Project Call 10.1T

Request for Proposals

Concept Papers Due: September 9, 2026

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 for technical 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 and showcase video. 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). For Technical Concepts, the starting Biomanufacturing Readiness Level (BRL) of a given Concept will also be a factor. 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 no-cost extensions will 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 (5:00 pm ET)
Virtual Summit	September 29 – October 2, 2026
Invite for Full Proposal	October 19, 2026
Full Proposal Due	January 7, 2027 (5:00 pm ET)
Proposal Review	January 2027
Award Decisions Announced	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.

Technology development Concepts and Full Proposals shall be within NIIMBL Biomanufacturing Readiness Level (BRL) 4-7. More information on BRL can be found at: https://www.niimbl.org/industry-solutions/brls/.

Invited Full Proposals will be accepted with the following constraints:

- A maximum $500,000 funding for Technology 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
- Technology development proposals will be required to complete a NIIMBL BRL assessment.

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 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 of 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 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 5:00PM EST November 30, 2026, to request a State of Delaware cost

[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.

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 expects inclusion of Tier 3 industry members for Technology development projects. Project teams without one or more Tier 3 industry members must complete the required SMM exemption justification form (Appendix H).

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

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 in 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). PIs 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 and video 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.

For Technology development Concepts, the Concept BRL Appendix must also be submitted via the NIIMBL Gateway by the same deadline. There is no page limit for the Concept BRL Appendix.

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, contribution to enhanced portfolio within the ecosystem.
- For technology development concepts: BRL justification of the proposed concept and planned BRL transition from at least BRL 4 to a higher BRL; this should be addressed in the Concept Paper, Slide Deck, and the Concept BRL Appendix (template available at: https://www.niimbl.org/projects-programs/project-call-10-1/.)

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
Concept BRL Appendix (if applicable)	No page limits File Type: .pdf
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 on the Project Call Webpage)
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 on the Project Call Webpage)
Appendix E	BRL Evaluation Detailed BRL Form (.pdf)

- Additional Proposal Appendices (not counted towards the page count)

Appendix F	References
Appendix G	List of Acronyms
Appendix H	Tier 3 industry member partner exemption request
Appendix I	Project Partner Organization Identification Form

All documents listed above should be included in one .pdf file with the exception of Appendices B, D, and E, 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 webpage. There is not a template for the LOC.

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 technology development objectives and how they are consistent with the Project Call topic area and NIIMBL goals, initial and anticipated final BRL level, and the projected impact of the project. 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

Technology Development proposals: Identify the project call Priority Topic area being addressed. Describe the specific problem or current state-of-the art within the context of the relevant Priority Topic area of this project call. Summarize prior work done in the area, preliminary results, and the starting and expected ending BRL of the work being proposed. Describe how this proposal is an improvement over the existing solutions or state-of-the art and how the proposed project will uniquely contribute to solving the above-mentioned problem.

2. Project Description

Describe the project segments, tasks, deliverables, milestones, and go/no-go decision points, must 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. Value Proposition

Summarize the impact of the proposed project on the overall goals and objectives of NIIMBL and describe the overall value proposition. This should be from the perspective of NIIMBL, as well as the broader NIIMBL community and/or the United States biopharmaceutical manufacturing industry. Show how the project will advance the BRL of the technology by addressing the questionnaire for exit from the current BRL. Examples of impact include technical impact on productivity, quality, efficiency, efficacy, potency, safety, and/or any other important factors identified in the key areas below (see Section 6). Economic impact in this sector might include factors such as scalability of technical projects, the future of biomanufacturing, and/or estimated economic impact on a company or on the industry broadly, or any other relevant measure. Describe how the project engages a wide range of stakeholders within the NIIMBL member community and/or the broader United States biopharmaceutical manufacturing ecosystem. Measurable or quantifiable improvements are strongly encouraged.

4. 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 synergistic work across project team members, particularly 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: NA

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/.

Appendix E: BRL Evaluation

A detailed BRL assessment form. See Detailed BRL Form.

Additional Proposal Appendices

Appendix F: References

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

Appendix G: List of Acronyms

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

Appendix H: Tier 3 industry member partner exemption request

If a Tier 3 Industry Member is not a proposed project partner, then the required exemption form must be submitted with the full proposal. The exemption request contains two components: 1. How do you know that there is no Tier 3 industry member available for this project? 2. The basis upon which it was determined to be fair and reasonable not to include a Tier 3 industry member. If a Tier 3 industry member is part of the project team, this appendix is NA. The required template is available for download at: https://www.niimbl.org/projects-programs/project-call-10-1/ .

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), and also the BRL 4-7 space for Technology Development Concepts.

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

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

Impact – 40%

- The importance of the industrial problem or need being addressed.
- The proposal's ability to provide a solution to that need.
- The proposed solution's differentiation from, or complementarity to, existing solutions and related initiatives.
- The potential benefit to the project team, the broader NIIMBL community, and the biopharmaceutical manufacturing industry.
- The speed with which project benefits and outcomes are expected to be realized.

Technical Assessment – 60%

- The merit of the technical approach.

- The likelihood that the proposed approach and project plan will achieve the stated objectives.
- Whether project deliverables, milestones, and timelines are realistic.
- The clarity and appropriateness of the project's success criteria.
- The qualifications and expertise of the project team, including project management capabilities.
- For technology development projects, the starting BRL and expected BRL progression.

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
- For Technology development Proposals: starting BRL and expected progression of BRL.
- Increased geographic, organizational/institutional, academic/professional portfolio within the NIIMBL member community and/or the broader United States biopharmaceutical manufacturing ecosystem.

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 intended to be exhaustive. All approaches and concepts consistent with the overall goals described in the project topic areas will be considered. As the biopharmaceutical industry continues to diversify across product modalities, manufacturing platforms, and digital capabilities, there is an increasing need for platform technologies that improve manufacturing flexibility, accelerate development timelines, strengthen process understanding, and enable more intelligent, data-driven manufacturing. Industry participants consistently identified opportunities to advance artificial intelligence (AI), digital manufacturing, process analytical technologies (PAT), advanced manufacturing platforms, emerging therapeutic modalities, and future manufacturing infrastructure as areas where pre-competitive collaboration can provide broad benefit across the industry.

NIIMBL seeks collaborative proposals that develop enabling technologies, platform capabilities, and integrated solutions that improve manufacturing robustness, scalability, and readiness across multiple therapeutic modalities. Note that a single proposal may only address one priority topic area. Proposers may submit more than one proposal with a unique priority topic area. NIIMBL seeks proposal ideas aligned with these needs, as described in the sections below.

6.1 Intelligent Biomanufacturing Through Artificial Intelligence, Digitalization, and Advanced Process Control

Biopharmaceutical manufacturing continues to generate unprecedented volumes of process, analytical, operational, and manufacturing data. However, these data often remain fragmented across development, manufacturing, quality systems, and supply chain operations, limiting the industry's ability to make timely, data-driven decisions. As manufacturing processes become increasingly complex and product portfolios continue to diversify, manufacturers require intelligent systems capable of integrating information across the product lifecycle to improve process understanding, accelerate technology transfer, reduce manufacturing deviations, and enable predictive manufacturing.

Artificial intelligence, machine learning, digital twins, integrated process modeling, and intelligent automation have emerged as transformative technologies capable of fundamentally changing how manufacturing processes are developed, optimized, and controlled. This topic seeks innovative computational frameworks, digital infrastructure, and intelligent manufacturing technologies that improve process performance while supporting scalable implementation across multiple therapeutic modalities.

Proposals should aim to:

- Develop AI and machine learning tools that improve process understanding, optimization, and predictive manufacturing performance.
- Develop digital twin frameworks capable of integrating upstream, downstream, analytical, and manufacturing information to support process development, scale-up, and lifecycle management.
- Develop hybrid mechanistic and data-driven models that improve prediction of critical process parameters and product quality.
- Demonstrate intelligent decision-support systems, including Agentic AI, that improve manufacturing planning, process monitoring, troubleshooting, or operational efficiency.
- Establish interoperable manufacturing data architectures and standardized data models that facilitate integration across manufacturing platforms.
- Develop predictive process control strategies that reduce variability and improve manufacturing robustness.
- Demonstrate platform technologies that can be broadly applied across multiple therapeutic modalities and manufacturing facilities.

6.2 Advanced Process Analytics, Product Quality, and Real-Time Manufacturing Control

Continued advances in biologics, cell and gene therapies, antibody-drug conjugates (ADCs), and other emerging therapeutic modalities require equally advanced analytical technologies capable of supporting increasingly complex manufacturing processes. Current reliance on offline testing often delays decision making, limits process understanding, and constrains implementation of advanced manufacturing strategies.

This topic seeks innovative analytical technologies that provide real-time insight into manufacturing performance, improve process understanding, strengthen quality management systems, and support implementation of real-time release testing (RTRT). Emphasis should be placed on platform analytical technologies that can improve manufacturing performance across multiple product classes.

Proposals should aim to:

- Develop next-generation Process Analytical Technology (PAT) capable of real-time monitoring of critical

process parameters and critical quality attributes.

- Advance inline, online, and at-line analytical technologies suitable for commercial manufacturing environments.
- Develop advanced sensor technologies capable of monitoring complex biological processes.
- Enable robust implementation of real-time release testing.
- Develop AI-enabled quality monitoring and predictive quality management systems.
- Improve analytical characterization of emerging modalities, including ADCs and complex biologics.
- Develop multivariate analytical approaches that strengthen process understanding and reduce manufacturing variability.
- Integrate analytical technologies into automated and continuous manufacturing systems.

6.3 Advanced Manufacturing Platforms and Process Intensification

The continued expansion of biologics and advanced therapeutic products requires manufacturing platforms that are increasingly flexible, scalable, automated, and cost-effective. Manufacturers continue to face challenges implementing continuous processing, process intensification, modular facilities, and integrated manufacturing strategies while maintaining product quality and operational efficiency.

This topic seeks innovative manufacturing platforms that improve manufacturing flexibility, reduce development timelines, lower cost of goods, and support efficient technology transfer across diverse therapeutic modalities.

Proposals should aim to:

- Develop integrated continuous biomanufacturing platforms.
- Advance process intensification technologies across upstream and downstream operations.
- Develop modular and flexible manufacturing systems adaptable to multiple product classes.
- Improve automation across process development and manufacturing workflows.
- Advance high-throughput downstream purification technologies.
- Develop innovative membrane and filtration technologies.
- Improve integration between upstream, downstream, and analytical operations.
- Demonstrate scalable manufacturing platforms that improve productivity while reducing manufacturing complexity.

6.4 Platform Technologies for Emerging and Next-Generation Biotherapeutics

Emerging therapeutic modalities—including multispecific antibodies, antibody-drug conjugates, engineered proteins, RNA-based therapeutics, cell-free expression systems commercial scale, and novel biologic platforms—continue to outpace current manufacturing technologies. Manufacturing challenges associated with these products often require entirely new production platforms, analytical methods, and process development strategies.

This topic seeks foundational platform technologies that improve manufacturability, scalability, analytical characterization, and commercial readiness of emerging therapeutic modalities while providing broad applicability across the industry.

Proposals should aim to:

- Develop novel expression systems for difficult-to-express proteins and complex biologics.
- Advance alternative microbial and non-mammalian production platforms with work to address scale-up and commercial challenges.
- Improve manufacturing technologies for multispecific antibodies, fusion proteins, and engineered biologics.
- Develop platform manufacturing technologies for antibody-drug conjugates and other conjugated therapeutics.
- Advance analytical methods for characterization of complex biologics and conjugated products.
- Develop innovative conjugation technologies and drug-to-antibody ratio characterization methods.
- Demonstrate broadly applicable manufacturing approaches suitable for multiple emerging therapeutic modalities.

6.5 Transformative Platform Technologies for the Future Biomanufacturing Enterprise

Future biopharmaceutical manufacturing will require increasingly resilient, resource-sparing, digitally connected, and adaptable manufacturing ecosystems capable of supporting rapidly evolving therapeutic modalities and changing global supply chains. Manufacturers continue to seek transformative platform technologies that reduce manufacturing complexity, efficiently use resources, strengthen domestic manufacturing capabilities, and enhance responsiveness to future public health needs.

This topic seeks innovative manufacturing technologies that provide broad, long-term benefit to the U.S. biopharmaceutical manufacturing ecosystem by enabling the next generation of flexible, connected, and resource-efficient manufacturing enterprises.

Proposals should aim to:

- Develop technologies that improve manufacturing supply chain resilience.
- Advance manufacturing practices that efficiently use resources and materials.
- Develop flexible manufacturing networks capable of supporting multiple therapeutic platforms.
- Advance rapid-response manufacturing technologies applicable during future public health emergencies.
- Develop platform technologies that improve manufacturing interoperability across facilities and organizations.
- Demonstrate future manufacturing architectures that integrate digitalization, automation, and advanced analytics.
- Develop enabling technologies that significantly reduce manufacturing cost, complexity, or development timelines while improving overall manufacturing readiness.

7. Abbreviated List of Acronyms

AI	Artificial Intelligence
ADCs	Antibody-drug conjugates
BRL	NIIMBL Biomanufacturing Readiness Level
Co-PI	Co-Principal Investigator
CPPs	Critical Process Parameters
FDP	Federal Demonstration Partnership
FFRDC	Federally Funded Research and Development Centers
GC	Governing Committee
IP	Intellectual Property
IRB	Institutional Review Board (for Human Subjects Research)
MTA	Material Transfer Agreement
NIIMBL	National Institute for Innovation in Manufacturing Biopharmaceuticals
PAT	Process Analytical Technology
PC10.1	Project Call 10.1
PI	Principal Investigator
RFP	Request for Proposals
RTRT	Real-Time Release Testing