



The National Institute for Innovation in Manufacturing Biopharmaceuticals

AMERICAN INNOVATION AT WORK

Project Call 10.1 (T/W)
Webinar

RFP Released: August 3, 2026

Kelvin Lee, Institute Director
Denise Bierlein, Contract Analyst

NIIMBL Project Call 10.1

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.

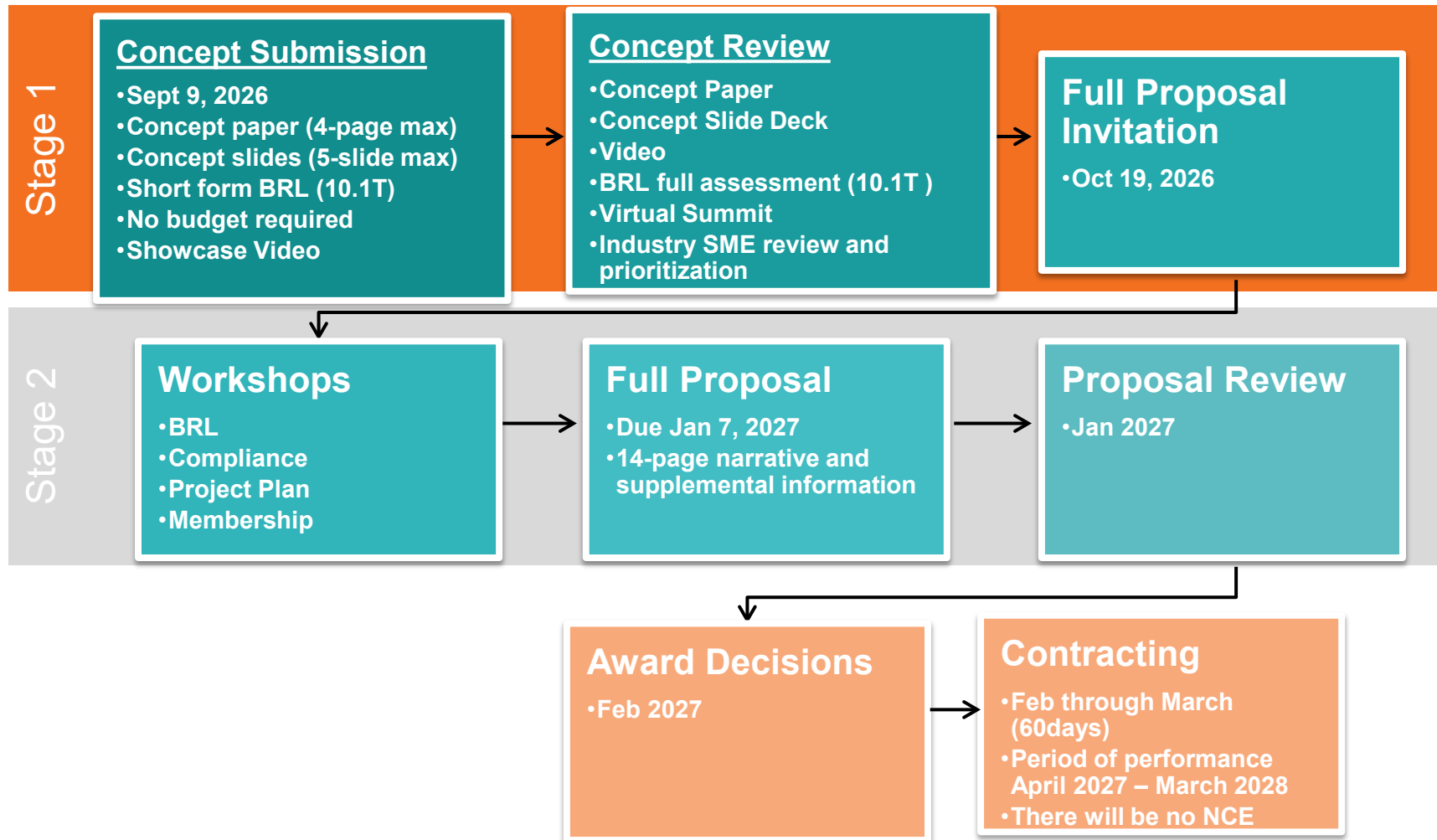
Project Call 10.1 seeks proposals addressing technology development (10.1T) and workforce development (10.1W) priority areas identified by industry members in consultation with Federal stakeholders:

- This webinar provides a summary of Phase 1 of the PC10.1 process.
- Full details can be found in the RFP for PC10.1

<https://www.niimbl.org/projects-programs/project-call-10-1/>

Project Call 10.1

Process Overview: A Two-Stage Process



Project Call 10.1

Details at a Glance

All Proposals

Minimum 1:1 Cost Share (NIIMBL : Partners)
Higher Cost Share ratios (X:1, X>1) are more competitive
≤ 12-month project duration
≤ 4-project plan segments

Maximum NIIMBL funds \$500,000

10.1T Proposals | 10.1W Proposals

\$4.0MM NIIMBL

+

\$4.0MM CS

Total Funding
(combined across PC10.1T and PC10.1W)



4



Priority Technology Development Areas

- Intelligent Biomanufacturing Through Artificial Intelligence, Digitalization, and Advanced Process Control
- Advanced Process Analytics, Product Quality, and Real-Time Manufacturing Control
- Advanced Manufacturing Platforms and Process Intensification
- Platform Technologies for Emerging and Next-Generation Biotherapeutics
- Transformative Platform Technologies for the Future Biomanufacturing Enterprise

Priority Workforce Development Areas

Catalyze Cross-Regional Workforce Development Solutions

- Expand coordination across regions to share resources, expertise, and proven workforce models.
- Build sustainable structures that reduce duplication and improve consistent, accessible training pathways nationwide.

Workforce Development for Advanced Therapeutic Modalities

- Identify talent and skill needs for next-generation biologics such as peptides, GLP-1 therapies, ADCs, bispecific antibodies, and radiopharmaceuticals.
- Develop and pilot hands-on training aligned with emerging industry requirements for technician, scientist, and engineering roles focused on next-gen biologics.

Developing a Digitally Fluent Biomanufacturing Workforce

- Integrate practical digital, AI, and automation skills into workforce programs to close current fluency gaps.
- Create scalable, adaptable learning modules that prepare workers to succeed in data-rich, automated environments.

NIIMBL Biomanufacturing Readiness Level (BRL) PC10.1 T

- BRL is a combination of readiness of the technology and the ability to use it in a manufacturing setting.
- Two purposes for assessment docs
- Determine the BRL – needs to be BRL4 to 7
- Ensure that the proposed work contributes to advancing the technology to a higher BRL
- The questions span a wide range of activities needed to develop technologies, and authors are encouraged to involve knowledgeable partners in this process. This can also aid in partner selection.
- BRL will be a key factor assessed by NIIMBL for both Concept and Full Proposal evaluations
- Required to use NIIMBL templates at the RFP website for submissions

<https://www.niimbl.org/industry-solutions/brls/>

Concept Evaluation

NIIMBL large-industry members and federal stakeholders will:

- Confidentially evaluate proposed concepts
- Short BRL form (PC10.1T)

This will be done ***both*** via:

- Sharing the submitted Concept files with reviewers and
- Invitation to a “*Virtual Summit*” to provide an opportunity for discussion

The Concept 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 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



Showcase Video

As part of the submission process, the Principal Investigator (PI) is strongly encouraged to:

- Submit a 90 second (500MB max) video recording that presents a high-level conceptual overview of their proposed project.
- This video should be similar in format to an elevator pitch or a lightning talk, as typically seen at NIIMBL national meetings.
- It will serve as supplemental information to the main submission documents and will be reviewed by large industry evaluators during the decision-making process.
- Please ensure that the content of the video is non-confidential and designed to clearly convey the core concepts and vision of your proposal without delving into sensitive or proprietary details.
- For assistance in creating your video, consider viewing this [instructional video](#) which offers simpler techniques for recording your presentation.
- This innovative approach allows PIs to engage directly with evaluators, enhancing the impact and clarity of their research ideas.

Virtual Summit

- NIIMBL will host a virtual summit designed to foster enhanced interactions between Principal Investigators (PIs) and key stakeholders from large industry SMEs and federal agencies.
- This summit is an integral part of our RFP process and aims to provide a dynamic platform for in-depth discussion and networking.
- As a PI, you will have the opportunity to participate in the scheduled 2-hour office session.
- These sessions are designed to facilitate either one-on-one or group discussions with large company SMEs, allowing you to present your concept proposal and receive expert feedback.
- This interactive format is intended to enrich the collaborative experience, providing valuable insights that enhance your understanding of industry feedback and needs.

Project Call 10.1 Notification of Invitation to Full Proposal



Phase 1 is complete with a decision towards full proposal application (by invitation only)

Invitations will be sent Mid-Oct 2026

Submission Requirements

Automatic Rejections will occur during the compliance review, and applications will not move forward to SME reviews if RFP requirements are not met. Please plan accordingly and send any questions to projectcalls@niimbl.org well in advance of the submission date.

Concept Submission (Phase 1):

- ☐ Concept Papers **MUST** be submitted before the deadline, September 9, 2026, 5:00PM EST.
- ☐ Concept proposer **MUST** be an individual from a NIIMBL member organization or a Federal employee.
- ☐ All required forms/components of the application are submitted

Full Proposal (Phase 2):

- ☐ Full Proposal **MUST** be submitted before the deadline, January 7, 2027
- ☐ The **Lead** organization and **all partners** of the proposal team **MUST** be NIIMBL member organizations or Federal agencies.
- ☐ Proposal Team
 - ☐ must include at least two organizations
 - ☐ If no SMM is participating an SMM Exemption form is required for Technical applications
- ☐ Budget and cost share requirements must be correct for all Project Partners
 - ☐ The Quad Chart budget summary will prevail if there is a discrepancy between submitted budgets and the Quad Chart.
- ☐ All required forms/components of the application are submitted

NEW Submission Site

New NIIMBL Gateway Portal:

- ☐ To request a new NIIMBL Gateway account, visit gateway.niimbl.org and click the Register card to submit an account request.
- ☐ Review the Concept and Full Proposal system overview videos on the RFP website, email projectcalls@niimbl.org with any questions.
- ☐ A new feature allows a delegate to complete the application on behalf of the lead PI
- ☐ Technical reviews will be conducted within the new system.

New proposal formatting:

Concept (Phase 1):

- ☐ Identify the Lead Proposer and Lead Organization on the Project Team tab
- ☐ All required fields and supporting documents must be completed before the application can be submitted

Full Proposal (Phase 2):

- ☐ The Project Plan will be completed directly in the submission hub. File uploads will not be accepted
- ☐ The system will enforce document file type requirements
- ☐ Add all Partner Organizations doing substantive programmatic work to the Project Team tab

Post Award:

- ☐ Technical reports will be completed by the Project Team within the new NIIMBL Gateway portal



Summary of Concept Submission Requirements

Required Submission Materials

1. Concept Paper

1. Single-spaced, 11-point Arial font (or larger equivalent font)
2. Maximum of 4 pages, not including references
3. Upload as PDF and mark NIIMBL Confidential

2. Concept Summary Slide Deck

1. Max 5 slides, must use NIIMBL Template, standard size (16:9)
2. Upload as .ppt or .pptx and mark NIIMBL Confidential

3. Short Concept BRL form (only for Technology Development)

1. .pdf file upload

4. Showcase Video (Strongly Encouraged)

1. 90 Seconds
2. 500 MB max
3. MP4 format

Project Call 10.1: Phase 1 Webinar Closing Notes

Visit our website:
[NIIMBL.org](https://www.niimbl.org)

Concept
Submission
September 9, 2026

New submission hub, NIIMBL Gateway: gateway.niimbl.org

An FAQ for the Concept Stage will be updated periodically at the PC10.1 webpage:
<https://www.niimbl.org/projects-programs/project-call-10-1/>

Link to Submission Hub for Concepts is also available at the PC10.1 webpage; it is strongly recommended that proposers and reviewers request their new system login well in advance of the due date.

Email us with any and all questions: projectcalls@niimbl.org

