

Request for proposal # 2024-004



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Request for proposal number: 2024-004

For: Small-scale manufacturing of a prototype dual-chambered injection device

1. Request for proposal schedule

Activity	Date and time
Request for proposal (RFP) released	2/20/2024
Confirmation of interest in submitting a proposal	2/27/2024
Deadline for fact-finding questions	2/27/2024
PATH to respond to fact-finding questions	3/15/2024
Deadline for submission of proposal in response to the RFP	4/5/2024
Award decision (to be followed by contract negotiations)	4/26/2024

Note: PATH may change the dates at its discretion. Changes will be communicated to those who confirmed their intent to submit a proposal.

2. PATH statement of business

PATH is a global nonprofit dedicated to achieving health equity. With more than 45 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world's most pressing health challenges. Learn more at www.path.org.

3. Contracting requirements

- 3.1 The contracting authority shall be PATH or any one of its affiliates either directly or on behalf of operations countries or programs.
- 3.2 The commercial contracting terms and conditions will be negotiated with the successful supplier toward the end of the selection process.
- 3.3 By submitting a proposal, the supplier confirms that they will abide by the RFP terms and PATH policies, especially our Code of Ethics (<https://www.path.org/about/code-ethics/>), and general good

practices regarding inclusivity, diversity, fair trading, health and safety, records management, anti-fraud and corruption, and environmental policy, among others.

- 3.4 Duration of the contract is estimated to be 12 months.

4. Solicitation terms and conditions

- 4.1 **Notice of nonbinding 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.
- 4.2 **Confidentiality:** Suppliers shall treat all information provided by PATH as part of this solicitation as confidential. If any information is inappropriately released, PATH may seek appropriate remedies as allowed under applicable law.
- 4.3 **Conflict of interest disclosure:** Suppliers bidding on PATH business (also referenced herein as “bidders”) must disclose, to the procurement contact listed in section 5.1 of this 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, a board membership, other employment, or ownership or rights in intellectual property that may 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.
- 4.4 **Acceptance:** Bidder’s submission of a proposal means the bidder accepts all terms and conditions set forth in the RFP. PATH’s acceptance of a proposal does not mean acceptance of the proposal’s 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 RFP finalists’ proposals, as well as the option of accepting partial components of a proposal if appropriate.
- 4.5 **Right to final negotiations:** PATH reserves the option to negotiate on the final costs and final scope of work and reserves the option to limit or include third parties in such negotiations at PATH’s sole and full discretion.
- 4.6 **Third-party limitations:** PATH does not represent, warrant, or act as an agent for any third party because of this solicitation. This solicitation does not authorize any third party to bind or commit PATH in any way without our express written consent.
- 4.7 **Proposal validity:** Proposals submitted under this RFP shall be valid for at least 90 days following the date the proposal is due. The validity period shall be stated in the proposal submitted to PATH.
- 4.8 **Limitation of liability:** The terms and conditions set forth in this RFP do not exclude or limit the liability of PATH or the supplier in relation to fraud or in other circumstances giving rise to liability under any applicable law.
- 4.9 **Tender costs and liability:** Bidders are responsible for obtaining all information necessary for preparation of their proposal and for all costs and expenses incurred in preparation of the proposal. Subject to the “Limitation of liability” section in this RFP (section 4.8), the bidder accepts by their participation in response to this RFP, including without limitation the submission of the proposal, that it will not be entitled to claim from PATH any costs, expenses, or liabilities that it may incur in tendering a response to this RFP, irrespective of whether their proposal is successful.

- 4.10 **PATH's variation or termination rights:** PATH reserves the right to vary or terminate this RFP process with written notice to all suppliers from which it has received proposals. It is intended that this solicitation process will take place in accordance with the provisions of this RFP, but PATH reserves the right to terminate, amend, or vary (to include, without limitation, in relation to any time scales or deadlines) the solicitation process by notice to all suppliers from which it has received proposals. Subject to section 4.8, "Limitation of liability," PATH will have no liability for any losses, costs, or expenses caused by its termination, amendment, or variation of this RFP.
- 4.11 **Joint venture or consortium or subcontractors:** Any lead supplier that submits a proposal in response to this RFP takes responsibility and accountability for enforcing the RFP requirements set forth herein among the members of the joint venture or consortium, and each of their advisers, subcontractors, and staff.
- 4.12 **Payment and invoicing:** PATH will pay correctly addressed and undisputed invoices within 30 days. Suppliers shall ensure comparable payment provisions apply to payments to their downstream parties. Advance payment is not preferred. If an advance payment is envisaged and is other than industry or country known practice, such must be made clear in the financial proposal to PATH.
- 4.13 **PATH values and diversity, equity, and inclusion:**
- 4.13.1 Supplier diversity statement/commitment: PATH works to create mutually beneficial business relationships with diverse suppliers and consultants that strengthen the communities in which we operate. We are committed to developing mutually beneficial relationships with small, minority-owned, woman-owned, and other underrepresented business enterprises and consultants. The primary goal of PATH's Supplier Diversity Program is to provide opportunities to diverse suppliers and consultants that satisfy our procurement and contractual standards and reflect the communities we serve; build resilient supply chains that drive economic growth and cost savings; and finally, advance our commitment to diversity, equity, and inclusion.
- 4.13.2 Supplier diversity at PATH: Supplier diversity at PATH means that we seek and include small, minority-owned, woman-owned, and other underrepresented businesses and consultants in our procurement policies, practices, and vendor providers. PATH recognizes that supplier diversity creates a sustainable competitive advantage for the organization, enhances our commitment to equity, and has a positive impact on the communities we serve.
- 4.13.3 Planning and reporting: Suppliers are expected to live up to PATH's diversity, equity, and inclusion vision and state how they have included diverse supplier groups in their supply chain as they aim to partner with PATH in delivery of this project. The successful supplier will report to PATH every six months what portion of the work has been delivered through an inclusive workforce and underrepresented supplier groups.

5. Instructions for responding

- 5.1 **PATH contacts:** All communications regarding this solicitation shall be directed to the contacts below. Contacting third parties involved in the project, the review panel, or any other party may be considered a conflict of interest and could result in disqualification of the proposal. All documents

required as part of the proposal must be submitted to the contact email listed by the deadline for submission.

Contact email: dualchamberRFP@path.org

- The subject line of all emails regarding the proposal should read: RFP #2024-004 Your Company Name.
- All documents for this RFP should be submitted as Microsoft Word, Microsoft Excel, or Portable Document Format (PDF) files.

- 5.2 **Confirmation of interest:** Please send a statement acknowledging receipt of this solicitation and your intent to respond or not respond no later than the date noted in the schedule in section 1. Send the confirmation to the contact listed above. Once a confirmation of interest is received, a confidentiality agreement will be sent to the prospective bidder to enable provision of further details that may be needed to complete that bid.
- 5.3 **Proposal technical content:** Bidders are advised to provide only what is required. The proposal must be clear, concise, unambiguous, and directly address the requirements stated.
- 5.4 **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 short-listed.

6. Specifications/Scope

6.1 Scope of work/terms of reference/specifications:

Purpose: PATH is seeking a contract manufacturing organization (CMO) to produce a small-scale run of dual-chambered injection devices that will be evaluated by the PATH Product Development Engineering Laboratory. PATH expects that production can be non-Good Manufacturing Practices and non-sterile for this phase of the work.

Scope: The CMO will produce 200 prototype devices. This will include the following activities:

- Thermoforming a blister-type device from polymer film.
- Loading a desiccant tablet into the dry chamber.
- Heat sealing the two halves of the device together.
- Creating a frangible seal between the two chambers.
- Loading water into the liquid chamber.
- Sealing a needle port to the device to close off the liquid chamber.
- Loading the device and loose desiccant tablet into a foil pouch and sealing.
- Measuring mass to 0.01 mg of:
 - Desiccant tablets (for pouch and dry chamber)
 - Device with desiccant tablet
 - Device with desiccant tablet and water
 - Device with water, loose desiccant tablet, and pouch

The CMO will be responsible for providing equipment and tooling required to manufacture and assemble the devices. This will include multilayer heat-sealable foil pouching material.

PATH will provide:

- Design specifications
- Device body material (lamine film)
- Device port material
- Desiccant tablets

6.2 Deliverables:

- 200 prototype devices that meet the design specifications.
- Mass measurements of devices and associated materials for use in environmental testing.

7. Fact-finding questions

- 7.1 Fact-finding questions should be sent to the email listed in section 5.1 by the date in the RFP schedule (section 1). Fact-finding questions received after this deadline cannot be accommodated.
- 7.2 It is advisable that any fact-finding questions refer to a specific section of the RFP; and to the extent possible, be aggregated rather than sent individually.
- 7.3 In line with transparency principles, all fact-finding questions and all of PATH's responses to these questions will be shared with all those who confirmed their intent to bid. Questions will be anonymized and answered if PATH reasonably determines that such fact-finding questions do not disadvantage any potential supplier and are not commercially in confidence. If such are commercially in confidence, they shall be handled in line with PATH's policy on information and data.
- 7.4 PATH may request from a bidder additional information at any time ahead of award, and the bidder will be expected to provide the requested information within the time frame given. Failure by a bidder to provide supplementary information to PATH in a timely manner may lead to the proposal being rejected in full or disqualification from the procurement process.

8. Qualifications, evaluation criteria, and selection

- 8.1 **Supplier qualifications:** In relation to the scope, provide information on your overall qualifications, including:

Technical proposal: The technical proposal should describe how the scope will be achieved, demonstrate that the company meets required technical capabilities, and as appropriate, desired experience/qualifications. Please limit your proposal to a maximum of 5 pages. CVs, company informational materials, and other supporting documentation does not apply to the 5-page limit.

Required technical capabilities:

- Ability to:

- Thermoform polymer films.
- Heat seal plastic films and multilayer foil pouches.
- Heat seal after loading solid and liquid contents.
- Create frangible seals with polymer films.
- Plastic port insert heat seal.
- Availability of:
 - Low-humidity room (less than 20% relative humidity) with mass measurement and manufacturing capabilities.
 - Mass measurement to 0.01 mg.

Required documentation:

- Profile of relevant experience and examples of related work.
- Qualifications of key members of the proposed project team (attach CVs/resumes).
- Number of years in business.
- If your company has more than one location, please indicate the qualifications for the site that is responding.

Desired experience/qualifications:

- Demonstrated experience with the following:
 - Thermoforming polymer film.
 - Heat sealing plastic films and multilayer foil pouches.
 - Creating frangible seals in polymer films.
 - Plastic port insert heat sealing.
 - Medical device design/production.
- International Organization for Standardization 13485 certification and/or US Food and Drug Administration Quality System Regulation compliant.
- Other desirable qualifications:
 - Company is woman-owned and/or minority-owned.
 - Demonstration of using woman-owned and/or minority-owned suppliers.

Financial proposal: The financial proposal is expected to reflect reasonable and appropriate costs for the completion of the scope of work. The financial proposal should include an Excel budget and a budget narrative. There is no page limitation for the budget narrative. Please see the Annex for further details around expectations for the financial proposal.

Required financial information:

- A budget for the scope of work that contains enough detail to enable an analysis.

- A budget narrative that follows the budget layout and enables an understanding of how costs are derived.
- Completed tax form (W-8 or W-9).

8.2 Selection and evaluation criteria:

- Stage 1: Proposals will be checked for completeness in terms of submission on time, technical proposal, financial proposal, and all required information. Proposals that are correctly completed will proceed to Stage 2. Any proposals submitted late, incomplete, or with omissions may be rejected at this point. If a proposal is rejected at this stage, it will automatically be disqualified from further review.
- Stage 2: If a proposal passes the Stage 1 evaluation, it will be evaluated based on the required technical capabilities. If the proposal demonstrates that all of the required technical capabilities are met, it will proceed to Stage 3.
- Stage 3: If a proposal passes the Stage 2 evaluation, it will be evaluated in detail according to the evaluation methodology below. Information provided as part of qualification may be verified at this stage, and as part of the evaluation process.

8.3 Evaluation criteria: Proposals will be assessed to determine the most economically advantageous using the criteria and weightings in Table 1 and will be assessed strictly based on the proposal submitted.

Table 1. Proposal evaluation criteria and weighting.

Evaluation criteria	Weight (100%)
Desired experience/qualifications	45%
Required documentation	30%
Financial requirements	20%
Other desirable qualifications	5%

8.4 **Scoring model:** Desired experience/qualifications will be scored based on the model in Table 2.

Table 2. Proposal scoring model.

Assessment	Score	Summary	Interpretation
Excellent	3	Meets all requirements and qualifications. Exceeds expectations.	As well as addressing all or the vast majority of bullet points under each criterion heading, proposal demonstrates a deep understanding of the project. All solutions offered are linked directly to project requirements and show how they will be delivered.
Good	2	Meets all requirements and qualifications. Meets expectations.	Reflects that the bidder has addressed, in some detail, all or most of the bullet points listed under each criterion heading. Evidence is included that shows not only what will be provided but also gives some detail of how this will be achieved. Bidders should make clear how their proposals relate directly to the aims of the project and be specific, rather than general, in the way proposed solutions will deliver the desired outcomes.
Adequate	1	Meets most requirements and qualifications. Does not meet expectations.	Addresses the majority of the bullet points under each criterion heading, but lacks some clarity or detail on how the proposed solutions will be achieved. Evidence is provided; however, generic or general statements are not specifically directed toward the aims/objectives of the project.
Inadequate	0	Does not meet requirements or evidence of meeting requirements missing.	Reflects that the bidder has not provided evidence to suggest how they will address several bullet points under the evaluation criteria headings. Proposal is, in part, sketchy, with little or no detail given of how the project requirements will be met. Evidence provided is considered weak or inappropriate and it is unclear how the evidence relates to the desired outcomes.

The financial requirements and other desirable qualifications will be given yes (2 points) or no (0 points) scores, with the exception of the total cost. Total cost scoring is described in section 8.4.1.

8.4.1 **Financial evaluation:** The “total cost” will be evaluated for the purposes of financial evaluation and prices are not subject to any pricing assumptions, qualifications, or indexation other than that stated in the financial proposal. A maximum score of 8 (financial score/points allocated in the evaluation criteria) will be awarded to the proposal offering the lowest “overall cost.” Other proposals will be awarded a financial score by application of the following formula: (lowest overall cost/cost being evaluated) * 8 (rounded to one decimal

place) = financial score. The Annex provides detailed guidelines on inclusions and exclusions for your consideration in preparation of the financial proposal.

- 8.4.2 **Moderation and application of weightings:** The evaluation panel will moderate criteria that have substantial divergence among the individual scores and agree on the final score (as opposed to averaging scores). The score for each award criterion will be amalgamated to give a percentage score out of 100.
- 8.4.3 **The recommended winning supplier:** The recommended award winner will be the proposal that receives the highest score out of 100 (combined technical and financial scores) when applying the above evaluation methodology.
- 8.4.4 **Feedback:** After the winning supplier is announced, applicants who were not selected may request feedback on their submissions.

Annex. Financial proposal

The financial proposal should be submitted in Excel format with unlocked cells. Example tables for the Excel budget follow the cost description expectations in this Annex. The accompanying budget narrative can be used to further explain costs within the budget. The financial proposal should comply with the below guidelines.

Itemized costs

Provide itemized costs for the total scope of this project, based on the scope of work and deliverables outlined in section 6. The final scope of work may be subject to negotiation; however, bidder selection will be made against the original scope of work. Bids should include itemized costs for key elements of the scope of work, as follows:

- Staff assigned to scope.
- Roles and rates of staff.
- Estimated total level of effort and associated costs.
- Equipment purchases. Equipment is defined as having a useful life of more than one year and a value greater than US\$5,000. If the item does not meet this definition, it is considered a supply.
- Reimbursable costs (e.g., subcontracted resources, administrative costs, supplies, taxes).

Example tables for the budget spreadsheet (additional lines can be added as needed)

Labor

Name of expert	Role on the project	Day rate (US dollars)	No. days	Total cost (US dollars)
Expert y				
Expert z				
Expert w				
Expert q				
Total A				

Equipment

Item	Description	Total cost (US dollars)
Equipment name		
Equipment name		
Total B		

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Reimbursable expenses

Item	Unit cost (US dollars)	Quantity	Total cost (US dollars)
Subcontracted resources			
Administrative costs			
Supplies			
Taxes*			
Total C			

*Taxes should be zero if none apply and/or if there are relevant exemptions.

Grand total = total A + total B + total C.