# NIIMBL

The National Institute for Innovation in Manufacturing Biopharmaceuticals

## Project Call 4.1W
## Request for Proposals

Concept Papers due: October 22, 2020

Full Proposals due: February 4, 2020

VERSION October 1, 2020

# NIIMBL

## Contents

# 1. Executive Summary

The mission of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) 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 Project Call 4.1 with member-driven and industry-led priority topic areas for technical, workforce development, and global health projects. This document contains information for workforce projects. For information on technical projects, please reference Project Call 4.1T. For information on Global Health Fund (GHF) projects, please reference Project Call 4.1G.

**Funding Opportunity Title:** Project Call 4.1W (Workforce)

Stage 1: The Concept Phase includes the submission of a Concept Paper limited to 4 pages in length (not including references) and a short slide deck (see details below). No teaming, detailed budget, or cost share information is required at this stage. Concept Phase submissions must be submitted via the NIIMBL Proposal Submission Hub. All submissions must be received no later than 5:00 p.m. Eastern Time **Thursday, October 22, 2020**. Submissions received after the deadline, or that are not compliant with the page / slide limits, will not be considered.

Following submission of Concepts, each will be reviewed by industry subject matter experts to prioritize those Concepts that have the potential for the highest industry impact and likelihood of success. Factors for invitation to full proposals include the feedback from industry and alignment with prioritized areas noted in this RFP (see below). The Concept Phase (Stage 1) concludes with invitations or declinations issued for submission of a Full Proposal in Stage 2 of the process.

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 NIIMBL Proposal Submission Hub. Proposals must be received no later than 5:00 p.m. Eastern Time **Thursday, February 4, 2020**. Submissions received after the deadline, or otherwise non-compliant with the submission requirements (see below), 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).

| EVENT | DATE |
|---|---|
| **RFP Release** | October 1, 2020 |
| **Concept Paper Due** | October 22, 2020 |
| **Invite for Full Proposal** | Expected by December 1, 2020 |
| **Full Proposal Due** | February 4, 2021 |
| **Proposal Review** | February - March 2021 |
| **Award Decisions Made** | Expected end of March 2021 |

**Priority Topic Areas**

Workforce projects are expected in these high priority industrial-need categorie*s (in no particular order)*

1. Industry Awareness, Pipeline, and Talent Development
2. Technical Training Program Replication & Expansion
3. Remote Training Modules for Biopharmaceutical Manufacturing

**Opportunity Description:** Further details on project topics are found in Section 6.

**Total Amount to be Awarded**

NIIMBL will make available up to $2,800,000 to fund proposals submitted in response to a combination of the PC4.1T and PC4.1W request for proposals, subject to GC approval.

## 2. Project Requirements and Eligibility Criteria

**Project Types**

Proposals must be consistent with NIIMBL Bylaws. For Project Call 4.1W, Full Proposals are accepted with the following parameters:

- A maximum $350,000 of NIIMBL funding
- A minimum 1:1 (partners: NIIMBL) cost share requirement
  - All committed cost share must be from non-Federal funding sources.
  - Higher cost share ratio (partners:NIIMBL) will be considered favorably in the review
- 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[1]. 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 extremely 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

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[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.

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.

**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 as a NIIMBL member, an organization must be a member or have submitted a partially-executed NIIMBL Membership Agreement by **5:00 p.m. Eastern Time on Thursday, January 28, 2021.** Information on how to join NIIMBL is available at: [niimbl membership-information](#).

**Cost Share**

There is no requirement to have cost share documented or planned at the Concept Phase. However, 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 NIIMBL Bylaws and Membership Agreements.

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 applicable.

Project teams requesting State cost share funding may require additional review and approval from those State organizations to secure their commitment for cost share funding. Project proposal teams with state funding are encouraged to include confirmation of the support (PC4.1W Appendix G – Letters of Commitment). Project proposal teams must contact the appropriate State organization for additional information:

**Delaware**:       Contact Marta Rosario ([martar@udel.edu](mailto:martar@udel.edu)) by 5:00 p.m. Eastern Time on January 15, 2021 to request state cost share. The request should include a 1-paragraph description of the project, partners, and budget narrative.

**Massachusetts**: Massachusetts applicants planning to submit a full proposal and requesting

cost share from the Massachusetts Life Sciences Center should reach out to NIIMBLMA@masslifesciences.com early in the application process to confirm requirements and dates. MA applicants will be required to submit a draft application to NIIMBLMA@masslifesciences.com the week of January 4, 2021. Selected applicants will present their proposal in person to the Massachusetts Life Science Center mid-January 2021.

**North Carolina**: Contact Jon Horowitz (jmhorowi@ncsu.edu) at the NC State Office of Research and Innovation. Requests need to reach this office by 5:00 p.m. Eastern Time on December 15, 2020.

**Teaming**

There is no requirement to have any partners identified during the Concept Phase, but if partners have been identified they should be noted in the Concept Paper.

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. 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 (as documented in PC4.1W Appendix G – Letters of Commitment).

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. 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 PC4.1 Guide Information for Federal Stakeholders available at http://www.niimbl.org/project-call-4-1 and contact NIIMBL's Federal Technical Program Manager, Kelley Rogers (Kelley.Rogers@nist.gov), with questions regarding Federal participation.

**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 is available at: http://www.niimbl.org/project-call-4-1

**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 at: http://www.niimbl.org/project-call-4-1

# 3. Proposal Instructions

## 3.1 General Instructions

**Submissions**

Stage 1: Concept submissions must be submitted via the NIIMBL Proposal Submission Hub. All submissions must be received no later than 5:00 p.m. Eastern Time **Thursday, October 22, 2020**. Submissions received after the deadline, or otherwise not compliant with the requirements for a compliant Concept submission, will not be considered.

Stage 2: Full Proposal submissions must be submitted via the NIIMBL Proposal Submission Hub. Proposals must be received no later than 5:00 p.m. Eastern Time **Thursday, February 4, 2021**. Submissions received after the deadline, or otherwise not compliant with the requirements for a compliant proposal, will not be considered (see below for full requirements).

**Confidentiality**

Teams are expected to mark their submissions (both Concepts and Full Proposals) "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

The Concept Phase is designed to give proposers the opportunity to propose their project ideas for consideration by reviewers comprised of industry representatives and Federal stakeholders. Proposers will provide their concepts in the form of a written Concept Paper and a short Concept Slide Deck. Following this submission, NIIMBL will facilitate review of the Concept Papers and Concept Slide Decks by subject matter experts from industry members and federal stakeholders. The feedback from those reviews 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.

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 PC4.1W (http://www.niimbl.org/project-call-4-1). The Concept Slide Deck may not include recorded voiceover. The Concept Paper and Concept Slide Deck must be submitted via the NIIMBL Proposal Submission Hub by 5:00 p.m. Eastern Time on **Thursday, October 22, 2020**. Submitted concepts that do not adhere to the formatting and length limits for both the Concept Paper and the Concept Slide Deck 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 or desired project team partners and expertise (if known)
- Background and significance of problem to be solved
- Short summary of existing solutions and other known initiatives to solve this problem
- Short description of the proposed concept
- Value proposition to project partners, NIIMBL, the NIIMBL community, and/or the United States biopharmaceutical manufacturing industry.

|  | **Submission** | **Constraints** |
|---|---|---|
| **Concept Paper** | October 22, 2020, via NIIMBL Proposal Submission Hub | Single-spaced<br>1-inch margins<br>11-point Arial font (or equivalent)<br>Maximum of 4 pages<br>File Type: .pdf only |
| **Concept Slides** | October 22, 2020, via NIIMBL Proposal Submission Hub | Maximum of 5 slides, adhering to template provided (http://www.niimbl.org/project-call-4-1)<br>Standard size (4:3)<br>File Type: .ppt or .pptx only |

## 3.3 Stage 2: Full Proposal

The full proposal narrative must be no more than 14 pages. 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:

1. Project Partner Information Form(s), Letter(s) of Intent (not counted towards the page count)
2. Abstract (200 words max; not counted towards the page count)
3. Executive Summary (up to 1 page; not counted towards the page count)
4. Proposal Narrative (up to 14 pages)
5. 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) |

6. Additional Proposal Appendices (not counted towards the page count)

| Appendix E | References |
|---|---|
| Appendix F | List of Acronyms |
| Appendix G | Letter(s) of commitment |

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: http://www.niimbl.org/project-call-4-1

**Project Partner Information Form(s)**

Each unique project organization on the project proposal team must submit either a Project Partner Information 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 cost share are required to complete and submit the Project Partner Information Form. Industry partners who are only providing a leveraged cost share commitment should complete a Letter of Commitment (see Appendix G). All project proposal team organizations must be NIIMBL members or a Federal entity. Templates for the Project Partner Information Form and the Letter of Intent are available at: http://www.niimbl.org/project-call-4-1.

**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 workforce development objectives and how they are consistent with the Project Call topic area, NIIMBL goals, projected impact, as well as considerations for project sustainability. The Executive Summary is limited to one page, single-spaced, minimum 1-inch margins, 11-point Arial font (or larger equivalent font).

**Proposal Narrative**

The proposal narrative must be single-spaced, minimum 1-inch margins, 11-point Arial font (or larger equivalent font). The proposal narrative must include all the sections (1 to 5) described below and must not exceed 14 pages (not including references which is Appendix E).

1. **Background and Significance**

   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 project/program design, target audience(s), project segments, tasks, deliverables, milestones, and evaluation approach.

   NOTE: Appendix C will cross reference the Work Breakdown Structure (WBS) with the page number in the narrative where additional details can be found. Appendix C will also contain a Responsibility Assignment Matrix that will describe how the responsibilities for the work will be shared and a Gantt Chart. Appendix C does not count towards the total page count.

3. **Workforce Value Proposition**

   Summarize the overall value proposition and metrics for measuring project success. This could include descriptions of anticipated positive impacts to:

   - target audience;
   - educational partners (e.g. capacity-building, financial benefit);
   - initial industry stakeholders (saved time, reduced cost, better quality);
   - the overall NIIMBL community;
   - the United States biopharmaceutical manufacturing industry at large.

Describe 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 for a nominal fee.

4. **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 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 project is successful, how might NIIMBL best support 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 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, and while no format is prescribed, proposers are encouraged to use the NSF format as prescribed in PAPPG 20-1: https://www.nsf.gov/bfa/dias/policy/nsfapprovedformats/biosketch.pdf

## 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 budget information. The quad chart is limited to one page and must be submitted as a .ppt or .pptx file. The NIIMBL template is available at: http://www.niimbl.org/project-call-4-1

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

The WBS for the proposed project forms the foundation of the proposed project plan. Align the WBS with the Responsibility Assignment Matrix to describe how responsibility will be shared across the identified WBS elements. The Gantt chart will visually show how the work will be completed over time. 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: http://www.niimbl.org/project-call-4-1

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

Provide individual budget table (.xlsx) and cost justification (.docx) for the lead organization and each of the partner organizations requesting funding and/or committing cost share (including leveraged commitment) to the proposed project. Budgets are to be organized by WBS Level 2 Segments. The budget template allows for 5 WBS Level 2 Segments. Any project proposal team with more than 5 WBS 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: http://www.niimbl.org/project-call-4-1

Project teams are encouraged to budget for travel to a kickoff meeting and to present at the NIIMBL National Meeting, which occurs in late spring in Washington, D.C.

## **Additional Proposal Appendices**

## Appendix E: **References**

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

## Appendix F: **List of Acronyms**

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

Appendix G: **Commitment Letters**

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. If Commitment Letter(s) are not needed, this appendix is N/A.

# 4. Proposal Review and Evaluation

## 4.1 Stage I: Concept Evaluation Criteria

**NIIMBL Acceptance Criteria**

Concept Papers and Concept Slide Decks must comply with requirements outlined in this RFP. Concepts will be non-compliant and not considered further if they include either a Concept Paper that exceeds the maximum 4 pages, or a Concept Slide Deck that exceeds the maximum 5 slides. All administrative requirements, terms and conditions, and other appropriate disclosures will be assessed for completeness.

Automatic rejection will occur if the submission is received after the published deadline.

**Concept Paper and Concept Slide Deck Review**

NIIMBL will review submitted Concepts to ensure alignment with the NIIMBL mission (see Section 1 of this RFP) and industry interest.

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

For workforce projects, the Concept Phase evaluation criteria are:

1. The Concept's ability to address the topic's problem statement and a relevant industrial need.

2. The Concept's demonstration of awareness of any existing solutions or related initiatives to solve this problem.

3. 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 II: Full Proposal Evaluation Criteria

**NIIMBL Acceptance Criteria**

Full Proposals must comply with information requirements outlined in this RFP. Proposals will be assessed to ensure the budget is appropriate and reasonable for proposed work. All administrative requirements, terms and conditions, and other appropriate disclosures 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) budget parameters are not met, such as the maximum project budget and minimum cost share ratio.

**NIIMBL Subject Matter Expert Review Panel**

Workforce 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 address the topic's problem statement and a relevant industrial need.
- The proposal's demonstration of awareness of any existing solutions or related initiatives to solve this problem.
- The proposal's ability to provide a clear value proposition for the project team, the broader NIIMBL community, and 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 Workforce Activities Committee**

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 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 4.1 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.

# 5. Reporting

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

# 6. Project Call 4.1 Topics

1. **Industry Awareness, Pipeline, and Talent Development**

The biopharmaceutical manufacturing sector is poised for significant growth. As a community, it is critical to generate interest and awareness of biomanufacturing careers, grow a diverse talent pipeline, and connect talent with employers. In addition to traditional sources of life science talent, the biopharmaceutical manufacturing sector will need an increasingly diverse talent base that draws from new schools, new populations, and non-traditional academic disciplines including but not limited to data analytics, computer science, and business. While there are many programs aimed at promoting careers in STEM, many are (a) not focused on biopharma, (b) are company-specific, (c) are regional, (d) are focused primarily on K-12 populations.

The RFP invites proposals that seek to develop or expand the reach of programs that stimulate interest and career awareness in the biopharmaceutical manufacturing industry, grow the talent pipeline, and connect new talent with the biopharmaceutical manufacturing industry. Successful projects will:

- Focus on biopharmaceutical manufacturing.
- Offer direct value to NIIMBL industry members.

- Benefit the NIIMBL ecosystem broadly (not region-specific).
- Focus on a well-defined target population that could potentially include undergraduate students, graduate students, adults, displaced workers, disadvantaged populations, minorities, and/or transitioning military personnel.

## 2. Technical Training Program Replication & Expansion

Technical training and hands-on professional development is a valuable way for technicians, scientists, engineers, and professionals to expand their technical skills in the biopharmaceutical manufacturing industry. NIIMBL is fortunate to have a wealth of hands-on education, training, and professional development expertise available within our member universities, community colleges, and specialized training centers. That said, it can be challenging for companies to identify and evaluate suitable training opportunities due to differences in curriculum, technical expertise, and facilities.

The RFP invites proposals focused on building and enhancing partnership and collaboration across multiple organizations with a focus of developing capacity to deliver technical education and professional development across the United States. Approaches could include (but are not limited to):

- course or program-specific alignment and/or harmonization of learning objectives and curriculum;
- transfer of curriculum between existing training centers in response to demonstrated need;
- train the trainer projects focused on enhancing faculty and instructional staff expertise;
- expansion of successful NIIMBL-funded pilot programs.

## 3. Remote Training Modules for Biopharmaceutical Manufacturing

In response to the coronavirus pandemic, NIIMBL's entire membership community has been delivering an ever-increasing amount of highly-technical instruction virtually. Unfortunately, this poses new challenges as leveraging hands-on experiences to teach concepts, skills, and technologies specific to biopharmaceutical manufacturing is a recognized best practice. While this temporary paradigm shift will undoubtedly usher in new ways of teaching that add value for years to come, the replication and/or replacement of hands-on laboratory experience with remote learning options remains an inherently difficult and resource intensive endeavor.

The RFP invites proposals focused on the creation and deployment of innovative instructional modules for use in the delivery of remote instruction of specific biopharmaceutical manufacturing concepts, skills, and technologies.  While there is a maximum 18-month duration for proposed projects, shorter-duration (6-12 months) projects are strongly encouraged. Successful projects will focus on:

- Identifying specific biopharmaceutical manufacturing concepts, skills, and technologies for which remote options are needed.
- Utilizing concept appropriate delivery modalities, including but not limited to video (livestreamed or recorded), animation, simulation, virtual/augmented reality, as well as shippable "kits" for teaching hands-on skills to home-based students or employees.
- Developing discrete training modules that are made available (free or at-cost) for use by NIIMBL members in both academic, non-profit, and/or industry settings to augment existing education and training programs.

## 7. List of Acronyms

1. BRL: NIIMBL Biomanufacturing Readiness Level
2. Co-PI: Co-Principal Investigator
3. FDP: Federal Demonstration Partnership
4. FFRDC: Federally Funded Research and Development Centers
5. GC: Governing Committee
6. GHF: Global Health Fund
7. IP: Intellectual Property
8. NIIMBL: National Institute for Innovation in Manufacturing Biopharmaceuticals
9. NSF: National Science Foundation
10. PAPPG: Proposal & Award Policies & Procedures Guide
11. PC4.1T: Project Call 4.1 Technical
12. PC4.1W: Project Call 4.1 Workforce
13. PI: Principal Investigator
14. RFP: Request for Proposals
15. STEM: Science, Technology, Engineering and Mathematics
16. WBS: Work Breakdown Structure