and attachments. The Vendor's name should appear on every page, including attachments. Each attachment should be referenced appropriately within the proposal section and the attachment title should reference the proposal section it is applicable to.
- c. The cost proposal shall be typed using the formatting provided on the provided template in Appendix B.
- d. Printed copies are to be only bound with removable binder clips.

SECTION 8: PROPOSAL SUBMISSION

Interested vendors must submit proposals to provide the goods and/or services covered by this RFP on or before the date and time listed on the cover page of this solicitation. Responses received after this date and time, as registered by the official time clock in the reception area of the University of Rhode Island Purchasing Department, shall not be accepted.

Responses should be mailed or hand-delivered in a sealed envelope marked "RFP #100910" to

MAIL TO:

UNIVERSITY OF RHODE ISLAND
PO BOX 1773
PURCHASING DEPARTMENT
KINGSTON, RI 02881

COURIER:

UNIVERSITY OF RHODE ISLAND
PURCHASING DEPARTMENT
10 TOOTELL RD.
KINGSTON, RI 02881-2010

NOTE: Proposals received after the above-referenced due date and time will not be considered. Proposals misdirected to other University locations or which are otherwise not presented in the URI Purchasing Department by the scheduled due date and time will be determined to be late and will not be considered. Proposals faxed, or emailed, to the URI Purchasing Department will not be considered. The “official” time clock is located in the reception area of the URI Purchasing Department. **(Please be advised that FedEx/UPS do not always arrive by 10:30 am, you would be smart to send your submission to arrive at least one day early)**

SECTION 9: CONCLUDING STATEMENTS

Notwithstanding the above, the University of Rhode Island reserves the right to award on the basis of cost alone, to accept or reject any or all proposals, and to award it in its best interest.

Proposals found to be technically or substantially non-responsive at any point in the evaluation process will be rejected and not considered further.

The University may, at its sole option, elect to require presentation(s) by offerors clearly in consideration for award

If a Vendor is selected for an award, no work is to commence until a purchase order is issued by the University of Rhode Island Purchasing Department.

**APPENDIX A. PROPOSER ISBE RESPONSIBILITIES AND MBE, WBE, AND/OR
DISABILITY BUSINESS ENTERPRISE PARTICIPATION FORM**

A. Proposer's ISBE Responsibilities (from 150-RICR-90-10-1.7.E)

1. Proposal of ISBE Participation Rate. Unless otherwise indicated in the RFP, a Proposer must submit its proposed ISBE Participation Rate in a sealed envelope or via sealed electronic submission at the time it submits its proposed total contract price. The Proposer shall be responsible for completing and submitting all standard forms adopted pursuant to 105-RICR-90-10-1.9 and submitting all substantiating documentation as reasonably requested by either the Using Agency's MBE/WBE Coordinator, Division, ODEO, or Governor's Commission on Disabilities including but not limited to the names and contact information of all proposed subcontractors and the dollar amounts that correspond with each proposed subcontract.
2. Failure to Submit ISBE Participation Rate. Any Proposer that fails to submit a proposed ISBE Participation Rate or any requested substantiating documentation in a timely manner shall receive zero (0) ISBE participation points.
3. Execution of Proposed ISBE Participation Rate. Proposers shall be evaluated and scored based on the amounts and rates submitted in their proposals. If awarded the contract, Proposers shall be required to achieve their proposed ISBE Participation Rates. During the life of the contract, the Proposer shall be responsible for submitting all substantiating documentation as reasonably requested by the Using Agency's MBE/WBE Coordinator, Division, ODEO, or Governor's Commission on Disabilities including but not limited to copies of purchase orders, subcontracts, and cancelled checks.
4. Change Orders. If during the life of the contract, a change order is issued by the Division, the Proposer shall notify the ODEO of the change as soon as reasonably possible. Proposers are required to achieve their proposed ISBE Participation Rates on any change order amounts.
5. Notice of Change to Proposed ISBE Participation Rate. If during the life of the contract, the Proposer becomes aware that it will be unable to achieve its proposed ISBE Participation Rate, it must notify the Division and ODEO as soon as reasonably possible. The Division, in consultation with ODEO and Governor's Commission on Disabilities, and the Proposer may agree to a modified ISBE Participation Rate provided that the change in circumstances was beyond the control of the Proposer or the direct result of an unanticipated reduction in the overall total project cost.

B. MBE, WBE, AND/OR Disability Business Enterprise Participation Plan Form:

Attached is the MBE, WBE, and/or Disability Business Enterprise Participation Plan form. Bidders are required to complete, sign and submit with their overall proposal in a sealed envelope. Please complete separate forms for each MBE, WBE and/or Disability Business Enterprise subcontractor/supplier to be utilized on the solicitation.



**STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS DEPARTMENT
OF ADMINISTRATION
ONE CAPITOL HILL PROVIDENCE, RHODE ISLAND 02908**

MBE, WBE, and/or DISABILITY BUSINESS ENTERPRISE PARTICIPATION PLAN

Bidder's Name:

Bidder's Address:

Point of Contact:

Telephone:

Email:

Solicitation No.:

Project Name:

This form is intended to capture commitments between the prime contractor/vendor and MBE/WBE and/or Disability Business Enterprise subcontractors and suppliers, including a description of the work to be performed and the percentage of the work as submitted to the prime contractor/vendor. Please note that all MBE/WBE subcontractors/suppliers must be certified by the Office of Diversity, Equity and Opportunity MBE Compliance Office and all Disability Business Enterprises must be certified by the Governor's Commission on Disabilities at time of bid, and that MBE/WBE and Disability Business Enterprise subcontractors must self-perform 100% of the work or subcontract to another RI certified MBE in order to receive participation credit. Vendors may count 60% of expenditures for materials and supplies obtained from an MBE certified as a regular dealer/supplier, and 100% of such expenditures obtained from an MBE certified as a manufacturer. This form must be completed in its entirety and submitted at time of bid. **Please complete separate forms for each MBE/WBE or Disability Business Enterprise subcontractor/supplier to be utilized on the solicitation.**

Name of Subcontractor/Supplier:

Type of RI Certification: MBE WBE Disability Business Enterprise

Address:

Point of Contact:

Telephone:

Email:

Detailed Description of Work To Be Performed by Subcontractor or Materials to be Supplied by Supplier:

Total Contract Value (\$):

Subcontract Value (\$):

ISBE Participation Rate (%):

Anticipated Date of Performance:

I certify under penalty of perjury that the forgoing statements are true and correct.

Prime Contractor/Vendor Signature

Title

Date

Subcontractor/Supplier Signature

Title

Date

Appendix B - COST PROPOSAL

Title URI Pharmaceutical Development GMP Quality Assurance, Compliance and Validation Services

Vendor Name _____

	Quantity	Unit of Measure	Unit Price	Extended Price
Year One	100	Hours	\$_____	\$_____
Optional:				
Year Two	100	Hours	\$_____	\$_____
Year Three	100	Hours	\$_____	\$_____
Year Four	100	Hours	\$_____	\$_____
Year Five	100	Hours	\$_____	\$_____



Important Notice

Please note that the address for the URI Purchasing Office has changed although we have **not** moved and are still located in the Dining Services Distribution Center building.

Our new address is: 10 Tootell Road

Due to the added extension of Plains Road, the street name where our building resides has been changed and is now considered an extension of Tootell Road.

Also please remember to **always** write the Bid No. and the Bid Date/Time on the upper left-hand side of your envelope:

Bid No: _____

Bid Date/Time: _____

TO MAIL YOUR BID: University of Rhode Island
P.O. Box 1773
Purchasing Department
Kingston, RI 02881

TO COURIER YOUR BID: University of Rhode Island
Purchasing Department
Dining Services Distribution Center
10 Tootell Road
Kingston, RI 02881-2010