Request for Information

Ideas for Innovative Technical Solutions to Industry

Challenges in Filtration Practices of mRNA-LNP Drug Products

PMCM RFI 2025.001
RFI Release Date: August 12, 2025
Submission Due: October 1, 2025, 5:00 pm ET

1. Overview

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is dedicated to advancing biopharmaceutical manufacturing innovation, developing standards to enhance manufacturing efficiencies and speed, and cultivating a leading biopharmaceutical manufacturing workforce.

This Request for Information (RFI) seeks to gather insights and ideas regarding innovative approaches, current practices, and validation strategies for sterile filtration of lipid nanoparticle (LNP)-based products, including mRNA therapeutics (i.e., it is not a solicitation for funding proposals, however the goal is to explore potential solutions to guide the development of future funding opportunities).

This initiative aims to support NIIMBL's Preventive Medical Countermeasures (PMCM) program in biomanufacturing. **This RFI is open to all members of NIIMBL, as well as to non-members.** Responses are welcome whether they cover all, or – more realistically – well-defined subset(s) of the technical/scientific areas in scope of this request.

2. Background and Purpose

NIIMBL is seeking input from interested parties to gather insights and ideas aimed at advancing sterile filtration and filter validation practices for lipid nanoparticle (LNP)-based products, including mRNA therapeutics.

As LNPs become increasingly central to the delivery of advanced biologics, the biopharmaceutical industry faces unique challenges in ensuring robust, scalable, and compliant sterile filtration processes.

Traditional filtration and validation approaches, developed for simpler biologics, often fall short when applied to LNPs due to their complex size distribution and interactions with filter materials. These challenges, in addition to implementing pre-use filter integrity testing, can lead to product loss, and delays in development and commercialization. NIIMBL intends to lead a multi-stakeholder initiative to benchmark current practices, identify critical gaps, and explore innovative, fit-for-purpose solutions that can be adopted across the industry.

This RFI is intended to gather insights and capabilities from organizations and experts with relevant experience or technologies that could help inform a future Request for Application (RFA) where outputs could lead to industry guidance and position papers, and potentially new standards to improve the reliability and efficiency of sterile filtration for LNP-based products.

PMCM 2025.001 Website: https://www.niimbl.org/projects-programs/pmcm-rfi-2025-001/

3. Scope of Interest

NIIMBL invites submissions from interested parties to share information on, or potential solutions for:

1. **Benchmarking Current Practices**: Approaches to sterile filtration and filter validation currently used for LNP-based products, including clinical and commercial applications.
2. **Identifying and Addressing Challenges**: Technical and operational challenges related to particle size distribution, filter-material interactions, and maintaining product integrity during sterile filtration. Topics related to solving challenges with payload and/or novel LNP excipients are also of interest.
3. **Innovative Solutions**: Novel filtration strategies, including pre-filtration steps, new filter materials, or real-time monitoring technologies that enhance process control and product quality.
4. **Filter Validation strategies**: Development and/or adaptation of standardized test methods and filter validation strategies specific to LNPs, focusing on reproducibility and regulatory alignment.
5. **Expertise and Collaboration**: Identification of individuals or organizations with relevant expertise who may contribute to benchmarking, testing, or publication efforts, as well as any existing or potential partnerships.

NIIMBL is particularly interested in responses from academic researchers, technology developers, biopharmaceutical manufacturers, and filtration solution providers with demonstrated experience in LNP processing or sterile filtration innovation.

Note: This RFI does not constitute a solicitation for funding proposals - the goal is to explore potential solutions to guide the development of future funding opportunities.

4. Submission Details

To facilitate consistent and interpretable responses, NIIMBL requests that submissions be organized into the following sections, which align with the Scope of Interest. Respondents may choose to address one, several, or all five Scope of Interest sections. Each section response should be limited to no more than two pages.

0. **Introduction**
1. **Benchmarking Current Practices**
2. **Identifying and Addressing Challenges**
3. **Innovative Solutions**

4. **Filter Validation Strategies**
5. **Expertise and Collaboration**

Additional Guidance

- **Format:** Submissions should be in PDF format.
- **Length:** Maximum of two pages per section, no more than 12 pages total.
- **Technical Approach:** If applicable, include the following within the relevant section:
    - The technologies and methodologies you would employ and/or plan to develop to address the challenges of sterile filtration and filter validation for LNP-based products.
    - How your approach aligns with and addresses goals and objectives outlined in this RFI.
    - The scientific or empirical rationale supporting your approach, including any relevant data, case studies, or theoretical frameworks.
    - A clear differentiation between the technical aspects, practical applications, and anticipated benefits of your solution.
    - Any related initiatives or collaborations that may complement or enhance your proposed approach.
- **Cost Estimation:** If applicable, include a non-binding rough order of magnitude (ROM) cost estimate within the relevant section.
- **Confidentiality:** Do not include proprietary or confidential information unless explicitly marked.

Note: This RFI is not a solicitation for proposals for funding, and responses will not result in a contract or formal evaluation.

5. Submission Process

Submissions must be sent via the NIIMBL submission hub by the due date.

6. Use of Information

The insights and information gathered from this RFI will be used to inform strategic planning for future solicitations.

7. Encouragement for Broad Participation

NIIMBL welcomes responses from a diverse range of stakeholders, including academic institutions, biopharmaceutical manufacturers, technology developers, research consortia, and other subject matter experts. Whether your organization can contribute comprehensive solutions or targeted insights into specific aspects of sterile filtration or filter validation for LNP-based products, your input is highly valued. We also encourage feedback on the scope, focus areas, and structure of this RFI, as it will help refine our collective approach to addressing critical challenges in advanced biomanufacturing.

8. Conclusion

This RFI is a preliminary step towards identifying innovative solutions and collaborations that can advance the field of biomanufacturing. We look forward to engaging with the community to gather valuable information that will shape future initiatives.

For more information, please contact projectcalls@niimbl.org.