**Request for Proposal**

**Facility and Process Engineering Consultants**

**RFP # 2020-013**

I. Summary of Deadlines

|  |  |
| --- | --- |
| Release of Request for Proposal | April 6, 2020 |
| Confirmation of interest due | April 13, 2020 |
| Fact-finding questions received by | April 20, 2020 |
| Response to fact-finding questions | April 27, 2020 |
| **Proposals due** | May 5, 2020 |
| Selection of short-listed suppliers | May 15, 2020 |
| Bidders notified of decision | May 28, 2020 |

Note that PATH reserves the right to modify this schedule as needed. All parties will be notified of any changes simultaneously by email.

**II. PATH Statement of Business**

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. For more information, please visit [www.path.org](http://www.path.org).

**III. Project Background and Purpose of RFP**

**A. Project Background:** PATH is developing vaccines in various disease areas, including malaria, enteric diseases, and respiratory pathogens that could be bacterial, viral, or monoclonal antibodies. PATH is working with many partners in developing countries to support their facilities and quality systems to be compliant and efficient and increase global vaccine supply. This effort will leverage process engineers as consultants to support these needs. PATH’s goal is to put one or more Master Service Agreements (MSA) in place through December 2023 to cover process engineering needs for various PATH programs. The expectation is that the MSA(s) will allow for a broad agreement between PATH and the selected vendor(s) on an agreed-upon pricing strategy for the first year, and updated each subsequent year that the MSA is in effect. Annual pricing adjustments can be based on a fixed increase of X% per year, or an updated price list renewed each year. Once the MSA is put in place, work orders will be issued to capture program specific needs. The scope, timeline, and budget of each work order will be developed and negotiated separately.

**B. Purpose of the RFP:** To enable support of vaccine development and continued manufacturing of vaccines to meet global demand, PATH is seeking process engineers.

This RFP is being issued directly to several consulting firms who advertise experience and capabilities in process engineering, to solicit proposals for a competitive review and selection of the most qualified vendor(s). The intention is to first put a broad MSA in place with the most suitable vendor(s) and then subsequently develop work orders for project-specific scopes of work that would be attached to the MSA according to the needs of PATH’s vaccine development programs.

**C. Proposed Project Timeline:**

Timelines will vary for each work order under the MSA and will be defined by PATH and the selected vendor during the development and negotiation of each work order.

**IV. Scope of Work and Deliverables**

**Expertise requirements for the vendor:**

1. Offer a mix of senior, mid-level, and junior-level engineers, as needed, to ensure the appropriate levels of expertise and cost for each work order.
2. Individual consultants with expertise in Facility design, HVAC systems, installation, qualification, and validation of vaccine manufacturing equipment and systems.
3. Technically sound in understanding of mechanical, electrical, automation, and computer system validation.
4. Experienced at delivering commercial products at scale and a framework for making impactful technical decisions.

**Illustrative scope of work (may vary for specific work orders):**

1. Meeting with representatives of the relevant departments and management at the manufacturing site to align on objectives.
2. Facility walk-through to understand the layout and flow-through of personnel, product, raw materials, equipment, and segregation concept. Suggest any changes in the process flow or design etc., wherever applicable.
3. Environmental monitoring:
   1. Review documentation at each site pertaining to environmental monitoring programs, water systems, clean utilities, warehousing quality control, and assurance units.
   2. Conduct on-site evaluation during active manufacture, to observe implementation of current Good Manufacturing Practices, environmental monitoring procedures, and aseptic practices during formulation and filling.
4. Review the validated state of site Facility, Equipment, Water systems (WFI, and clean steam), Compressed air and Industrial gases as per the requirements of the process, HVAC systems, Manufacturing floor plan, and Automated systems, computer system validation.
5. Review validation master plans/project plans (VMP), revalidation plans and standard operating procedures (SOP), plant support groups (Operations, Maintenance, Technical Services, Quality, IQ, OQ, PQ, FAT, etc.), packaging, and storage, as necessary.
6. Review of documentation related to facility/equipment validation, equipment infrastructure, suitability for use, and preventive maintenance programs.
7. Conduct interviews with representatives of the relevant functional areas and document review to define an effective way to implement any remedial actions appropriate for compliance, safety, and efficacy that may be necessary for future approvals and Technology transfers.
8. Preparation of gap assessments reports with remedial actions and CAPAs.
9. Provide as-needed support of remediation activities, re-design, and improvement of status quo.
10. Conduct of a close-out meeting with the appropriate representatives from PATH and the Manufacturing facility to review the findings and recommendations.
11. Assessment of process steps or analytical methods and its related activities, commissioning, validation of equipment and processes
12. Assessment of quality engineering status, quality systems, critical systems such as WFI, clean steam, etc.
13. Assessment of good manufacturing practice in supply chain, such as shipment validation, cold chain logistics, etc.

**Not in scope:**

Assessments of any elements unrelated to vaccine manufacturing.

**Deliverables:**

1. A written report covering the activities defined in each work order. May include:
   1. Evaluation of current environmental monitoring plans and procedures.
   2. Evaluation of the facility, equipment status, and practices at the manufacturing facility to proactively identify any potential impediments to sustained manufacture of the vaccine.
   3. Identification of any gaps with prioritized recommendations for remediation, in an actionable fashion for evaluations.
2. Monthly teleconference or email updates, as requested

**V. Proposal Requirements - Financial**

1. Provide itemized costs for the illustrative scope of work and deliverables outlined in Section IV. Bids should include itemized costs for key elements of the scope of work, as follows:

1. Percent participation in total level of effort according to key staff
2. Rates for each level/position
3. Estimated total level of effort and associated costs for the illustrative scope of work
4. Itemization of all other costs, e.g., agency costs, agency fees, service tax, administrative costs, travel, supplies, etc.

***Special Note on Indirect costs:***

*Indirect costs are overhead expenses incurred as a result of the project but not easily identified with the project’s activities. These are administrative expenses that are related to overall general operations and are shared among projects and/or functions. Examples include executive oversight, existing facilities costs, accounting, grants management, legal expenses, utilities, and technology support that cannot be budgeted/invoiced as direct expenses. PATH requires substantiation of vendors’ indirect cost structures.*

*Please identify any indirect costs in your proposed pricing structure and provide a description of how indirect costs are estimated, what they cover, and how they are applied to the budgeted costs. To the extent possible, identifiable (allocable) costs should be documented and justified in the proposal as direct costs, including those for dedicated ongoing project management and support.*

*Please also note that PATH projects are funded by a variety of funders with varying indirect rate reimbursement policies. Indirect rate allowances required by PATH’s funders apply both to the primary grantee, sub-grantees, and subcontracts that are part of the proposal.*

**VI. Proposal Requirements – Technical**

* Description of technical approach.
* Discussion of project management and roles of project team.
* Timeline to meet the deliverables.
* Potential obstacles and plan to overcome them.
* Identification of major internal and external resources.

Provide information on your overall qualifications, including:

* Profile of relevant corporate qualifications.
* Profile of relevant experience and examples of related work.
* Qualifications of key members of the proposed project team (attach CVs and provide details of back-up/standby teams). Language capabilities of key team members, if applicable.
* Number of years in business.
* Annual revenue
* If your company has more than one location, please indicate these qualifications for the site that is responding.

**VII. Proposal Evaluation Criteria**

The following is a list of significant criteria against which proposals will be assessed. The criteria are listed in order of priority; however, they are not weighted.

1. Technical approach (as detailed Section VI)
2. Experience (as detailed in Section IV - Expertise Requirements for the Vendor)
3. Cost (as detailed in Section V).

Note: PATH reserves the right to include additional criteria.

# VIII. Instructions and Deadlines for Responding

A. PATH contacts:

Procurement Contact: Jessica Nguyen, jenguyen@path.org

Technical/Program Contact: Lakshmi Khandke, lkhandke@path.org

B. Confirmation of interest:

Please send a statement acknowledging receipt of this solicitation and your intent to respond or not respond no later than April 13, 2020. Send the confirmation to the contacts listed above.

C. Fact-finding questions:

Questions on this solicitation will be accepted via email to the contacts listed above through April 20th. Questions and answers to all questions will be provided to all participants who confirmed interest on April 27th, 2020. Inquiries after this date cannot be accommodated.

D. Proposals due:

Completed proposals should be submitted by email to the contacts listed above by May 5th, 2020. The subject line of the email should read: **RFP 2020-013 [ your company name]**

We advise that you send files in commonly recognized MS office or PDF formats. We will not accept responsibility for resolving technical transmission problems with proposals. A hard copy of the proposal should not be sent. Your proposal should only include information specific to accomplishing the scope of work. Additional information submitted outside of the proposal requirements will be reviewed at PATH’s discretion only. Elaborate materials, artwork or other information not directly related to the scope of work are not suggested.

**E. Selection of short-list:**

PATH reserves the right to select a short list from the bids received. PATH has the option to interview and discuss specific details with those candidates who are on the short-list.

F. Conclusion of process:

Applicants will be notified of PATH’s decision by no later than May 28th, 2020. Final award is subject to the terms and conditions included in this solicitation, as well as successful final negotiations of all applicable terms and conditions affecting this work.

**IX. Terms and Conditions of the Solicitation**

A. Notice of non-binding solicitation:

PATH reserves the right to reject any and all bids received in response to this solicitation and is in no way bound to accept any proposal.

B. Confidentiality:

All information provided by PATH as part of this solicitation must be treated as confidential. In the event that any information is inappropriately released, PATH will seek appropriate remedies as allowed.

Proposals, discussions, and all information received in response to this solicitation will be held as strictly confidential, except as otherwise noted.

All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section VIII. A. Contacting third parties involved in the project, the review panel, or any other party may beconsidered a conflict of interest and could result in disqualification of the proposal.

**C. Conflict of Interest Disclosure:**

Suppliers bidding on PATH business must disclose, to the procurement contact listed in the RFP, any actual or potential conflicts of interest. Conflicts of interest could be present if; there is a personal relationship with a PATH staff member that constitutes a significant financial interest, board memberships, other employment, and ownership or rights in intellectual property that may be in conflict with the supplier’s obligations to PATH. Suppliers and PATH are protected when actual or perceived conflicts of interest are disclosed. When necessary, PATH will create a management plan that provides mitigation of potential risks presented by the disclosed conflict of interest.

**D. Communication:**

All communications regarding this solicitation shall be directed to appropriate parties at PATH indicated in Section VIII. A. Contacting third parties involved in the project, the review panel, or any other party may beconsidered a conflict of interest and could result in disqualification of the proposal.

**E. Acceptance:**

Acceptance of a proposal does not imply acceptance of its terms and conditions. PATH reserves the option to negotiate on the final terms and conditions. We additionally reserve the right to negotiate the substance of the finalists’ proposals, as well as the option of accepting partial components of a proposal if appropriate.

**F. Right to final negotiations:**

PATH reserves the option to negotiate on the final costs and final scope of work, and also reserves the option to limit or include third parties at PATH’s sole and full discretion in such negotiations.

**G. Third-party limitations:**

PATH does not represent, warrant, or act as an agent for any third party as a result of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.

**H. Proposal validity:**

Proposals submitted under this request shall be valid for 90 days from the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.