HEARTLAND BIOWORKS

REQUEST FOR PROPOSALS

Filling Line with Hybrid Barrier System – *for Training Only*

Issued by:	The Heartland BioWorks Regional Tech Hub under The Applied Research Institute, Inc
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1. Background and Purpose

The Heartland BioWorks (HBW) Regional Tech Hub is developing a biomanufacturing training and demonstration facility located in Indianapolis IN, US, intended to support workforce development and industry engagement. The facility is being designed to reflect modern biopharmaceutical manufacturing practices while remaining accessible, flexible, and focused on instruction. The facility will include Upstream, Downstream, and Aseptic Filling training suites, where industry and academic trainees gain hands-on, practical training on the techniques and processes used in biomanufacturing production.

HBW is soliciting proposals for a fully functional, small-scale filling line integrated with a hybrid barrier system to train on aseptic filling operations. The equipment will be used exclusively for training and demonstration. It will not be used for GMP development or manufacturing of active products.

The vendor selected for this RFP will gain high-visibility exposure within a state-of-the-art biomanufacturing training facility used by a diverse audience of students, workforce trainees, and industry partners. This environment will provide a unique opportunity to showcase your technology,

strengthen brand recognition, and build familiarity with the next generation of skilled biomanufacturing professionals.

2. Scope of Supply

The selected vendor shall provide a syringe filling line integrated into a hybrid barrier system. The proposal should ideally encompass:

- Filling of syringes in a nested tub configuration
- Manual and/or semi-automated infeed, de-lidding/liner removal and outfeed of containers
- Fully automated filling and plunger insertion, including de-nesting and re-nesting of containers via a robotic arm(s)
- A hybrid barrier system for the filling line (look/feel of an isolator without flow/filtration of air)
- HMI-based control system with multiple interfaces
- Multiple glove ports, RTP's, etc. for simulation of typical aseptic line operations including loading of components, assembly of filling path, required interventions, and simulated environmental monitoring
- Testing, delivery, commissioning, and training services
- Option(s) for multi-container filling capabilities – vials and/or cartridges (provide as an add-on, refer to Compliance Section 9)

3. Intended Use and Design Philosophy

HBW will utilize the line exclusively for training of operators and/or technical support personnel. As such, emphasis will be placed on visibility, accessibility, line interaction and simulation of aseptic operations over high throughput. Priority should be given to the following:

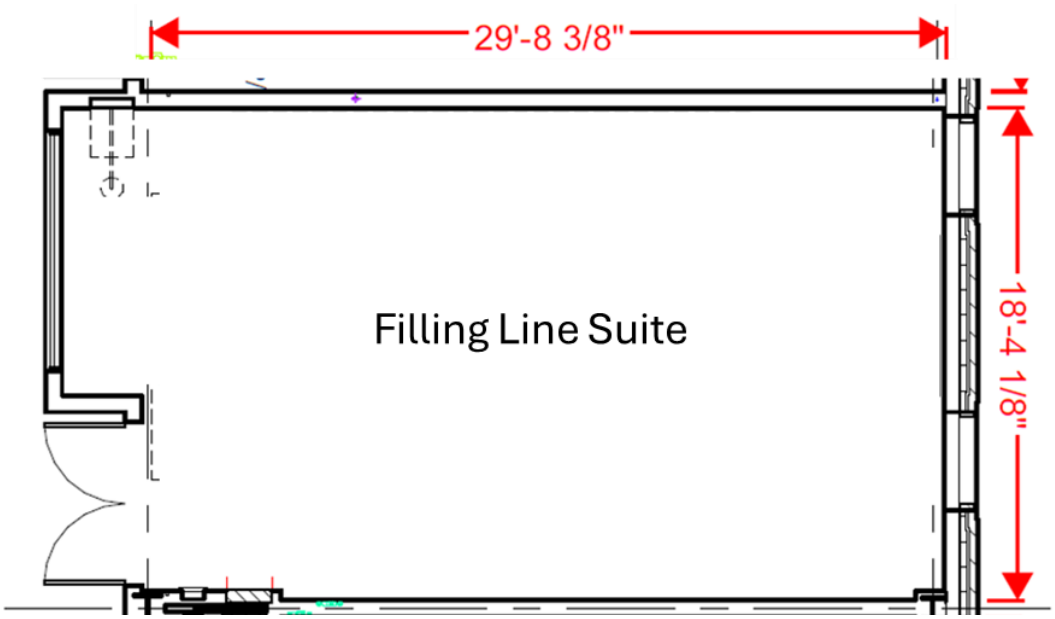
- Visibility of process steps for trainees observing and operating the line
- Ease of simultaneous access by multiple trainees
- Hands-on training of aseptic techniques, including open door and closed door part installation, closed door needle and insertion tube changes, machine recovery interventions, etc.
- Manual overrides, configurable recipes, and deliberate fault simulation
- Instructional feedback from inspection and rejection systems
- Modular or changeable container formats, where possible

Whenever access of gloves conflicts with visibility, HBW should be informed for a design decision.

4. Facility and Space Constraints

4.1 Available Space

- Approx. Room dimensions: 18 feet by 30 feet
- Ceiling height: 11 feet



4.2 Access Constraints

All system components — including the barrier enclosure, electrical cabinets, skids, and utility connections — should be capable of passing through a facility entry doorway measuring:

- Width: 6 feet
- Height: 7 feet

4.3 Layout Requirements

- Sufficient clearance must be maintained around all equipment to allow simultaneous access by multiple trainees; minimum of 4 feet to allow for door swings and people movement
- Access to emergency exits must not be obstructed by the proposed solution
- Vendors shall include full dimensional drawings (plan and elevation) of all supplied components, including electrical cabinets and utility connections
- Space requirements for all associated equipment must be detailed in the proposal

5. Procurement Process Overview

This procurement is conducted under a federal award subject to 2 CFR Part 200. All aspects of this solicitation, including vendor communications, evaluation, selection, and award, must comply with applicable federal procurement standards under 2 CFR §200.318 through §200.327.

To preserve the integrity and fairness of the process, individual questions will not be answered on a one-off basis. All inquiries must be submitted in writing to the designated point of contact. A Pre-Bid Conference and Q&A Session may be scheduled a week or two into the solicitation period to address all submitted questions collectively. Prospective respondents who wish to participate must notify the point of contact of their intent to attend; an invitation with meeting details will be issued upon receipt of notification. Any clarifications or addenda resulting from this session will be distributed to all known prospective respondents regardless of attendance.

The issuing organization reserves the right to conduct additional rounds of bid openings, including but not limited to revised proposals, best and final offers (BAFOs), oral presentations, or demonstrations, at its sole discretion. This right may be exercised when determined to be in the best interest of the project and consistent with full and open competition under 2 CFR Part 200. The issuing organization further reserves the right to reject any or all proposals, waive minor informalities, and incurs no obligation until a fully executed agreement is in place.

6. Proposal Evaluation Criteria

Proposals will be evaluated based on a combination of the following criteria and overall fit with project objectives:

- **Technical Capabilities:** how well the proposal addresses the filling line design elements outlined in section 9, Compliance Matrix, as well as how it satisfies the unique requirements needed in a training setting – visibility, configurability, trainee access, etc.
- **Vendor Support:** lead time, on-going customer support, equipment warranty, software support/upgrade, callout response, level of training provided
- **Total Cost of Ownership:** upfront capital, line testing, delivery, commissioning, maintenance, spare parts, consumables, etc.

7. Budgetary and Lead Time Guidance

HBW anticipates a budget not to exceed $1.7 million; however, vendors are encouraged to recommend solutions they believe best meet the objectives, including options that may fall above the range if justified by additional value or impact. Additionally, vendors may provide a base estimate with line item options/alternatives to reduce costs. Any options/alternatives should be accompanied by how each affects the price and capability/function of the filling line.

The project schedule currently has 10-12 months lead time for the filling line.

8. Proposal Submission Requirements

Proposals must be submitted to the POC (colin.zeh@theari.us) electronically in PDF format by the stated due date. Each proposal shall include:

- Executive summary (maximum 2 pages)
- Company overview and relevant reference installations
- Completed Compliance Matrix with Y / N / P responses and supporting comments for each item
- Detailed technical descriptions of all proposed equipment
- Layout drawings (plan and elevation) with dimensions
- Fully itemized pricing
- Lead time and project schedule
- Utility and infrastructure requirements
- Commissioning package details
- Maintenance, calibration, and lifecycle support plan
- Training program description

9. Compliance Matrix

Vendors must complete all fields in the matrix below. The Compliance column must contain Y, N, or P for every row. The Comments column should contain a description of how the proposal addresses the Feature/Requirement or reference to supporting documentation included in the proposal.

Compliance Matrix Key:

Y – Full compliance
N – Non-compliance (explain and propose alternative, if applicable)
P – Partial compliance (describe the extent and limitations)

General Filling Line Requirements			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
1.1	The filling line and associated equipment should have a proven operational history and demonstrated reliability. Vendor to provide details of relevant sites and installations.		
1.2	The filling line should allow easy access and viewing of filling components to facilitate training on aseptic setup, filling, container closure, maintenance, etc.		
1.3	The filling line should be constructed of industry standard materials, including ANSI 304 (at a minimum). For product contact parts, 316L is required. **Note:** *As the line will be used exclusively for training, HBW may consider alternative materials where cost savings are significant. Detail alternatives.*		
1.4	The filling line should be compatible with water-based solutions, including biopharmaceuticals, buffers, and microbiological growth media.		
1.5	The filling line and the associated infeed and outfeed systems should be integrated into a barrier system(s) as described in greater detail in *Section 6, Barrier System Features.*		

Process Operations and Controls Features			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
2.1	The filling line should be operated via a commercially supported HMI platform.		

	Vendor to detail HMI specifications, operating system, and software version.		
2.2	The line should be outfitted with at least two HMI's, one on the front and one on the back.		
2.3	The control system should allow data export to data acquisition system(s) to collect and evaluate data for training and demonstration purposes. Full MES integration is not required. If full MES integration is provided as a standard configuration, note specific MES system compatibility.		
2.4	Vendor to provide the full range of achievable line speeds, expressed in containers per minute for each container configuration. Note: *Preferred range should include line speed of less than 25 CPM to maximize process visibility for training.*		
2.5	The operating system should allow manual overrides of filling recipes to create troubleshooting scenarios and facilitate training opportunities (e.g. plunger placement height, ability to force sensors, provisions for service mode)		
2.6	The control system should support user access levels to allow trainees to interact with the HMI safely, including at least four role-based permission levels.		
2.7	As this is a training system, the control system should have no locked screens that require daily service passwords.		
2.8	As this is a training system, the PLC code should be unlocked with no black-box elements.		

Container Infeed/Outfeed Features			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
3.1	De-bagging, de-lidding, and de-lining of the nested tub should be executed within a containment enclosure via glove ports.		
3.2	The de-lidding and de-lining processes should be completed manually through glove ports. Semi-automated solutions will also be considered.		

3.3	Container feed into and out of the filling/container closure station(s) should be automated. Multi axis, robotic manipulation and handling of the nested tub is preferred. Vendor to detail the specifics of the robot(s) included in the design.		
3.4	Contained waste collection system(s) shall be provided to manage waste generated by de-bagging, de-lidding, and/or de-lining processes. Containers should be included in any drawings to ensure adequate space is available.		

Container Filling Features			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
4.1	The filling line should be capable of filling syringes in a nested tub configuration.		
4.2	Product should be transported to the filling line via peristaltic pumps with disposable fluid pathways.		
4.3	The peristatic pumps should be located outside of the barrier system.		
4.4	The “product” bag should be located outside the barrier system.		
4.5	The “product” tubing exiting the pumps should be connected through the barrier system to the filling line via a compatible aseptic connection port (e.g. SART, Iris, RTP or similar).		
4.6	The filling line should have the capability of operating with multiple filling needles (two is sufficient).		
4.7	If multiple filling needles are provided, the system should support the isolation or shut off of individual needles.		
4.8	Bottom-up filling of containers is required.		
4.9	Fill volume capability should range from 0.5-3ml. The standard operating scenario will utilize the 1mL long syringe. Vendor to detail achievable volume range and fill accuracy.		
4.10	In-process weight checking (IPC) is desired to detect under-fill or over-fill conditions. Vendor to detail additional costs to acquire this capability, if		

	applicable, and delineate costs between statistical IPC and 100% IPC.		
4.11	The filling system should include a “no unit, no fill” capability to ensure no containers are filled until the nest/container is present at the correct station.		
4.12	If syringes are removed from the nest or the nest is removed from the tub during the filling process, they should be automatically re-joined or re-positioned before exiting the line.		

Container Closure Features			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
5.1	The plunger bowl should be loaded via an inclined infeed ramp from an RTP port – i.e. plungers should not be fed into the bowl by direct manual intervention.		
5.2	Plunger insertion should be automated. Vendor to describe the standard mechanism utilized.		
5.3	The filling line should include an in-line container inspection system to verify plunger placement, accurate to +/-0.1mm.		
5.4	The filling line should include automated reject functionality for defective containers or containers that have failed IPC checks. Vendor to provide details on how this is performed.		
5.5	The filling line should alarm and stop after an individually configurable number of consecutive rejects from any given station occurs.		
5.6	The filling line should stop and alarm/alert the user if the rejection area is full and a reject event is required		

Barrier System Features			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
6.1	The barrier system enclosing the filling and container closure stations should have the look and feel of an isolator – e.g. stainless/glass construction, access through ports, clean design, etc.		

6.2	The barrier system should NOT include active air supply, pressure control or air filtration capability.		
6.3	The barrier system should have the capability of being "opened" via doors to allow for manual manipulation and increased visibility of operations.		
6.4	The barrier system should include interior lighting.		
6.5	The barrier system should include multiple glove ports (ideally 6 or more sets of glove ports), to accommodate multiple trainees.		
6.6	An initial supply of barrier gloves should be provided in the base bid. Vendor to detail ongoing replacement costs in the itemized quotation.		
6.7	The barrier system should include compatible, automated glove integrity testing (GIT) capability. Vendor to detail costs and methodology.		
6.8	The barrier system should include light curtains or light barriers for safety, as applicable.		
6.9	The barrier system should include provisions for hanging tools and/or consumables inside the enclosure for use during filling.		
6.10	The barrier system should include rapid transfer port(s) to demonstrate aseptic techniques such as the loading of plungers or the connection of the product feed lines to the filling needles. Vendor to detail the number and make/model of the port(s) included in the design.		
6.11	The barrier system should be outfitted with utility valving and power disconnects such that the filling machine can be locked out/tagged out locally in conformance with US standards.		

Delivery, Testing, Commissioning, Training, and Maintenance			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
7.1	Vendor shall provide a fully itemized cost breakdown, including equipment, barrier system, commissioning, training, optional components, applicable taxes, duties, delivery charges, etc.		

7.2	Vendor shall provide details on lead time, from issuing of purchase order to completed installation/commissioning.		
7.3	Vendor shall describe the expected product lifecycle, including if/when software or hardware support is expected to be discontinued.		
7.4	Vendor shall provide details of equipment warranty.		
7.5	Vendor shall provide details of ongoing software support and HMI OS update policy, including any associated costs.		
7.6	Vendor shall detail costs associated with installation, commissioning, and removal/disposal of all packaging materials.		
7.7	Vendor shall detail all activities and costs that are excluded from the proposal and would be the responsibility of HBW.		
7.8	Vendor shall specify all utility requirements with associated specifications, including electrical connections and capacities.		
7.9	Vendor shall provide full dimensional drawings (height, length, depth, weight) of all components, including electrical cabinets.		
7.10	Vendor shall provide dimensions and specifications of all shipping containers and packaging.		
7.11	Vendor shall specify maximum cable lengths allowed between the filling line and electrical cabinets.		
7.12	Vendor shall provide details of the commissioning and/or qualification package included in the proposal cost. *Note: As the installation is for training purposes only, full GMP qualification is not required. Vendor to describe how their proposal differs from that of a full GMP system qualification along with any cost implications.*		
7.13	Vendor shall provide details of any relevant maintenance and calibration package, specifying ongoing annual costs to HBW. *Note: As the installation is for training purposes only, reduced calibration frequency and/or standards may be*		

	appropriate. Vendor to describe how their proposal differs from that of a full GMP system along with any cost implications.		
7.14	Vendor shall provide a recommended spare parts list with part numbers, availability, costs, and lead times.		
7.15	Vendor shall provide details of reactive callout costs, including travel expenses, where applicable. Response times of maintenance team should be indicated.		
7.16	Vendor shall detail out any remote diagnostic or support capability available, along with the associated cost.		
7.17	Vendor shall provide training details included in their proposal (course content, number of trainees permitted, etc.) along with any associated cost. Training should include topics such as: • Equipment familiarization • Settings and format changes • Set-up and operation of the line • Use of the HMI • Safety considerations • Troubleshooting • On-going maintenance • Machine alignment, including full set of machine jigs to maintain alignment		
7.18	Vendor shall provide documentation, SOPs, and/or user manuals suitable for training staff to independently operate, maintain, and troubleshoot the system.		

Additional Capabilities (add-ons)			
No.	**Feature / Requirement**	**Compliance (Y/N/P)**	**Comments or Reference to Supporting Documentation**
8.1	Vendor shall describe how additional filling container platforms (cartridges and/or vials) could be accommodated by the proposed filling line or as an add-on capability. Vendor to provide description of add-on, additional equipment needed, drawings, space requirements and configuration, change parts, etc. The estimated cost for such add-on should be provided as a separate line item in the proposal		
8.2	While no active air flow, air filtration or barrier system pressurization is required in the base proposal, vendor to describe how		

	to incorporate an unfiltered supply of air (i.e fan) and pressure monitoring/controls to pressurize the filling line barrier system to more closely mimic production operations. Vendor to provide description of add-on, additional equipment, space requirements and configuration, etc. The estimated cost for such add-on should be provided as a separate line item in the proposal.		

10. General Terms and Conditions

Heartland BioWorks reserves the right to accept or reject any or all proposals received, to waive informalities, and to accept the proposal deemed most advantageous to Heartland BioWorks. This RFP does not constitute a commitment by Heartland BioWorks or The Applied Research Institute Inc. to award a contract.

All information submitted in response to this RFP will be treated as confidential. Vendors should clearly mark any information in their proposals that they consider proprietary.

Heartland BioWorks is an equal opportunity organization and encourages proposals from all qualified vendors.

Questions regarding this RFP cannot be addressed individually.

11. Federal Requirements

This procurement is funded by the United States Economic Development Administration (EDA) and is subject to applicable federal laws and regulations. Vendors must acknowledge and comply with the following federal requirements as a condition of proposal submission and contract award.

12.1 Federal Participation Disclosure

This project will be funded with Federal funds from the Economic Development Administration and therefore is subject to the Federal laws and regulations associated with that program.

12.2 Federal Contract Provisions (2 CFR Part 200)

The selected vendor's contract will include all required federal contract provisions as set forth in Appendix II to 2 CFR Part 200 – Contract Provisions for Non-Federal Entity Contracts Under Federal Awards. Vendor selection will be conducted in accordance with the procurement standards set forth in 2 CFR Part 200. By submitting a proposal, vendors acknowledge awareness of and willingness to comply with these provisions.

12.3 Proposal / Bid Form

All vendors must submit pricing in accordance with the Compliance Matrix in Section 9 of this RFP. Pricing shall be fully itemized per the requirements outlined in Section 9, including base equipment, barrier system, commissioning, training, optional add-ons, taxes, duties, delivery, and any other cost components. Add-on options shall be priced as separate line items. Failure to provide complete pricing in the specified format may result in disqualification of the proposal.

The point of contact for this RFP is **Colin Zeh (colin.zeh@theari.us).**