



Solicitation Information

Date: 5/3/2013

RFP # 7463370

TITLE: cGMP Document Management System

Submission Deadline: 5/31/2013 @ 11:00 AM (Eastern Time)

Questions concerning this solicitation may be e-mailed to the Division of Purchases at gary.mosca@purchasing.state.ri.us no later than **5/15/2013 @ 8:00 AM (Eastern Time)**. Please reference the RFQ # on all correspondence and send questions in a *Microsoft Word format*. Questions received, if any, will be answered and posted on the Internet as an addendum to this solicitation. It is the responsibility of all interested parties to download this information.

SURETY REQUIRED: No

BOND REQUIRED: No

Gary P. Mosca
Buyer II

Vendors must register on-line at the State Purchasing Website at www.purchasing.state.ri.us.

NOTE TO VENDORS:

Offers received without the entire completed three-page RIVIP Generated Bidder Certification Form attached may result in disqualification.

THIS PAGE IS NOT A BIDDER CERTIFICATION FORM

SECTION 1 – INSTRUCTIONS AND NOTIFICATIONS TO OFFERERS:

The Rhode Island Department of Administration/Division of Purchases, on behalf of The University of Rhode Island is soliciting proposals for cGMP Document Management System from qualified OFFERERS, and in accordance with the terms of this Request for Quotations and the State's General Conditions of Purchase, which is available at www.purchasing.ri.gov.

To access the State's General Conditions of Purchase, enter our website, click on RIVIP, then click on General Information and then click on Rules and Regulations. Once the Rules and Regulations are displayed, scroll to the bottom of the page and double click on Appendix A, which contains the State's General Conditions of Purchase.

The scope of work is described herein.

Potential Offerers are advised to review all sections of this solicitation carefully and to follow instructions completely, as failure to make a complete submission as described elsewhere herein may result in rejection of the proposal.

Alternative approaches and/or methodologies to accomplish the desired or intended results of this procurement are solicited. However, proposals which depart from or materially alter the terms, requirements, or scope of work defined by this Request will be rejected as being non-responsive.

The state reserves the right to award to one or more offerer. The State also reserves the right to award this project based on pricing alone.

All costs associated with developing or submitting a proposal in response to this Request, or to provide oral or written clarification of its content shall be borne by the offerer. The State assumes no responsibility for these costs.

Proposals are considered to be irrevocable for a period of not less than sixty (60) days following the opening date, and may not be withdrawn, except with the express written permission of the State Purchasing Agent.

All pricing submitted is to be considered fixed, unless otherwise indicated herein.

Proposals misdirected to other State locations or which are otherwise not present in the Office of Purchases at time of opening for any cause will be determined to be late and will not be considered.

It is intended that an award pursuant to this request will be made to a prime contractor, who will assume responsibility for all aspects of the work. Joint venture and cooperative proposals will not be considered, but subcontractors are permitted, provided that their use is clearly indicated in the OFFERER's proposal, and that the subcontractor(s) proposed to be used are identified in the proposal.

In accordance with Title 7, Chapter 1.1 of the General Laws of Rhode Island, no foreign corporation, a corporation without a Rhode Island business address, shall have the right to transact business in the state until it shall have procured a Certificate of Authority to do so from the Rhode Island Secretary of State (401-222-3040). *This is a requirement only of the selected vendor(s).*

Bidders are advised that all materials submitted to the State of Rhode Island for consideration in response to this RFQ will be considered to be public records, as defined in Title 38 Chapter 2 of the Rhode Island General Laws, without exception, and will be released for inspection immediately upon request, once an award has been made.

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 RFQ.

The offerer should be aware of the State's Minority Business Enterprise (MBE) requirements, which addresses the State's goal of ten per cent (10%) participation by MBE's in all State procurements. For further information, contact the MBE Administrator, at (401) 222-6253 or visit the website at www.rimbe.org.

SECTION 2 – SCOPE OF WORK

BACKGROUND AND PURPOSE

INTENT:

To select and implement a proven cGMP Document Management System for The University of Rhode Island, College of Pharmacy (URI COP) in order to:

- Handle the large volume of documentation needed for the production of pharmaceutical and biologicals under strict FDA guidelines. A small facility such as the one at the URI College of Pharmacy literally to tens of thousands of individual documents.
- Manage the adjustment of documentation that constantly changes as work progresses.
- Control and update all of the documentation needed for validation and quality control at the facility.

SPECIFIC REQUIREMENTS:

1. Control of documents

Manage and control documents created in Microsoft Office or similar applications such as policies, standard operating procedures (SOPs), facility plans, instructions, etc.

Must meet requirements of ISO 9001.

- Manage on-line editing, reviews and electronic approval
- Manage on-line versioning
- Maintains automatic versioning history of transaction for audit trail
- Provides automated document updating of insert fields with versioning information like version, authorizer, version dates.
- Tree view folder structures with security controls on viewing, modify, printing etc.
- Automated review schedules that notify staff when review is due
- Provides document status reporting

2. Maintain and control training

- Manage and control all training records
- Link training records against a document such as SOP
- Set up on-line training competency tests against a document or group of documents
- Maintain staff qualifications, licenses and skills

- Design the fields and layout of the training records required
- Provide notification for re-training when a document is updated
- Set up user competency tests
- Keep track of training status
- Assign defaults on who is responsible to trainers and trainees
- Set triggers to automatically notify someone when a set criteria has changed

3. Maintain and control records

Manage and control electronic records (such as training, calibration, maintenance, using schedules behind each record to notify who is responsible for maintaining the record from time to time.

- Design the fields and layout to be completed on each page
- Assign defaults on who is responsible
- Import data by linking to external sources
- Set triggers to automatically notify someone when a set criteria has changed

4. Users

- We require a solution which will allow us to have 5 users simultaneously using it.

5. Hardware

- We will require the provision of the hardware appropriate to run the solution, it should either be installed by the vendor prior to delivery or onsite by the vendor.
- The hardware should have a 3 year onsite warranty from the manufacturer.
- A UPS capable of running the hardware for 1 hour should be provided.

6. Support

- We will require an initial 1 year support contract included with the system and pricing for the next 4 years provided for annual renewal. The system should remain operable in the case that the support contract is not renewed.

7. Location of the system

- The system will be physically housed in the URI College of Pharmacy cGMP facility on hardware provided by the vendor.

8. Applicable regulations and standards

- ISO 9001
- ISO 1385
- US Federal regulations (21CFR Part 11)

GENERAL DESCRIPTION:

The successful offer will provide a “turn-key” solution (software and hardware) that will ensure the implementation and maintenance of a cGMP Documentation Management System in accordance with federal regulations (21CFR Part 11) and other worldwide recognized quality standards : ISO9001 and ISO 13485.

The solution must be a robust, secure, solution with a proven track record.

GENERAL SCOPE OF WORK TO BE PREFORMED:

Successful offerer will provide a cGMP Document Management System (software and hardware) that is validated in accordance with FDA&ICH rules and regulations. They will also provide training for all intended users.

PROJECT KEY COMPONENTS

- Provide access to a document management system that meets the project requirements.
- Train users from URI COP.
- Insure that all required specifications are met.
- Provide ongoing technical support.

PROPOSAL QUESTIONS & SUBMISSION

Questions, in **Microsoft Word Format**, concerning this solicitation, may be e-mailed to the Division of Purchases at gary.mosca@purchasing.state.ri.us no later than the date & Time indicated on page 1 of this solicitation. Please reference the RFQ # on all correspondence.

Responses to questions received, if any, will be provided, as an Addendum to this RFQ, and posted on the Rhode Island Division of Purchases website at www.purchasing.ri.gov. It is the responsibility of all interested parties to download this additional information. *If technical assistance is required to download, call the Help desk at (401) 222-2142, ext. 134.*

Responses to this solicitation to provide the required services must be received by the Division of Purchases **on or before the date & time indicated on page one of this document.**

Responses (a clearly marked original plus 4 copies should be mailed or hand-delivered in a sealed envelope marked RFQ #7463370 RFQ Title: **cGMP Document Management System** to;

RI Dept. of Administration
Division of Purchases, 2nd floor
One Capitol Hill
Providence, RI 02908-5855

NOTE: Proposals received after the above-referenced due date and time will not be considered. Proposals misdirected to other State locations or which are otherwise not presented in the Division of Purchases by the scheduled due date and time will be determined to be late and may not be considered. Proposals faxed, or emailed, to the Division of Purchases will not be considered. The "official" time clock is located in the reception area for the Division of Purchases. **(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)**

RESPONSE CONTENTS

Responses should include the following:

- A completed and signed three-page RIVIP generated bidder certification cover sheet (downloaded from the RI Division of Purchases Internet home page at www.purchasing.ri.gov)
- A completed and signed W-9 Form downloaded from the RI Division of Purchases Internet home page at www.purchasing.ri.gov
- A separate, signed and sealed, Cost Proposal reflecting the fee structure proposed for this scope of service (**Phase II, for applicants that are "short-listed"**)
- A *separate* Technical Proposal describing the background, qualifications, and experience with and for similar programs, as well as the work plan or approach proposed for this requirement.
- In addition to the multiple hard copies of proposals required, Respondents are requested to provide their proposal in electronic format (CDRom or Diskette). Microsoft Word / Excel OR PDF format is preferable. Only 1 electronic copy is requested.

EVALUATION CRITERIA

Responses will be evaluated in two parts. Part one will require the technical submission and will be evaluated on the following criteria:

The Technical Proposal must contain the following sections:

a. Executive Summary

The Executive Summary is intended to highlight the contents of the Technical Proposal and to provide State evaluators with a broad understanding of the offeror's technical approach and ability.

b. Offeror's Organization and Staffing

This section shall include identification of all staff and/or subcontractors proposed as members of the project team, and the duties, responsibilities, and concentration of effort which apply to each (as well as resumes, curricula vitae or statements of prior experience and qualification).

c. Work Plan/Approach Proposed

This section shall describe the offeror's understanding of the State's requirement, 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 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. 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 tutor training methodology will be utilized in the program.

- d. Previous Experience and Background, including the following information:
- i. A comprehensive listing of similar projects undertaken and/or similar clients served, including a brief description of the projects;
 - ii. A description of the business background of the offeror (and all subcontractors proposed), including a description of their financial position.
- e. The offeror's status as a Minority Business Enterprise (MBE), certified by the Rhode Island Department of Administration, and/or a subcontracting plan which addresses the State's goal of ten per cent (10%) participation by MBE's in all State procurements. Questions concerning this requirement should be address to Charles Newton, M.B.E. Officer, at (401) 222 6253.

SECTION 5 - EVALUATION AND SELECTION

The State will commission a Technical Review Committee, which will evaluate and score all proposals, using the following criteria:

Criteria	Possible Points
Executive summary	5
Offerer's organization & staffing	10
Meets requirements	30
Offerer's work plan & previous experience	5
Total Possible Technical Points	50 Points
Cost [calculated as (lowest responsive cost proposal) divided by (this cost proposal) times 50 points]	50
Total Possible Points	100 Points

All OFFERERS must receive a minimum score of 35 points on the technical submission. Offers not scoring at least 35 points will not be considered further.

A Technical Review Sub-Committee will review all submissions. After review, one or more OFFERERS may be invited to present to the sub-committee and answer questions.

Proposals found to be technically or substantially non-responsive at any point in the evaluation process will be rejected and not considered further. The State reserves the right to reject any or all proposals submitted and to waive any informalities in any vendor's proposal. The State may, at its sole option, elect to require presentation(s) by offerors clearly in consideration for award.

The ranked findings and selection recommendation will be submitted to the State's Architectural/ Engineering Consultant Services Selection Committee, and forwarded to the Director of Administration for final selection consideration.

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