



The National Institute for Innovation in Manufacturing Biopharmaceuticals

Project Call 10.1W

Request for Proposals

Concept Papers Due: September 9, 2026 (5 pm ET)

Full Proposals Due: January 7, 2027

VERSION July 2026



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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 10.1, with industry-led priority topic areas workforce development proposals.

Funding Opportunity Title: Project Call 10.1

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 NEW proposal submission hub, [NIIMBL Gateway](#).

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 the 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, NIIMBL is requesting Showcase Videos (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 the submission of a Full Proposal (Stage 2). Declination notices will be sent to unsuccessful proposers. Deadlines and key dates are summarized in Table 1.

Stage 2: 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 NEW proposal submission hub, [NIIMBL Gateway](#).

Submissions received after the deadline (see Table 1), or are 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 60 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.

Note: PC10.1 includes an accelerated timeline for proposal preparation, SME review, contracting, and project execution. All projects must be completed within 12 months, and no-cost extensions will NOT be permitted. To support successful project management within this condensed schedule, NIIMBL recommends limiting projects to no more than three project partners and four project plan segments.

Large Industry members may participate in an advisory capacity by providing a Letter of Commitment (LOC). If they will not be directly contributing to project tasks or deliverables, they should not be identified as project participants in the project plan. Any cost-share contributions associated with their advisory role may be described in the LOC.



Important: NIIMBL has launched a new proposal and reporting submission platform, NIIMBL Gateway. All proposers and SME reviewers must create a new account and obtain new login credentials to access the system. To request a NIIMBL Gateway account, visit gateway.niimbl.org and click the Register card to submit an account request.

Table 1. Summary of Key Dates and Deadlines

EVENT	DATE
Concept Paper Due	September 9, 2026 (by 5:00 pm ET)
Virtual Summit	September 29 – October 2, 2026
Invite for Full Proposal	October 19, 2026
Full Proposal Due	January 7, 2027 (by 5:00 pm ET)
Proposal Review	January 2027
Award Decisions Announced	Expected by February 9, 2027

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

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

Stage 2: 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: <https://www.niimbl.org/membership/>.

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 at least one week 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 12-month period of performance

This project call solicits proposals for Institute-Wide Projects; however, projects may request to be treated as Partner-Specific Projects¹. 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 Proposal Phase: Teams must meet the required minimum cost share requirement as cash or in-kind. Each organization's project related cost share requirement is defined in its NIIMBL Membership Agreement, and these requirements differ by: (1) organization type and (2) membership tier.

Cost share contribution guidelines:

- The overall project budget meets the required total cost share (1:1).
- Each organization meets the cost share rules in its own Membership Agreement.
- Each project partner should contribute cost share to support their role/commitment in the scope of work.
- Not every project partner is required to contribute cost share.
- Some project partners may contribute more than the minimum required in their Membership

¹ 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.



Agreement.

- Large Industry members only committing leveraged cost share should document their commitment in their LOC to align with their role on the project. Leveraged cost share will be counted towards the team's total cost share.

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).

Contact Marta Rosario, (martar@udel.edu) by 5:00 PM EST November 30, 2026, 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 narrative and slide deck.

Full Proposals must have at least two distinct member organizations participating in 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 commitment. (Appendix I).

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.

Note: For PC10.1 NIIMBL recommends limiting total project partners to three. Large Industry members may participate in an advisory capacity by providing a Letter of Commitment (LOC). If they will not be directly contributing to project tasks or deliverables, they should not be identified as project participants in the project plan. Any cost-share contributions associated with their advisory role may be described in the LOC. All project partners should have a clear substantive role in meeting the objectives of the scope of work.

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 [Guide for Information for Federal Stakeholders](#).

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 [Human Subjects Research Guidance Document](#).

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 Activities Involving Vertebrate Animals Guidance Document.

3. Proposal Instructions

3.1 General Instructions

Submissions

Stage 1: Concept submissions must be submitted via the [NIIMBL Gateway](#). 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). PI's with accepted concepts will be notified about participating in a virtual summit.

Stage 2: Full Proposal submissions must be submitted via the [NIIMBL Gateway](#). 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-10-1/>.



The Concept Paper, and Concept Slide Deck must be submitted via the [NIIMBL Gateway](#) 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	NA - The Project Plan will be completed within the new submission hub, NIIMBL Gateway .
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, 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-10-1/>.

Project Partner Organization Identification Form

Each project partner participating on the team must submit one of the following:

- Subrecipient Commitment Form
- Subrecipient Letter of Intent (LOI)
- Letter of Commitment (LOC)

Which form should be Submitted?

Submit a Subrecipient Commitment Form if:

- Organization is requesting NIIMBL funding and/or committing cost share under 2 CFR 200



- Organization is not a member of the Federal Demonstration Partnership (FDP)
- Typically for small industry and academic organizations

Submit a Subrecipient Letter of Intent (LOI) if:

- Organization is requesting NIIMBL funding and/or committing cost share under 2CFR 200
- Organization is a member of the Federal Demonstration Partnership (FDP)
- Typically for large academic organizations

Submit a Letter of Commitment (LOC) if:

- Organization is providing resources in support of their role in the project as leveraged cost share. Please note that the commitment should be quantified in the LOI.
- Volunteer participating organizations essential to completing the project but not contributing cost share, should document their desire to participate and describe the resources (if any) they will provide in support of the project.

Templates can be found on the [Project Call website](#).

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 [NIIMBL Gateway](#). 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: The Project Plan must cross-reference the applicable page number(s) in the proposal narrative where additional details are provided. The Project Plan must clearly identify the project partner(s) responsible for each segment, task, deliverable, milestone, and go/no-go decision point to define and document the roles and responsibilities of all participating organizations. In addition, each segment must include the corresponding start and end month to visually depict the project schedule and timeline for the execution and completion of tasks, deliverables, milestones, and go/no-go decision points. This information should provide reviewers with a clear understanding of project sequencing, accountability, and progress throughout the period of performance.

Note: New for this project call, the project plan will be built in the new submission hub, [NIIMBL Gateway](#).

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.
- **Access to Deliverables.** 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. In cases where there is a discrepancy between the submitted budgets and the quad chart budget the quad chart funding and cost share amounts will prevail. The quad chart is limited to one page and must be submitted as a .ppt or .pptx file. The NIIMBL template is available at: <https://www.niimbl.org/projects-programs/project-call-10-1/>.

Appendix C: N/A

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 4 Project Plan Level 2 Segments. Any project proposal team with more than 4 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: <https://www.niimbl.org/projects-programs/project-call-10-1/>.

Additional Proposal Appendices

Appendix E: N/A

Appendix F: References

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

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: N/A

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 the appropriate forms. Templates are available for download at: <https://www.niimbl.org/projects-programs/project-call-10-1/>.

Project Plan –

Note: New for this project call, the project plan will be built in the new submission hub, [NIIMBL Gateway](#).

The Project Plan must cross-reference the applicable page number(s) in the proposal narrative where additional details are provided. The Project Plan must clearly identify the project partner(s) responsible for each segment, task, deliverable, milestone, and go/no-go decision point to define and document the roles and responsibilities of all participating organizations. In addition, each segment must include the corresponding start and end month to visually depict the project schedule and timeline for the execution and completion of tasks, deliverables, milestones, and go/no-go decision points. This information should provide reviewers with a clear understanding of project sequencing, accountability, and progress throughout the period of performance.

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.

Note: 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; or (e) for any noncompliance with required elements of the RFP.

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.
- The proposal's ability to adequately describe strategies to ensure sustainability regionally as well as within the NIIMBL community.

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 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 financial 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

5. Reporting

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

Note: project reporting will be completed in the new submission hub, [NIIMBL Gateway](#).

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.

Workforce Development Topics

The U.S. biopharmaceutical industry is experiencing an unprecedented period of growth, with companies announcing nearly \$500 billion in domestic investments in manufacturing, research, and development infrastructure. These investments are expanding production capacity across both established and emerging biomanufacturing hubs and accelerating the adoption of new technologies, advanced therapeutic modalities, and modern manufacturing practices. To fully realize the impact of this historic investment, the nation must ensure that its workforce development ecosystem can produce a sufficient supply of skilled talent, adapt to evolving industry needs, and efficiently scale proven training approaches across regions. The following topics are intended to support innovative projects that strengthen workforce readiness, address emerging skill requirements, and enhance collaboration across the biopharmaceutical talent development ecosystem to meet the industry's growing demand for a highly skilled workforce.

Topic 1: Catalyze Cross-Regional Workforce Development Solutions

The U.S. biopharmaceutical workforce development ecosystem is regionally distributed. While these regional networks have generated innovative programs and strong local outcomes, they often operate independently, limiting opportunities to share resources, leverage expertise, replicate successful approaches, and address workforce challenges at a national scale. This fragmentation can result in duplicative efforts, inefficiencies, uneven access to specialized training, and inconsistent workforce pathways for learners and employers. As biomanufacturing continues to grow across established hubs as well as emerging regions, including U.S. territories and other developing life sciences markets, there is an increasing need for greater coordination, alignment, and knowledge sharing across workforce ecosystems.



To address this challenge, we seek proposals that strengthen cross-regional workforce alignment and collaboration by scaling best practices and proven models as well as expanding mechanisms for sharing training content and workforce development resources across geographic regions. Projects may facilitate coordination across specialized training centers to broaden access to high-quality education and hands-on learning opportunities; establish communication channels, communities of practice, or partnership networks; develop frameworks for aligning workforce strategies and training approaches; or adapt and scale proven workforce development models for use in new regions. Competitive proposals will foster stronger connections among education, industry, workforce, and economic development stakeholders and produce sustainable structures that enhance national coordination, reduce duplication, and support more consistent and accessible workforce pathways across the biopharmaceutical sector.

Topic 2: Workforce Development for Advanced Therapeutic Modalities

The biopharmaceutical industry is undergoing a significant shift toward advanced therapeutic modalities, including peptide-based medicines such as GLP-1 therapies, antibody-drug conjugates (ADCs), bispecific antibodies, radiopharmaceuticals, and other next-generation biologics. At the same time, unprecedented investment in U.S. biopharmaceutical manufacturing and research infrastructure is creating demand for a workforce with skills that extend beyond those traditionally associated with monoclonal antibody production, vaccines, and gene therapies. As companies expand manufacturing capacity and commercialize these emerging modalities, employers are increasingly seeking talent with specialized knowledge of novel processes, technologies, quality systems, and manufacturing platforms.

To address this emerging workforce gap, we seek proposals that either (1) assess current and future workforce needs associated with advanced therapeutic modalities and/or (2) develop, pilot, and disseminate hands-on educational and training programs that prepare students and incumbent workers for technician, scientist, and engineering roles. Proposed projects may include labor market analyses, employer engagement activities, competency mapping, curriculum, laboratory, simulation-based learning, as well as faculty upskilling. Competitive proposals will demonstrate strong collaboration among industry, community colleges, universities, and workforce stakeholders and will generate actionable resources that help educational institutions align training programs with the evolving talent needs of the advanced therapeutics ecosystem.

Topic 3: Developing a Digitally Fluent Biomanufacturing Workforce

The biopharmaceutical industry is increasingly reliant on digital technologies, automation, advanced analytics, and data-enabled manufacturing systems to improve productivity, quality, and operational performance. As these technologies become embedded across research, development, manufacturing, quality, and supply chain operations, there is a growing need for workers at all levels to possess foundational digital fluency and the ability to effectively interact with modern manufacturing environments. However, many education, training, and workforce development programs have been slow to integrate digital competencies into biopharmaceutical curricula, creating skill gaps that can limit workforce readiness and technology adoption. As digital transformation continues to accelerate across the industry, there is a need for accessible, scalable approaches that equip both new and incumbent workers with the knowledge and skills required to thrive in increasingly automated and data-rich workplaces.

To address this challenge, we seek proposals that develop and implement scalable, shareable approaches for building digital fluency within the biopharmaceutical workforce. Projects may integrate digital and automation competencies into existing education and training programs or develop new modules, micro-credentials, professional development offerings, simulations, or other learning experiences focused on practical skills such as interacting with digital systems, automated workflows, interpreting and utilizing manufacturing data, and operating within connected production environments.



Proposals should clearly identify the target population, define the specific digital competencies to be addressed, and demonstrate strong alignment with current and emerging industry workforce needs. Competitive proposals will produce adaptable models, curricula, or training resources that can be implemented across diverse educational and workforce settings to strengthen digital readiness throughout the biopharmaceutical talent pipeline.



7. Abbreviated List of Acronyms

ADCs	Antibody-drug conjugates
Co-PI	Co-Principal Investigator
FDP	Federal Demonstration Partnership
FFRDC	Federally Funded Research and Development Centers
GC	Governing Committee
GLP-1	Glucagon-like peptide
IP	Intellectual Property
IRB	Institutional Review Board (for Human Subjects Research)
LOC	Letter of Commitment
MTA	Material Transfer Agreement
NIIMBL	National Institute for Innovation in Manufacturing Biopharmaceuticals
PC10.1	Project Call 10.1
PI	Principal Investigator
RFP	Request for Proposals