



The National Institute for Innovation in Manufacturing Biopharmaceuticals

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# Universal Connectivity for In-Process Analytics in Biopharmaceutical Manufacturing

## Request for Information (BD RFI 2024.001)

RFI Release Date: July 23, 2024

Submission due: August 30, 2024 (5pm ET)

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## 1. Overview

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is dedicated to advancing biopharmaceutical manufacturing innovation, developing standards to enhance manufacturing efficiencies and speed, and cultivating a leading biopharmaceutical manufacturing workforce. This Request for Information (RFI) seeks to gather insights and ideas (i.e. it is not a funding opportunity solicitation for proposals) regarding the development of a Universal Connectivity System for at-line/inline analytical instrumentation. This initiative aims to support NIIMBL's Big Data program in biomanufacturing.

## 2. Background

NIIMBL invites submissions from interested parties to share information on potential solutions for a Universal Connectivity System. This system is envisioned as an OT/IT (see definitions) core to facilitate seamless data integration and advanced analytics within biomanufacturing processes, thus enabling data-driven decision making and process optimization.

Purpose of this RFI:

- Understand the market capabilities and the associated costs for creating a universal connectivity framework.
- Gather insights that could shape the scope of future RFAs or RFPs.
- Aggregate data to inform stakeholders and potentially influence government and industry standards.

Note: This RFI does not constitute a solicitation for funding proposals. The information collected may guide the development of future funding opportunities (RFAs or RFPs).

## 3. Detailed Request

### **Proposed System Functionality:**

- The system is envisioned as a core OT/IT infrastructure based on IIoT principles.
- The system should be able to work in a vendor-agnostic environment and integrate seamlessly with various analytical instruments and existing IT systems, including legacy equipment, from a wide variety of vendors.
- The system is expected to be scalable and capable of adapting to future technological advancements.

### **Goals:**

1. Enhance data integration across biomanufacturing processes.
2. Enable advanced analytics for data-driven decision making.

### **Objectives:**

1. Assess integration capabilities with existing and new analytical instruments.
2. Evaluate compatibility with current IT infrastructure and potential for future expansion.

### **Application Areas:**

- A. Application in real-time monitoring of biomanufacturing processes.



B. Use in quality control and assurance protocols.

## 4. Submission Details

- A. Technical Approach: A brief description of the following:
  - 1) What technologies and methodologies will be used in your project?
  - 2) How will each goal and objective be addressed in your approach?
  - 3) How does your project apply to the specified areas, and what theoretical or empirical backing supports this application?
  - 4) Can you clearly differentiate the technical aspects, practical applications, and benefits of your approach?
  - 5) Are you aware of any other relevant initiatives that could support this request? If so, please describe them.
  
- B. Organizational Capabilities: An overview of an organization's capabilities, instrumentation, and facilities that could support the development of such a system.
  
- C. Cost Estimation: Rough order magnitude (ROM) budget for the development of the proposed system or component(s). This estimate will help us understand the potential financial implications and is not binding. This RFI is not a solicitation for proposals for funding.

## 5. Submission Process

Submissions must be sent via the NIIMBL Submission Hub by the due date. Late submissions will not be considered.

## 6. Use of Information

The insights and information gathered from this RFI will be used to inform strategic planning for future solicitations. It may also contribute to broader discussions with government stakeholders about the needs and opportunities in biomanufacturing.

## 7. Encouragement for Broad Participation

We encourage submissions from a wide range of stakeholders, including academic institutions, industry, technology providers, and consortia. Whether you can offer comprehensive solutions or insights into specific aspects of the universal connectivity challenge, your input is valuable. Feedback on this RFI's scope, requirements, and objectives is also welcome, as it will help refine our approach to addressing the needs of the biomanufacturing sector.

## 8. Conclusion

This RFI is a preliminary step towards identifying innovative solutions and collaborations that can advance the field of biomanufacturing. We look forward to engaging with the community to gather valuable information that will shape future initiatives.

For more information, please contact [projectcalls@NIIMBL.org](mailto:projectcalls@NIIMBL.org).



## Abbreviated List of Acronyms

1. RFI: Request for Information
2. RFA: Request for Application
3. RFP: Request for Proposal
4. OT/IT: convergence and integration of Operational Technology (OT) systems with Information Technology (IT) systems
5. IIoT: Industrial Internet of Things
6. NIIMBL: National Institute for Innovation in Manufacturing Biopharmaceuticals
7. IT: information technology