

# Project Call 9.1W Request for Proposals

Concept Papers Due: September 16, 2025

Full Proposals Due: January 29, 2026

VERSION August 2025



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## 1. Executive Summary

The mission of NIIMBL (the National Institute for Innovation in Manufacturing Biopharmaceuticals) is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce. NIIMBL is pleased to announce this Request for Proposals (RFP) for Project Call 9.1, with member- driven and industry-led priority topic areas workforce development proposals.

#### **Funding Opportunity Title: Project Call 9.1**

Stage 1: The Concept Phase includes the submission of a Concept Paper and a short slide deck. Principal investigator (PI) with accepted concepts will be notified about participating in a virtual summit and will be requested to upload a Showcase Video at that time. No teaming, budget, or cost share information is required at this stage but if information is available for a given Concept, it may be included at the Concept stage. Concepts may only be submitted by NIIMBL members or a Federal employee although non-members may be contemplated as part of the proposed team. Concept submissions must be submitted via the NIIMBL Proposal Submission Hub.

Submissions received after the deadline (Table 1), or that are not compliant with this RFP, will not be considered and will be declined without review.

Following submission of Concepts, each submission will be reviewed by NIIMBL, Industry, and Federal stakeholder subject matter experts to prioritize those Concepts that have the potential for the highest industry impact and likelihood of success. To help facilitate the review and potential teaming at the Full Proposal stage, NIIMBL is requesting Showcase Videos submissions (a short, 90 second maximum, video that summarizes the main points of the proposed project and desired teaming opportunities). The Concept Phase (Stage 1) concludes with invitations issued for submission of a Full Proposal (Stage 2). Declination notices will be sent to unsuccessful proposers. Deadlines and key dates are summarized in Table 1.

<u>Stage 2</u>: The Full Proposal Phase includes submission of a 14-page proposal with teaming, detailed budget, cost share, and other requirements listed in this announcement. Full Proposal submissions must be submitted via the NIIMBL Proposal Submission Hub.

Submissions received after the deadline (see Table 1), or otherwise non-compliant with the submission requirements, will not be considered.

The Full Proposal Phase concludes with a decision to fund or not fund the proposal by the NIIMBL Governing Committee (GC). Awarded project teams will be expected to complete contracting within 90 days after formal notification of the award. NIIMBL reserves the right to rescind offers of funding to awarded project teams that have not completed contracting within that time frame.



**Table 1. Summary of Key Dates and Deadlines** 

EVENT	DATE
Concept Paper Due	September 16, 2025 (by 5:00 pm ET)
Virtual Summit	September 25, 26, & 30, 2025
Invite for Full Proposal	October, 2025
Full Proposal Due by 5:00 pm ET	January 29, 2026
Proposal Review	February 2026
Award Decisions Announced	Expected by March 2026

#### **Priority Topic Areas**

The priority topic areas are summarized in Section 6.

#### **Total Amount to be Awarded**

NIIMBL will make available up to \$4,000,000 to fund both Technology and Workforce Development proposals submitted in response to this Open Project Call.

## 2. Project Requirements and Eligibility Criteria

#### **Proposer Eligibility**

<u>Stage 1</u>: Concept Phase, only the lead Concept proposer must be an individual from a NIIMBL member organization or a Federal employee.

<u>Stage 2</u>: Full Proposal Phase, the lead project proposer AND all members of the proposed project team must be a NIIMBL member or a Federal employee. To participate on a project proposal team, an organization must be a member or have submitted a partially executed NIIMBL Membership Agreement by 5:00 p.m. Eastern Time at least one week prior to the due date for the Full Proposal (see Table 1).

Information on how to join NIIMBL is available at: <a href="https://www.niimbl.org/membership/">https://www.niimbl.org/membership/</a>.

#### **Project Constraints**

Concepts and Full Proposals must be consistent with NIIMBL Membership Agreements, the NIIMBL Bylaws, and should be labeled as NIIMBL Confidential.



Invited Full Proposals will be accepted with the following constraints:

- A maximum of \$500,000 of NIIMBL funding for Workforce development proposals
- A minimum of 2 project partners (see Teaming section below)
- All project partners must be NIIMBL members before the submission deadline
- A minimum 1:1 (partners: NIIMBL) cost share requirement
- All committed cost share must be from non-Federal funding sources.
- Projects with higher cost share ratio (partners: NIIMBL) will be more competitive.
- A maximum of 18-month period of performance

This project call solicits proposals for Institute-Wide Projects; however, projects may request to be treated as Partner-Specific Projects<sup>1</sup>. License rights to intellectual property developed in Institute-Wide Projects and Partner-Specific Projects are treated differently; therefore, project teams should carefully review Article IV of the NIIMBL Bylaws before requesting that a project be authorized as Partner-Specific. NIIMBL envisions occasions where Partner-Specific projects are applicable to the technology being advanced will be rare. If Project teams plan to request permission to be treated as Partner-Specific, they must make this request in the Proposal Narrative and provide a justification for the request. Such a designation will be reviewed prior to project authorization to ensure it is appropriate for the type of project being proposed.

Approval for a project to be designated as Partner-Specific is subject to the special approval of the Governing Committee, which will review the justification closely to determine if a Partner-Specific designation is in line with the intent of the distinction.

#### **Cost Share**

There is no requirement to have cost share documented or described at the Concept Phase.

Full Proposals must offer and document the required minimum cash or in-kind cost share commitment in the budget that is submitted as part of the Full Proposal. Cost share must be consistent with requirements in the NIIMBL Membership Agreement. Project teams should be aware that the institutional cost share requirements for NIIMBL member organizations vary based on institution type (e.g., industry, academic/non-profit organization) and tier level. Due to these different cost share obligations, project teams may allocate cost share commitments amongst team members however necessary to meet the minimum overall project cost share. For example, not every team member is required to commit cost share, and some team members may exceed the ratio required by their Membership Agreement. However, the project team collectively must still meet the requirement, and each project team member must individually meet their requirements per their Membership Agreement, as

<sup>&</sup>lt;sup>1</sup> Institute-wide Projects address broad challenges faced by the biomanufacturing industry at large, with the goal of developing solutions that will benefit the overwhelming majority of manufacturers. Partner-specific Projects address the needs of more narrow sectors of the biopharmaceutical industry and are more limited in participation and IP than Institute-Wide Projects, performed pursuant to a Project Award Agreement. See Article IV of the NIIMBL Bylaws for more information related to intellectual property rights.



For Delaware based organizations requesting state of Delaware cost share support, additional review and approval is required. Project proposal teams should include confirmation of the support (Appendix I).

**Delaware**: Contact Marta Rosario, (martar@udel.edu) by 5:00 p.m. Eastern Time two weeks before the full proposal due date (see Table 1) to request a State of Delaware cost share commitment. The request should include a 1-paragraph description of the project, title, partners, and budget narrative.

#### **Teaming**

There is no requirement to have all partners identified during the Concept Phase. If partners have been identified, they should be noted in the Concept Paper and slide deck.

Full Proposals must have at least two distinct member organizations participating on the project. Each project proposal team shall have a designated lead partner that coordinates the activities of all partners on the project team. Teams that are led by industry members are strongly encouraged.

NIIMBL highly encourages industry participation on workforce projects. Industry participation can range from the inclusion of an industry member as a project participant to documenting the support of an industry member via a letter of support. (Appendix H).

Note: When appropriate, project proposal teams may seek collaboration with Federal Organizations, National Laboratories, or Federally Funded Research and Development Centers (FFRDCs) within the limits of their mission, rules, and Federal approvals. In accordance with regulations, Federal entities are not permitted to commit cost share towards NIIMBL projects to meet the team obligation.

#### **Federal Agency Participation**

NIIMBL Project Calls are open to Federal proposers. NIIMBL welcomes and encourages the participation of Federal employees in the project call process, both during the Concept Phase and the Full Proposal Phase. Federal employees may suggest a project that NIIMBL should undertake as a community, participate on a project team, or lead a project, as appropriate, within the mission and constraints of their agency. Federal employees may determine if participation in specific NIIMBL projects would be beneficial. Participation in this Project Call process and any resulting projects must be compatible with agency missions and any constraints related to accepting resources from NIIMBL. In general, NIIMBL will try to accommodate the unique needs of Federal proposers in this process to reduce barriers to participation. Federal employees should review the <u>Guide for Information for Federal Stakeholders</u>.

#### **Human Subjects Activities**

If proposing activities with human subjects, all activities involving human subjects must satisfy the requirements of the Common Rule for the Protection of Human Subjects, as provided for by the Department of Health and Human Services in 45 C.F.R. Part 46 and codified by the Department of



Commerce in 15 C.F.R. Part 27. The Common Rule, and the institutional policies that enforce its requirements in activities involving human subjects, exist to ensure adequate protection of human subjects. Additional guidance related to activities involving human subjects can be found in the <a href="https://doi.org/10.1001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-11.0001/june-1

#### **Vertebrate Animal Activities**

If proposing activities with vertebrate animals, all activities must comply with the Laboratory Animal Welfare Act of 1966 (as implemented in 9 C.F.R. Parts 1, 2 and 3), and all other applicable statutes pertaining to the care, handling, and treatment of warm-blooded animals held for research, teaching, or other activities. Additional guidance related to activities involving vertebrate animals is available in <a href="Activities Involving Vertebrate Animals Guidance Document">Activities Involving Vertebrate Animals Guidance Document</a>.

## 3. Proposal Instructions

#### 3.1 General Instructions

#### **Submissions**

<u>Stage 1</u>: Concept submissions must be submitted via the NIIMBL Proposal Submission Hub. All submissions must be received no later than the deadline in Table 1. Submissions received after the deadline, or otherwise not compliant with the requirements of the Concept phase, will not be considered (see below for full requirements). Pl's with accepted concepts will be notified about participating in a virtual summit and will be requested to upload a Showcase Video at that time.

<u>Stage 2</u>: Full Proposal submissions must be submitted via the NIIMBL Proposal Submission Hub. Proposals must be received no later than the deadline in Table 1. Submissions received after the deadline, or otherwise not compliant with the requirements of the full proposal phase, will not be considered (see below for full requirements).

#### Confidentiality

Teams are expected to mark their submissions (both Concepts and Full Proposals) as "NIIMBL Confidential," in accordance with the NIIMBL Bylaws, limiting access to NIIMBL members or Federal representatives. The exception is the Full Proposal Abstract, which will be released to the public if an award is made.

#### 3.2 Stage 1: Concept Phase

NIIMBL will facilitate the review and prioritization of the Concept Papers, Slide Deck, and Showcase Videos by subject matter experts from industry members and federal stakeholders, as noted in Table 1. The feedback will identify the Concepts that are best aligned with industry needs and priorities and will inform the selection of invitations to submit a Full Proposal in Stage 2 of the process.

Applicants are strongly encouraged to submit a 90 second video that will be shared with SME reviewers to complement their application. See guidance documents on the Project Call website.



To be considered during the Concept Phase, proposers must submit their Concept Paper, which must be single-spaced, 1-inch margins, 11-point Arial font (or larger equivalent font), and a maximum of 4 pages (not including references); along with a short PowerPoint slide deck (maximum 5 slides), that adheres to the template provided for this project call at: https://www.niimbl.org/projects-programs/project-call-9-1/.

The Concept Paper, and Concept Slide Deck must be submitted via the NIIMBL Proposal Submission Hub by the deadline in Table 1.

Submitters invited to the virtual summit will be provided with further instructions for attendance.

Submitted concepts that do not adhere to the formatting and length limits will be considered non-compliant and will not be considered for further review.

The Concept Paper must include:

- Submitter name and organization
- Concept title
- Topic area to be addressed
- Identified project team partners and/or desired project team partners and expertise (if known)
- Background and significance of the problem to be solved
- Current state of the art; short summary of existing solutions to solve the problem
- Description of the proposed concept
- Value proposition to project partners, NIIMBL, the NIIMBL community, and/or the United States biopharmaceutical manufacturing industry. Considerations include: return on investment, time to impact in the industry, and contribution to enhanced portfolio within the ecosystem.

Table 2. Summary of Concept submission documents. Submission deadlines are listed in Table 1.

	Constraints
Concept Paper	Maximum of 4 pages
	File Type: .pdf only
Concept Slides	Maximum of 5 slides
	Standard size (4:3)
	File Type: .ppt or .pptx only
Video	90 seconds max
	500 MB max
	Preferred format: MP4



#### 3.3 Stage 2: Full Proposal

The proposal narrative must be no more than 14 pages single-spaced, 1-inch margins, 11-point Arial font (or larger equivalent font). When properly labelled, the full proposal is NIIMBL confidential except for the abstract, which will be released to the public if an award is made.

The full proposal must address and include the following:

- Abstract (200 words max; not counted towards the page count)
- Executive Summary (up to 1 page; not counted towards the page count)
- Proposal Narrative (up to 14 pages)
- Required Proposal Appendices (not counted towards the page count)

Appendix A	Biosketches
Appendix B	Quad Chart (.ppt or .pptx file – see template)
Appendix C	Project Plan (includes Work Breakdown Structure, Responsibilities Assignment Matrix, and Gantt Chart) (.doc file – see template)
Appendix D	Individual Organization Budgets (.xls file – see template)

Additional Proposal Appendices (not counted towards the page count)

Appendix E	Not Applicable for Workforce Projects
Appendix F	References
Appendix G	List of Acronyms
Appendix H	Not Applicable for Workforce Projects
Appendix I	Project Partner Organization Identification Form

All documents listed above should be included in one .pdf file with the exception of Appendices B, C, and D, which should be uploaded separately in their appropriate file format. A proposal completion checklist can be found at: https://www.niimbl.org/projects-programs/project-call-9-1/

#### **Project Partner Organization Identification Form**

Each unique project organization on the project proposal team must submit either a Subrecipient Commitment Form or a Letter of Intent. If your organization is a Federal agency or is a participant in the Federal Demonstration Partnership (FDP) Clearinghouse, your organization should submit a Letter of Intent. All other organizations requesting NIIMBL funding and committing 2 CFR 200 cost



share are required to complete and submit the Subrecipient Commitment Form. Templates can be found on the <u>Project Call website</u>.

Industry partners who are only providing a leveraged cost share commitment, or volunteer participating organizations essential to completing the project should complete a Letter of Commitment documenting their desire to participate and describe the resources they will provide in support of the project. There is no template for letters of commitment.

#### **Abstract**

The abstract includes the names and information of the lead organization, each partner organization, the PI, all co-PIs, and a brief description of the proposal. This description is limited to 200 words. It will be released to the public if an award is made; therefore, teams are expected to ensure that it does not contain any confidential or proprietary information.

NOTE: The Abstract should be included in the pdf of your proposal documents. You will also be required to copy and paste the Abstract into a text field in the Submission Hub. The names and organizations are not included in the 200-word count.

#### **Executive Summary**

Summarize the proposed work including the workforce development objectives and how they are consistent with the Project Call topic area and NIIMBL goals. The Executive Summary is limited to one page.

#### **Proposal Narrative**

The proposal narrative must include all the sections (1 to 4) described below (not including Appendix F).

#### 1. Background and Significance

Workforce development proposals: Identify the project call Priority Topic area being addressed. Evaluate and provide a summary of existing solutions (e.g., programs, solutions, and related initiatives undertaken by industry and educators) that could potentially be leveraged in this project. Describe how this proposal is an improvement over the existing solutions and how the proposed project will uniquely contribute to solving those issues.

#### 2. Project Description

Describe the project segments, tasks, deliverables, milestones, and go/no-go decision points, to include potential Material Transfer Agreements (MTA), and Institutional Review Board (IRB) reviews. Describe the success criteria / evaluation approach for the project, including metrics for measuring project success. Deliverables must be specific and quantitative.

NOTE: Appendix C the Project Plan must cross reference the page number(s) in the narrative where additional details can be found. Appendix C must contain a Responsibility Assignment Matrix (RAM) that will describe the project segments, tasks, deliverables, milestones, and go/no-go decision



points, to include potential MTAs, and IRB reviews.

Describe the success criteria / evaluation approach for the project, including metrics for measuring project success. Deliverables must be specific and quantitative.

Describe how the responsibilities for the work will be shared and a Gantt Chart that will show how the work will be performed over time. Appendix C does not count towards the total page count.

#### 3. Workforce Value Proposition

Summarize the overall value proposition for the NIIMBL community and metrics for measuring project success. Measurable or quantifiable improvements are strongly encouraged. These include:

- Anticipated Positive Impacts. Descriptions of anticipated positive impacts to learners, academic and non-profit organizations involved, industry partners, the broader NIIMBL community, as well as the United States biopharmaceutical manufacturing ecosystem at large.
- <u>Access to Deliverables</u>. Descriptions of plans for making program deliverables, tools, and strategies available to NIIMBL members. For projects that are intended to develop or refine curriculum or training programs and then offer these programs for a cost, NIIMBL expects teams to make these deliverables and/or project outputs available to NIIMBL members for free or at-cost discounted rate.

#### 4. Workforce Project Financial Sustainability Considerations

As NIIMBL would like to see projects create a lasting impact, describe strategies for ensuring the project continues to add value, which ensures proposals provide a clear value proposition for the project team, for the NIIMBL community, for NIIMBL as an organization, and for the industry at large. This could include strategies for:

- *Industry Relevance*. Describe any envisioned approaches to ensuring educational content remains current and relevant with respect to industry needs.
- Local/Regional Sustainability. Once project funding has ended, describe strategies for ensuring deliverables and/or education and training solutions will continue to add value.
- *Information Sharing*. Describe any potential strategies for communicating or sharing findings, best practices, and lessons learned from this project.
- *National Impact / Scale-Out*. If the project is successful, how might NIIMBL consider scaling solutions out to other regions to benefit the community or industry at large? (e.g., Could a train-the-trainer strategy work for this project?)

#### 5. Description of Team

Identify the Principal Investigator (PI) from the lead organization for the project proposal team, the co-PIs from other partner organizations, and other senior/key personnel. In addition, each project



team must identify a Project Manager to manage and oversee the project execution. The Project Manager should not be the PI for the project. Describe the project management approaches to ensure the synergistic work across project team members, in particular any handoff of work between organizations. Include how the team will ensure timelines, budget and risk will be actively managed and decisions will be made.

NOTE: Additional senior/key personnel (those team members who are not identified as the PI or co-PIs) may include staff whose participation and/or leadership is critical for the success of the project. Postdoctoral or graduate students or laboratory technicians should not be considered senior/key personnel. For all identified team members, include their responsibilities and roles in the project.

#### **Required Proposal Appendices**

#### **Appendix A: Biosketches**

Provide biosketches for the PI, all co-PIs, and Project Manager only. Biosketches are limited to two pages each.

#### **Appendix B: Quad Chart**

Complete a quad chart providing an overview of the proposal's methodology and approach, highlights from the work breakdown structure, the impact, team composition, and the total team budget. The quad chart is limited to one page and must be submitted as a .ppt or .pptx file. The NIIMBL template is available at: <a href="https://www.niimbl.org/projects-programs/project-call-9-1/">https://www.niimbl.org/projects-programs/project-call-9-1/</a>

## Appendix C: Project Plan - Work Breakdown Structure, Responsibilities Assignment Matrix, and Gantt Chart

The Project Plan serves as the foundation for the proposed initiative. Align the Project Plan with the Responsibility Assignment Matrix (RAM) to describe how responsibility will be shared across the identified Project Plan elements. The Gantt chart will visually show how the work will be completed. One Project Plan is required for each project proposal team and must include all proposed work. The Project Plan must be submitted as a .doc or .docx file. A template is available for download at: https://www.niimbl.org/projects-programs/project-call-9-1/.

#### Appendix D: Individual Organization Budget/Cost Justification

Provide separate budget tables (xlsx) and cost justifications (docx) for the lead organization and each of the partner organizations requesting funding and/or committing 2 CFR 200 cost share.

Large Industry leveraged cost share commitments should be documented in their Letter of Commitment.

Budgets are to be organized by Project Plan Level 2 Segments. The budget template allows for 5 Project Plan Level 2 Segments. Any project proposal team with more than 5 Project Plan Level 2 Segments is asked to email projectcalls@niimbl.org for further direction on how to complete the budget forms.



The budget template and separate cost justification templates are available for download at: <a href="https://www.niimbl.org/projects-programs/project-call-9-1/">https://www.niimbl.org/projects-programs/project-call-9-1/</a>.

Project teams are encouraged to budget for travel to present at one NIIMBL National Meeting, which occurs in the summer in Washington, D.C.

#### **Additional Proposal Appendices**

**Appendix E: NA** 

#### **Appendix F: References**

Provide a complete list of references cited in the project proposal. If references are not used, indicate NA.

#### **Appendix G: List of Acronyms**

Provide a complete list of acronyms used in the project proposal. If acronyms are not used, indicate NA.

#### Appendix H: NA

## Appendix I: Project Partner Organization Identification Form (3-types of forms, see section 3.3)

Each unique project organization on the project proposal team must submit either a Subrecipient Commitment Form or a Letter of Intent. Templates are available for download at: <a href="https://www.niimbl.org/projects-programs/project-call-9-1/">https://www.niimbl.org/projects-programs/project-call-9-1/</a>.

Include Letters of Commitment from (a) volunteer participating organizations essential to complete the project or from an end user of the developed technology; (b) large industry members who are only committing leveraged cost share; (c) state cost share commitments.

### 4. Proposal Review and Evaluation

#### 4.1 Stage 1: Concept Evaluation Criteria

#### **NIIMBL Acceptance Criteria**

Concept Papers, Slide Decks, and Showcase Videos must comply with requirements outlined in this RFP. Automatic rejection will occur if the submission is received after the published deadline or from a non-NIIMBL member.

#### Concept Paper, Concept Slide Deck and Showcase Video Review

NIIMBL will review submitted Concepts to ensure alignment with the NIIMBL mission (see Section 1 of this RFP), suitability of work within the Topic areas (see Section 6 of this RFP)

NIIMBL industry members and Federal stakeholders will review concepts and provide feedback to NIIMBL that will be used to prioritize a subset of Concepts for invitation to Full Proposals.



The Concept Phase evaluation criteria for reviewers are:

- The Concept's ability to address the topic's problem statement and a relevant industrial need.
- The Concept's demonstration of awareness of existing solutions.
- The Concept's ability to provide a clear value proposition for the project team, the broader NIIMBL community, and/or the biopharmaceutical manufacturing industry.

#### 4.2 Stage 2: Full Proposal Evaluation Criteria

#### **NIIMBL Acceptance Criteria**

Full Proposals must comply with the requirements outlined in this RFP. Proposals will be assessed to ensure the budget/cost share commitment is appropriate and reasonable for the proposed work. All administrative requirements, terms and conditions, and other requirements will be assessed. NIIMBL also reserves the right to request information regarding senior/key personnel's current and pending support after the submission of the full proposal. By requesting this information, NIIMBL will be able to better assess the capability of the senior/key personnel to conduct the proposed scope of work.

Automatic rejection will occur if (a) the submission is received after the published deadline; (b)the project team includes only a single member organization; (c) all budget parameters are not met; (d) any member of the team is not a NIIMBL member or Federal Employee.

#### **NIIMBL Subject Matter Expert Review Panel**

Proposals will undergo a merit review by a panel of subject-matter experts, and will be assessed using the following criteria:

#### Impact - 40%

- The proposal's ability to provide a solution to an industrial need.
- The proposed solution's difference from or complementarity to existing solutions or related initiatives.
- The speed with which the benefits of the project are realized.
- The proposal's ability to provide a clear value proposition for the project team, the broader NIIMBL community, and/or the biopharmaceutical manufacturing industry.

#### Technical Assessment - 60%

- The merit of the technical approach.
- Whether the project deliverables and timelines are realistic.
- The project's clarity of criteria for success.



• The team's inclusion of the needed technical expertise, including project management.

#### **NIIMBL Workforce Activities Committee Review of Workforce Development Proposals**

The NIIMBL Workforce Activities Committee will perform an impact review using the following criteria:

- The proposal's ability to provide a solution to an industrial need.
- Whether the technical approach and project plan are likely to result in success.
- The proposal's ability to provide a benefit to NIIMBL members.
- Whether the project complements the existing NIIMBL workforce portfolio.
- The proposal's ability to adequately describe strategies to ensure sustainability regionally as well as within the NIIMBL community.

#### **NIIMBL Governing Committee**

The NIIMBL Governing Committee will take into account the total Project Call funding that is available and perform a strategic review of the proposals. The GC will consider the following:

- Benefit to NIIMBL members
- NIIMBL sustainability
- Complementarity to existing NIIMBL project portfolio
- Cost and scope alignment with proposed benefits
- Cost share commitment
- Industry involvement
- Increased geographic, organizational/institutional, academic/professional portfolio within the NIIMBL member community and/or the broader United States biopharmaceutical manufacturing ecosystem5. Reporting

Project reporting requirements will be outlined in the Project Award Agreement.

## 6. Project Call Topics

The narratives for each of the project topic areas below are not meant to be exhaustive. All approaches and concepts consistent with the overall goals described in the project topic areas will be considered.

#### **6.1 Workforce Development Topics**

The biopharmaceutical manufacturing sector continues to see significant growth. As a community, it



is critical to enhance the workforce and support the growth of the domestic biopharmaceutical industrial base. Project Call 9.1W will build NIIMBL's portfolio in this area by seeking proposals in 7 different topic areas that fall within the three broad themes of 1) workforce pipelines and talent development, 2) technical curriculum development, and 3) partnership.

#### **Workforce Pipelines and Talent Development**

#### **Topic 1: Stimulate Knowledge and Interest in Biopharma Manufacturing Careers**

The lack of awareness, knowledge of, and interest in biopharmaceutical manufacturing careers is a foundational pipeline development issue as effective career outreach materials are difficult to obtain, company specific, and often not tailored to specific audiences including, but not limited to K-12 students, college students, teachers and guidance counselors, and career changers. This RFP invites proposals to pilot and/or scale initiatives focused on increasing knowledge and interest in the biopharmaceutical manufacturing industry and careers. Proposals impacting rural regions in the United States as well as regions with developing biopharmaceutical manufacturing economies are strongly encouraged.

#### Topic 2: Accelerate Career and Leadership Advancement in Biopharma Manufacturing

The rapid growth of the biopharmaceutical manufacturing industry in recent years has led to unusually fast career advancement among engineers, scientists, and technicians. On the one hand, scientific and engineering professionals are reaching mid-level management roles after just a few years of experience. While technically proficient, these emerging leaders often lack formal training in the core management and leadership skills required to effectively lead teams, manage operations, manage budgets, and support organizational growth. Similarly, the increased industry adoption of non-degree pathways has yielded a new pipeline of high-performing technicians. While these technicians perform well and get promoted, continued career advancement could be facilitated through upskilling in industry-specific critical thinking, business communication, and related interpersonal skills. This RFP invites proposals that address the urgent need to develop scalable, targeted education, training, and mentoring programs for early-career professionals who have recently transitioned—or are on the cusp of transitioning—into mid-level roles. Proposals may include the development of modular, just-in-time learning experiences focused on people management, communication, conflict resolution, project oversight, regulatory decision-making, budgeting, and cross-functional collaboration. Projects may also explore mentorship models, peer learning cohorts, or partnerships with industry to co-deliver content. The goal is to equip these critical segments of the workforce with the tools and confidence to succeed in leadership roles and ensure the long-term strength of the biopharma manufacturing talent pipeline.

#### **Technical Curriculum Development**

#### **Topic 3: Build an Al-Ready Biopharmaceutical Manufacturing Workforce**

The biopharmaceutical industry is undergoing a rapid digital transformation, fueled by advancements in artificial intelligence (AI), machine learning (ML), and other digital tools. These technologies are revolutionizing how therapies are developed, manufactured, and delivered—



creating a critical need for a workforce that is not only scientifically proficient but also AI literate. To meet this moment, we need innovative educational strategies that prepare students and professionals to thrive in this evolving landscape. This RFP invites proposals that address actionable ideas for building an AI-ready biopharmaceutical manufacturing workforce. Proposals may include integrating AI into existing biotech or biomanufacturing education and training programs, designing new courses, modules, or micro-credentials, as well as developing replicable and scalable activities and experiences using AI tools and platforms. By equipping current and future biomanufacturing professionals with the skills necessary to effectively embrace, utilize, integrate, and leverage AI in the development, production, and quality assurance of biopharmaceutical products, we can ensure that we have a workforce that is prepared to meet the demands of a rapidly-evolving industry.

#### Topic 4: Pilot Lower-Cost Options for Biopharmaceutical Manufacturing Education

The high cost associated with biopharmaceutical manufacturing training facilities, equipment, and consumables can make program development and piloting challenging. This RFP invites proposals that pilot innovative, lower-cost training approaches that reduce institutional expenses while maintaining educational value. Projects may explore both high-tech solutions—such as virtual or augmented reality simulations—and low-tech alternatives that are especially relevant for underresourced settings. Proposals should emphasize strategies that provide meaningful exposure to biopharma concepts and skills, even in the absence of expensive equipment, and demonstrate potential for scalability, sustainability, and alignment with industry needs. Collaborations with institutions that have limited access to advanced training infrastructure or serve emerging biomanufacturing regions are strongly encouraged.

#### **Partnership**

#### **Topic 5: Catalyze Cross-Regional Workforce Development Partnerships**

To ensure a robust and geographically representative biopharmaceutical workforce, NIIMBL seeks proposals that foster innovative partnerships across regions. Projects should aim to connect academic institutions, industry stakeholders, workforce boards, and community-based organizations to collaboratively design and implement scalable workforce development models or replicate and scale successful programs from one region to another. Emphasis should be placed on aligning training programs with regional industry needs, sharing best practices, and leveraging existing infrastructure to expand access to high-quality biopharmaceutical manufacturing education and career pathways.

#### Topic 6: Building a Future Biopharma Workforce Through Cross-Sector Pathways

As regional ecosystems across the country work to establish or expand their biopharmaceutical manufacturing capacity, a critical challenge is ensuring a steady pipeline of skilled talent. While students are being trained in biopharma manufacturing programs, many regions are still developing the infrastructure and employer base to absorb this workforce. This RFP invites proposals that support the strategic placement of students into adjacent industries (e.g., medical device manufacturing, diagnostics, food and beverage bioprocessing, industrial biotechnology, and



advanced materials production) to strengthen regional talent ecosystems, grow the biomanufacturing industrial base, and prepare students for future biopharmaceutical manufacturing opportunities. Proposals should focus on low-effort, high-impact strategies that help students recognize the transferability of their skills, gain relevant industry experience, and remain engaged in the broader life sciences and advanced manufacturing landscape. By embedding students in adjacent sectors today, regions can cultivate a workforce that is both immediately employable and well-positioned to transition into biopharma roles as local capacity grows.



## 7. Abbreviated List of Acronyms

Co-PI Co-Principal Investigator

FDP Federal Demonstration Partnership

FFRDC Federally Funded Research and Development Centers

GC Governing Committee

IP Intellectual Property

IRB Institutional Review Board (for Human Subjects Research)

MTA Material Transfer Agreement

NIIMBL National Institute for Innovation in Manufacturing Biopharmaceuticals

PC9.1 Project Call 9.1

PI Principal Investigator

RAM Responsibility Assignment Matrix

RFP Request for Proposals