NIIMBL

The National Institute for Innovation in Manufacturing Biopharmaceuticals

Project Call 2.2W
Request for Proposals

Concept Papers due: January 10, 2019

Full Proposals due: May 9, 2019

VERSION November 30, 2018

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NIIMBL

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 2.2 with member-driven and industry-led priority topic areas for technical and workforce development projects. This document contains information for workforce projects. For information on technical projects, please reference Project Call 2.2T.

Funding Opportunity Title: Project Call 2.2W (Workforce)

Stages: Stage 1: The Concept Phase includes the submission of a 4-page Concept Paper. 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, January 10, 2019**. Submissions received after the deadline will not be considered.

Following submission of Concept Papers, invitations will be issued to participate in the Project Call 2.2 Summit, where proposers will have multiple opportunities to network and discuss their project during a short rapid-fire presentation and an open poster session.   This Phase concludes with invitations issued to submit a full proposal in Stage 2 of the process.

Stage 2: 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, May 9, 2019**. Submissions received after the deadline will not be considered.

This Phase concludes with a decision to fund or not fund the proposal by the NIIMBL Governing Committee (GC).

EVENT	DATE
RFP Release	November 30, 2018
RFP FAQ Webinars	December 5, 2018
Concept Paper Due	January 10, 2019
Invite to Project Call 2.2 Summit	Anticipated the week of January 14, 2019
Project Call 2.2 Summit	Anticipated the week of February 18, 2019
Invite for Full Proposal	Anticipated the week of March 4, 2019
RFP FAQ Webinars	TBD
Full Proposal Due	May 9, 2019
Proposal Review	May 14-28, 2019
Committee Review	May 14-28, 2019
Award Decisions Made	Anticipated June 19, 2019

Funding Opportunity Description:

Further details on project topics are found in Section 6.

Workforce projects are expected in these high priority industrial-need categories:
(In no particular order)

1. De-Risked Training Environments
2. Technical Training Capacity-Building Projects
3. Virtual Reality / Augmented Reality Training
4. Industry Immersion Frameworks
5. Best Practice Research

Total Amount to be Awarded: NIIMBL will make available up to $4,500,000 to fund proposals submitted in response to both the PC2.2T and PC2.2W request for proposals, subject to GC approval.

2. Project Requirements and Eligibility Criteria

Project Types

This project call solicits proposals consistent with NIIMBL Bylaws. For Project Call 2.2, two types of proposals are accepted with the following parameters:

1. Small Proposals: Small proposals are a maximum $300,000 of NIIMBL funding and are required to meet a minimum 1:1 (NIIMBL: partners) cost share requirement.
2. Large Proposals: Large proposals are a maximum $600,000 of NIIMBL funding and are required to meet a minimum of 1:1.25 (NIIMBL: partners) cost share requirement.

All committed cost share must be from non-Federal funding sources.

Period of Performance:

Proposals must not exceed 12 months.

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, a 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 **5:00pm Eastern Time on Monday, April 29, 2019.** Information on how to join NIIMBL is available at www.niimbl.org.

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 (Appendix G). Project proposal teams must contact the appropriate State organization for additional information:

Delaware: Contact Marta Rosario (martar@udel.edu) by 5:00 p.m. on April 25, 2019 to request state cost share. The request should include a 1-paragraph description of the project, partners, and budget narrative.

Massachusetts: Massachusetts applicants should submit a draft application to NIIMBLMA@masslifesciences.com by April 24, 2019. Applicants may need to present their proposal in person to the Massachusetts Life Science Center the week of April 29, 2019.

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. on March 1, 2019.

Teaming

There is no requirement to have any partners identified during the Concept Phase. A goal of the Project Call 2.2 Summit is to help concept proposers connect with industry members (across all tier levels), and other NIIMBL members to identify partners and cost share opportunities.

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 Appendix G). All workforce projects must

still have at least two distinct organizations participating on the project as project participants.

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 also request invitations to the Project Call 2.2 Summit to 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 Information on NIIMBL Project Call 2.2 for Federal Stakeholders 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:
https://niimbl.org/Downloads/PC2_2_Guide_HumanSubjects.pdf

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:
https://niimbl.org/Downloads/PC2_2_Guide_VertebrateAnimalActivities.pdf

3. Proposal Instructions

3.1 General Instructions

Submissions

Stage 1: Concept Paper 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, January 10, 2019**. Submissions received after the deadline 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, May 9, 2019**. 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 "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 before a panel of reviewers comprised of industry representatives and Federal stakeholders. Proposers first present their concepts in the written form of a Concept Paper. Following this submission, NIIMBL will host the Project Call 2.2 Summit, where invited proposers will have multiple opportunities to network and discuss their project during a brief rapid-fire presentation and a poster session. This Phase concludes with invitations issued 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, 11-point Arial font (or larger equivalent font) and a maximum of 4 pages; via the NIIMBL Proposal Submission Hub by Thursday, January 10, 2019.

The Concept Paper must include:

1. Submitter name and organization
2. Concept title
3. Topic area to be addressed
4. Identified project team partners or desired project team partners and expertise (if known)
5. Background and significance of problem to be solved
6. Short summary of existing solutions and other known initiatives to solve this problem
7. Short description of the proposed concept

8. Short description of the proposed value proposition to partners, NIIMBL, the NIIMBL community, and/or the United States biopharmaceutical manufacturing industry

	Submission	Constraints
Concept Paper	January 10, 2019, via NIIMBL Proposal Submission Hub	Single-spaced 11-point Arial font (or equivalent) Maximum of 4 pages File Type: .pdf only

Project Call 2.2 Summit

The Project Call 2.2 Summit is designed to provide proposers an opportunity to share their concepts with the community for review and evaluation purposes and to provide proposers an additional venue to form teams. Due to practical considerations for engagement from industrial partners, NIIMBL expects to invite no more than 100 concepts to participate in the Project Call 2.2 Summit. All concepts will be reviewed to ensure alignment with the NIIMBL mission (see Section 1) and industry interest. Following this review, invitations will be issued during the week of January 14, 2019 to participate in the Project Call 2.2 Summit. Only concepts that have been invited will be eligible to participate in the Summit.

Upon receiving an invitation to present at the Project Call 2.2 Summit, proposers will be required to prepare two additional documents that will be used during the Project Call 2.2 Summit: a slide deck to be displayed during the proposer's brief presentation, and a poster. Proposers will be required to submit their concept slides prior to the Summit, but will not be required to submit their poster to NIIMBL in advance. Note: though the slides and poster are "NIIMBL Confidential," teams should be aware that the presentation will be to an in-person and remote, limited audience of NIIMBL members and Federal stakeholders.

	Submitted upon receiving invitation	Constraints
Concept Slides	Via NIIMBL Proposal Submission Hub	Rapid-fire presentation Marked "NIIMBL Confidential" File Type: .ppt, .pptx only
Concept Poster	Not submitted to NIIMBL in advance of Summit	48" x 36" horizontal orientation

Each proposer is expected to attend the Project Call 2.2 Summit in person, although exceptions to in-person attendance may be considered on a case-by-case basis. During the Project Call 2.2 Summit, submitters will have an opportunity to present their ideas directly to the industry panel and Federal representatives by delivering a brief oral presentation and by

participating in an extended poster session. The Project Call 2.2 Summit will likely be scheduled during the week of February 18. More detailed information will be forthcoming.

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) (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
Appendix C	Project Plan (includes Work Breakdown Structure, Responsibilities Assignment Matrix, and Gantt Chart)
Appendix D	Individual Organization Budgets

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

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

A proposal completion checklist can be found at:
http://www.niimbl.org/Downloads/PC2_2_Guide_ProposalChecklist.pdf

Project Partner Information Form(s)

Each unique project organization on the project proposal team must submit a Project Partner Information Form. If your organization is a Federal agency or is a participant of the Federal Demonstration Partnership (FDP) Clearinghouse, your organization may instead elect to submit a Subrecipient Letter of Intent. If your organization is not a Federal agency or a member of the FDP, your organization is required to complete and submit the Project Partner Information Form. All project proposal team organizations must be NIIMBL members or a Federal entity.
https://niimbl.org/Downloads/NIIMBL_Project_Partner_Information_Form_FINAL_112018.pdf

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.

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.

Proposal Narrative

The proposal narrative must be single-spaced, 11-point Arial font (or larger equivalent font). The proposal narrative must include all the sections described below and must not exceed 14 pages.

1. **Background and Significance**

   Identify the project call topic area being addressed and describe the specific problem being addressed. For projects focused on the development and/or delivery of education and training, evaluate and provide a summary of existing solutions within the United States or elsewhere (e.g. strategies, 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 segments, tasks, milestones, and deliverables. If project deliverables include the development and/or delivery of education and training, deliverables should be described with respect to:

   - *Learning Modality*. Description of the learning modalities to be utilized in education and training delivery (e.g. lecture, hands-on, AR/VR, e-Learning, blended learning).
   - *Program Design*. High-level summary of the education and training delivery strategy (e.g. anticipated course/program length, number of individuals impacted).
   - *Infrastructure*. Description of infrastructure required to support development and delivery of education and training. For example, this could include a description of instructional, facility, utilities, and equipment (for hands-on and lecture courses) or specialized development and delivery platforms and tools in the case of digital solutions (e-learning, VR/AR).
   - *Audience*. Description of the anticipated audience (e.g. students, incumbent employees, train the trainer, underserved populations, K-12).
   - *Prerequisite Knowledge*. Description of the prior knowledge, experience, skills, or competencies that are needed to understand the program content or activities.
   - *Learning Objectives*. Summary of the proposed learning objectives.

- *Evaluation / Outcome*. Description of how learners will be evaluated in addition to description of any degrees or credentials earned (e.g. certificate of completion, academic certificate, credential, etc.).

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 with respect to the development of an educated and trained workforce. This could include descriptions of anticipated positive impacts to:

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

If project deliverables include the development and/or delivery of education and training, describe plans for making courses and/or materials available to NIIMBL members.

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

personel. In addition, each project team must identify a Project Manager to manage and oversee the project execution. 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 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: https://www.nsf.gov/pubs/policydocs/pappg17_1/pappg_2.jsp#IIC2f]

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: https://niimbl.org/Downloads/PC2_2_Template_AppendixB_ProposalQuadChart.pptx

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 WBS is required for each project proposal team and must include all proposed work. The WBS must be submitted as a .doc or .docx file. A template is available for download at: http://www.niimbl.org/Downloads/PC2_2_Template_AppendixC_ProjectPlan.docx

Appendix D: **Individual Organization Budget**

Provide individual budget workbooks for the lead organization and each of the partner organizations requesting funding and/or committing cost share 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 workbook. The budget template is available

for download at:
https://niimbl.org/Downloads/Appendix_D_Individual_Organization_Budget_workbook.xlsx

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 volunteer participating organizations essential to complete the project or from an end user of the developed technology. If commitment Letter(s) are not needed, this appendix is N/A.

4. Proposal Review and Evaluation

4.1 Stage I: Concept Paper Evaluation Criteria

NIIMBL Acceptance Criteria

Concept Papers must comply with information requirements outlined in this RFP. Any pages beyond the 4-page limit will be removed before distribution to the review panel. All administrative requirements, terms and conditions, and other appropriate disclosures will be assessed for compliance with this RFP.

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

Concept Paper Presentation - The Project Call 2.2 Summit

No more than 100 concept proposers will be invited to participate in the Project Call 2.2 Summit. If more than 100 concept Papers are received that comply with the information outlined in this RFP, NIIMBL will review concept Papers to ensure alignment with the NIIMBL mission (see Section 1) and industry interest. Following this review, invitations will be issued during the week of January 14, 2019 to participate in the Project Call 2.2 Summit. Only concepts that have been invited will be eligible to participate in the Summit.

Concept presentations will be made to a panel of NIIMBL industry members and Federal stakeholders. The NIIMBL industry members will evaluate proposed concepts for the purpose of inviting a full proposal submission, with consideration of the total available funding ceiling.

For workforce projects, the Concept Phase evaluation criteria are:

1. The Concept Paper's ability to address the topic's problem statement and a relevant industrial need
2. The Concept Paper's demonstration of awareness of any existing solutions or related initiatives to solve this problem
3. The Concept Paper'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

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.

Automatic rejection will occur if: 1) the submission is received after the published deadline, 2) the project team includes only a single member organization, and 3) budget parameters are not met, such as the maximum project budget and 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%

1. The proposal's ability to address the topic's problem statement and a relevant industrial need
2. The proposal's demonstration of awareness of any existing solutions or related initiatives to solve this problem
3. The proposal's ability to provide a clear value proposition for the project team, the broader NIIMBL community, and the biopharmaceutical manufacturing industry
4. The proposal's ability to adequately describe strategies to ensure sustainability regionally as well as within the NIIMBL community

Technical Assessment – 60%

5. The merit of the technical approach
6. Whether the project deliverables and timelines are realistic
7. The project's clarity of criteria for success
8. The team's inclusion of the needed technical expertise, including project management

NIIMBL Workforce Activities Committee

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

1. The proposal's ability to provide a solution to an industrial need
2. Whether the approach and project plan are likely to result in success
3. The proposal's ability to provide a benefit to NIIMBL members
4. Whether the project complements the existing NIIMBL technology portfolio
5. 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 2.2 funding that is available and perform a strategic review of the proposals. The GC will consider the following:

1. Benefit to NIIMBL members
2. NIIMBL sustainability
3. Complementarity to existing NIIMBL project portfolio
4. Cost and scope alignment with proposed benefits
5. Cost share commitment
6. Industry involvement

5. Reporting

Project reporting requirements will be outlined in the Project Award Agreement and will include

1. Administrative
    a. Monthly invoices to include cash or cost share
2. Technical
    a. Monthly project update and team teleconferences
    b. Quarterly report
    c. Final report
    d. Annual presentation to NIIMBL membership
    e. Post-Award Impact Reporting

6. Project Call 2.2 Topics

Project Call 2.2 topics areas were developed and prioritized by NIIMBL's Tier 1 companies and the Workforce Activities Committee and approved through the Governing Committee. To the extent that collaboration with Federal Organizations, National Laboratories, or Federally Funded Research and Development Centers (FFRDCs) is appropriate for the success of a proposed project, consider options to include these individuals or organizations.

Workforce Project Topics are suggested based on existing NIIMBL workforce projects as well as discussion and prioritization of topics by Tier 1 companies with a focus on further developing a NIIMBL community-wide workforce development plan. Topics include:

1. De-Risked Training Environments

Current industry approaches to hands-on training for many fundamental biomanufacturing skills (i.e. aseptic operations, core production skills, quality control/analytical) require valuable on-the-job approaches to training. This approach is inefficient as scheduling training in core production areas diverts equipment and human resources from operations. In addition, this approach introduces unnecessary risk into cleanroom and production environments. As a result, the design and development of new on-site training approaches that decouple training from core production and testing facilities could greatly accelerate trainee qualification (or requalification) and reduce time to competence in role. This would allow for intense and extended skills practice prior to skill certification. Approaches could include (but are not limited to) deployable mobile training assets (i.e. bus, trailer, skids, etc.) as well as dedicated and/or standalone training rooms or facilities.

2. Technical Training Capacity-Building Projects

Hands-on professional development is a valuable way for technicians, scientists, engineers, and professionals to expand their technical skills in the biopharmaceutical manufacturing industry. Hands-on curriculum exists at a number of training centers, universities, and community colleges across the United States. That said, it can be challenging for companies to identify suitable opportunities in close geographic proximity. For this reason, there is a need to enhance collaboration between academic partners with a focus of developing the capacity to deliver technical professional development in new regions of the United States. Approaches could include (but are not limited to) transfer of curriculum between existing training centers in response to demonstrated local industry need as well as train the trainer projects focused on enhancing training capability within individual companies. New training centers may also be warranted based on regional needs.

3. Virtual Reality / Augmented Reality Training

Biopharmaceutical operations involve detailed and tedious interactions with manufacturing systems. Training approaches using augmented or virtual reality have the potential to reduce the time to competency and develop skills in a low risk environment outside of the clean room. Projects that advance the use of these training modes in biopharmaceutical manufacturing should identify operations most amenable to AR/VR technology, and test the concept to show the value compared to traditional learning modes.

4. Industry Immersion Frameworks

Relevant experience and familiarity with the biopharmaceutical manufacturing industry is a common need for both students and educators. Students participating in industrial-based internships and co-ops have a leg up in hiring. Similarly, college faculty with subject matter

expertise and experience in the industry are better able to design curriculum that meets industry needs. That said, design and management of industry immersion program take time, company personnel to supervise participants, and requires coordination between both academic and industry partners. As a result, there is a need to pilot new approaches and easily reproducible models for enabling students (internships and co-ops) and/or faculty (sabbaticals) to benefit from industry immersion experiences.

5. Best Practice Research

Benchmarking and best practice research is a valuable endeavor that can enable the biopharmaceutical manufacturing community to learn from both each other and other industries. For many organizations, however, time is limited, and best practice research is often neglected. As a result, there is an interest in projects focused on research (i.e. systematic review, landscape analysis, literature review) of applied best practices and models for one of the following:
- Strategies for knowledge management
- Approaches to bridging generational differences in training
- Strategies for measuring ROI for training approaches and training metrics
- Best practices in K-12 pipeline development, outreach, and awareness

7. List of Acronyms

1. GC: Governing Committee
2. RFP: Request for Proposals
3. FAQ: Frequently Asked Questions
4. FFRDC: Federally Funded Research and Development Centers
5. MRL: Manufacturing Readiness Level
6. WBS: Work Breakdown Structure
7. AR/VR: Virtual Reality / Augmented Reality
8. PI: Principal Investigator
9. Co-PI: Co-Principal Investigator
10. NIIMBL: National Institute for Innovation in Manufacturing Biopharmaceuticals
11. PC2.2T: Project Call 2.2 Technical
12. PC2.2W: Project Call 2.2 Workforce