The National Institute for Innovation in Manufacturing Biopharmaceuticals

Request for Information

"Equipment in Residence: An FDA/NIIMBL Collaboration" RFI 2026.03

RFI Release Date June 23, 2026

Submission Due Date: July 21, 2026 (5 pm ET)

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) invites interested parties to submit to participate in the "Equipment in Residence Program: An FDA/NIIMBL Collaboration" (abbreviated EiRP).

Questions related to this Request for Information can be sent to projectcalls@niimbl.org.

2. Background

NIIMBL is working collaboratively with the U.S. Food and Drug Administration (FDA) on a program whereby new and emerging manufacturing-related and analytical measurement technologies can be made temporarily available to FDA staff for research and demonstration purposes. The program is called the "Equipment in Residence Program: An FDA/NIIMBL Collaboration" and envisions technologies that are placed in an FDA laboratory for a period of at least three months and typically no more than twelve months.

As part of this effort, NIIMBL receives from the FDA a list of general technology areas of interest. NIIMBL issues a Request for Information from relevant organizations within the biopharmaceutical manufacturing ecosystem with new or emerging technologies that address those general technology areas of interest. Organizations with technologies or equipment of interest may then be invited to share more information through a Request for Application.

Selected organizations will have their equipment / technology placed in residence at an FDA laboratory for a limited period of time. Title to the equipment is planned to be transferred to NIIMBL at the University of Delaware prior to placement at the FDA laboratory, or it may be retained by the equipment vendor in limited cases. The FDA will not purchase, nor retain title to, any selected equipment. The selected organization must be able to provide technical assistance and training to relevant FDA staff, as well as maintain and repair the equipment as needed, during the period of residency at FDA. Other government agencies may collaborate with FDA on research, as needed. At the end of the program the equipment will be returned to NIIMBL for use in NIIMBL activities. Selection for or participation in the EiRP is not is not to be construed as either an actual or implied endorsement of the organization, equipment, or technology by the Department of Health and Human Services or FDA.

The program is intended to test technologies from industry members where the equipment is on the market, or for which beta prototype instruments may be available. However, a non-profit organization with robust, reliable equipment that meets the intent of the program is welcome to submit information in response to this EiRP Request for Information.

Purpose of this RFI:

The EiRP is intended to establish a test bed for evaluation of new technologies used in medical product manufacturing to increase efficiency of evaluation and adoption of new technologies. This will provide FDA staff with exposure to novel technologies and equipment in

a pre-competitive space (not related to a specific product submission or a directly regulated product) to gain a better understanding of technologies in alignment with FDA priorities. Additionally, a select group of FDA researchers will use the technologies to address regulatory science gaps with the aim of publishing technical manuscripts of their findings.

FDA is interested in using the initial EiRP cycles to address the following **issues**:

- ISQPPS (identity, strength, quality, purity, potency, stability) technologies that would complete potency assays or demonstrate potency
- Process analytical technologies (PAT) and/or process validation technologies
- Equipment/technology features of interest would be automated data acquisition, high-throughput in-line/near-line capabilities, quantitative longitudinal analysis allowing for real time process controls. Any proposal addressing FDA interests will be considered; 2 specific example technologies of interest are highlighted below.

Note: This RFI does not constitute a solicitation for funding research proposals.

Two Example Areas of Interest for 2026:

Automated Live-Cell Imaging and Analysis System	**Circular Dichroism (CD) Spectropolarimeter**
Description: Automated live-cell imaging and analysis system designed for operation within a standard tissue culture incubator, enabling continuous, real-time monitoring of living cells using phase and multi-color fluorescence imaging. The system must support high-throughput, longitudinal analysis of complex biological systems including 3D cultures, co-culture models, and cell interactions.	Description: A modern circular dichroism (CD) spectropolarimeter to support studies linking protein secondary structure to biological function. The system should require minimal sample volumes and support automated data collection through autosamplers, auto-clean functionality, and high-throughput plate-based formats (96-well or greater).
Hardware: • Automated time-lapse imaging within a standard incubator environment • Whole-well imaging capability • Phase contrast imaging with automated object counting • Multi-channel fluorescence imaging (minimum three-color capability) • Quantitative analysis of cell proliferation, viability, morphology, migration, and cell-cell interactions • High-throughput imaging and analysis across multiple plates simultaneously	Hardware: • CD spectropolarimeter main unit • Autosampler with auto-clean functionality • 96-well plate reader module (or equivalent high-throughput format) • Temperature-controlled sample cell / Peltier temperature control unit for heating and cooling sample temperature. Temperature range of 5 to 80 °C or broader. • Secondary and tertiary structure analysis

• 4x, 10x, and 20x magnification capability • Compatible with a standard tissue culture incubator with >200 L internal volume	• Automated thermal ramp experiments to measure protein folding and unfolding transitions • Capable of detecting signal from low-concentration or limited-volume samples; flexible sensitivity settings to accommodate a range of sample types • Automated data acquisition via autosampler and 96-well or greater • Integrated auto-clean functionality to minimize cross-contamination and reduce manual handling between samples • Nitrogen gas purge system or equivalent (for far-UV measurements)
Software (all should be capable of automated and longitudinal data acquisition and analysis): • Phase object counting • Whole-well imaging • Fluorescence image acquisition and processing • Single-cell tracking and quantitative analysis • Supports longitudinal, human-relevant assays • Cell morphology analysis • Quantitative analysis of cell migration	Software (all should be capable of automated and longitudinal data acquisition and analysis): • Spectral acquisition and real-time data display • Automated data collection and scheduling for high-throughput runs • Temperature control and thermal ramp programming • Secondary structure deconvolution module – enables quantitative estimation of secondary structure composition from CD spectra • Thermodynamic analysis module – supports fitting of folding/unfolding curves and calculation of thermodynamic parameters (T_m, ΔH, ΔG)

3. Submission Details

Please submit all the following information:

A. Cover Page: Name of Organization submitting information; Name, Title, and Email of individual submitting information; Title of submission.

B. Technology: A brief description of submitters' equipment / technology and readiness for commercialization (limit 1200 words maximum plus 2 figures):

- Provide an overview of the technology and its capabilities.
- Provide additional information that describes the broad capabilities of the equipment, what is innovative about the equipment, how it aligns with any of the issues identified

above and if the technology is well-aligned with one of the two example areas of interest for 2026. Priority for this first round will be for submissions that are well-aligned with one of the two example areas of interest for 2026: explicitly state which area and explicitly mention which of the hardware and software components from these two example areas are addressed and which are not addressed by the technology.

- Provide a brief description of any significant facility or infrastructure requirements beyond what is found in a typical laboratory (special power requirements, external gasses, vibration sensitivity, HVAC, operates in a biosafety cabinet, etc.).
- Share if the equipment is commercially available, at prototype stage, or in beta testing.
- Describe any consumables that are associated with the equipment.
- Provide a rough cost estimate to acquire the technology for use under the EiRP program. If there are options, state the cost for each of the options individually.

4. Submission Process

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

Table 1. Timeline

EVENT	DATE
Submission Due by 5:00 pm ET	Tuesday, July 21, 2026
Review Period:	Mid-July 2026
Invitation to RFA Announced	Late-July 2026 (planned) Second round expected 2027
Request for Application Due	August 2026 (Planned) Second round expected 2027
Contracting Window	August - September 2026 (Planned) Second round expected in 2027
Estimated Project Start Dates	September 15, 2026 (Planned first round) March 1, 2027 (Planned second round)

No funds will be awarded. This is a Request for Information only. For the Equipment in Residence Program participants, the planned Request for Application process will address details of next steps. NIIMBL intends to procure a selected technology.

5. Eligibility Criteria

Membership

Any relevant organization is invited to submit a response to this RFI. However, if a specific organization is invited to respond to a subsequent Request for Application, it should be a

NIIMBL member at the time of submitting the application, (see table 1).

Please contact projectcalls@niimbl.org to inquire about membership opportunities.

6. Information Review and Evaluation

NIIMBL Review and Acceptance Criteria

Applications must comply with the requirements outlined in this RFI. All formatting requirements, administrative requirements, terms and conditions, and other requirements will be assessed for completeness.

NIIMBL will review submissions and ensure suitability of the technology and alignment with the FDA's goals.

7. Abbreviated List of Acronyms

CBER	Center for Biologics Evaluation and Research
FDA	Food and Drug Administration
NIIMBL	National Institute for Innovation in Manufacturing Biopharmaceuticals
RFA	Request for Application
RFI	Request for Information