

# Enabling scalable LNP manufacturing: A cost-efficient approach for tomorrow's RNA therapies

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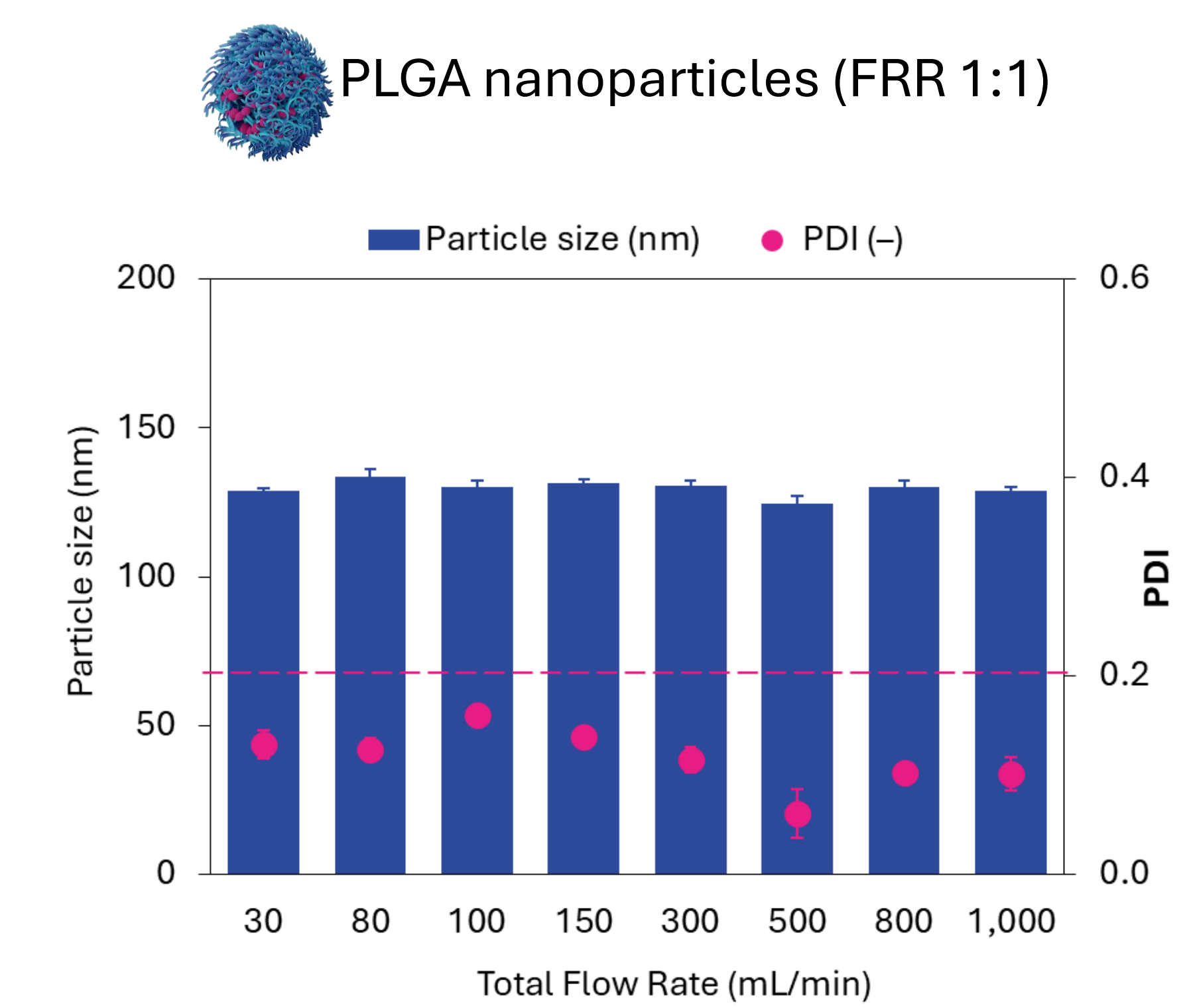
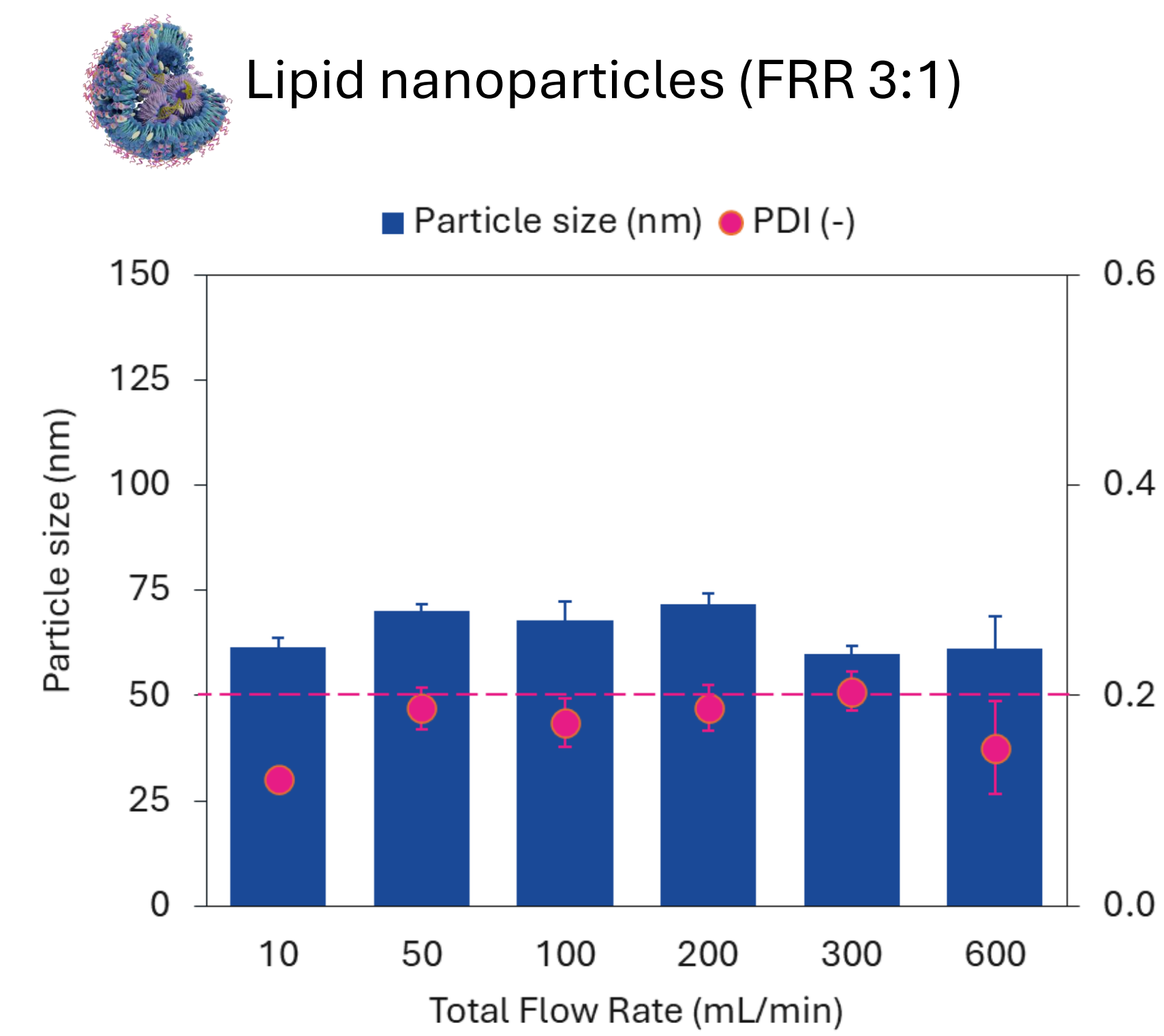
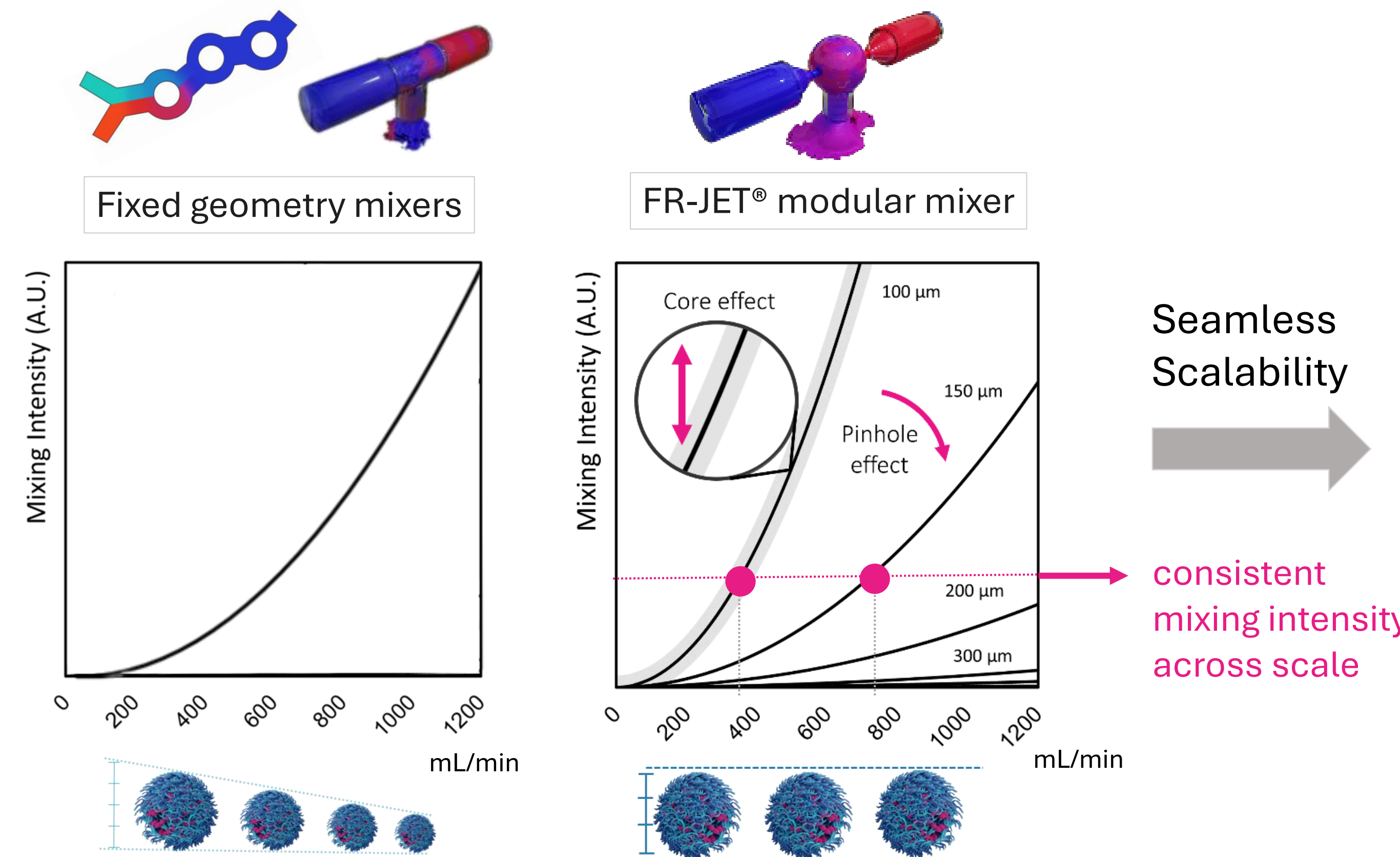


## INTRODUCTION

Nanoparticle-based therapies, including lipid nanoparticles (LNPs), have emerged as transformative platforms in cell and gene therapy. However, a recognized challenge in the field is that conventional manufacturing processes are not well-suited to the demands of mRNA therapeutic development. While large-batch manufacturing has historically defined the industry, there is a growing market need for solutions capable of producing small GMP batches in an aseptic manner — whether to serve small patient populations or enable truly individualized therapies. The FR-JET® modular mixer was developed to address these challenges, offering a platform that maintains consistent nanoparticle size distribution across process scales — from R&D to GMP manufacturing — through an innovative spherical mixing chamber and interchangeable modular inserts.

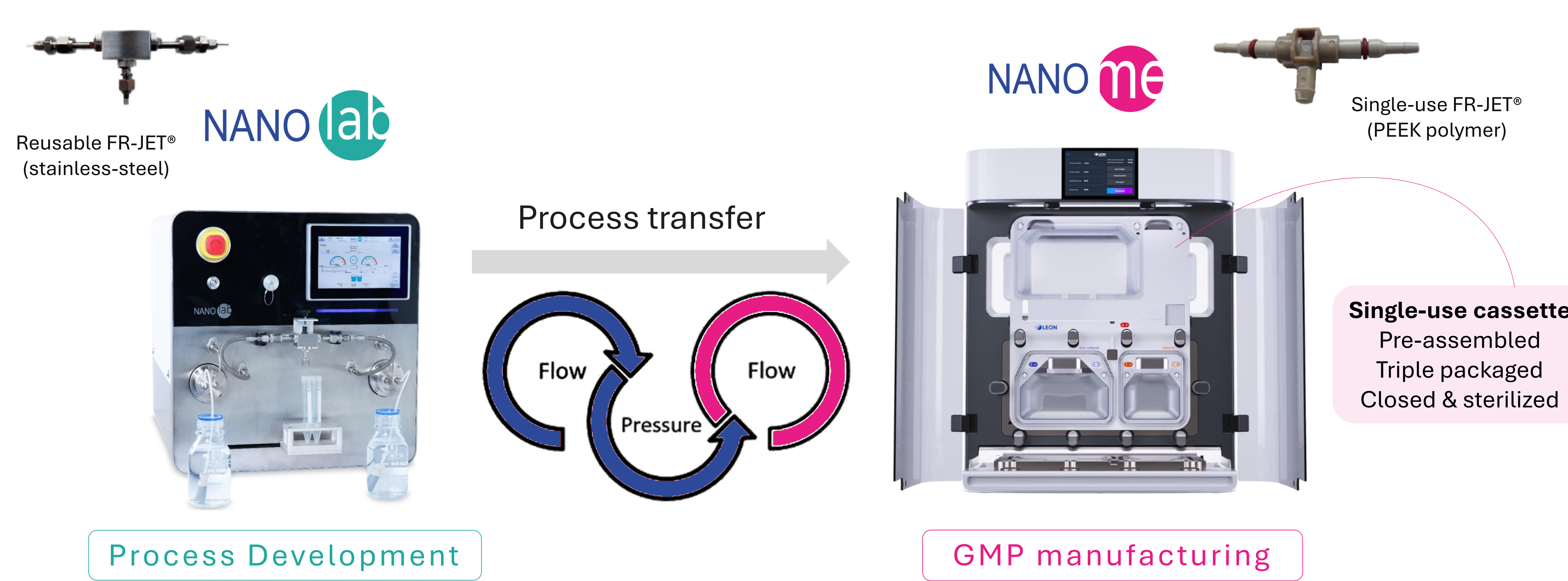
## The FR-JET® Modular Mixer: A Quality-by-Design Platform for Precise and Scalable Nanoparticle Manufacturing

The FR-JET® modular mixer features two key innovative features: a **spherical chamber** (1–5 mm diameter) that optimizes mixing dynamics, and **modular pinhole inserts** (100–600 µm) that allow precise control of mixing intensity across scales. The interchangeable core and inserts enable fine-tuning of flow conditions, ensuring consistent particle size distribution at different process scales. Modeling the interplay between flow, geometry, and performance reveals predictable trends, including the effects of chamber size, pinhole configuration, and flow rate on mixing efficiency. This level of control provides drug developers with a broader design space to tailor NP size as well as ensure product quality during scale-up.



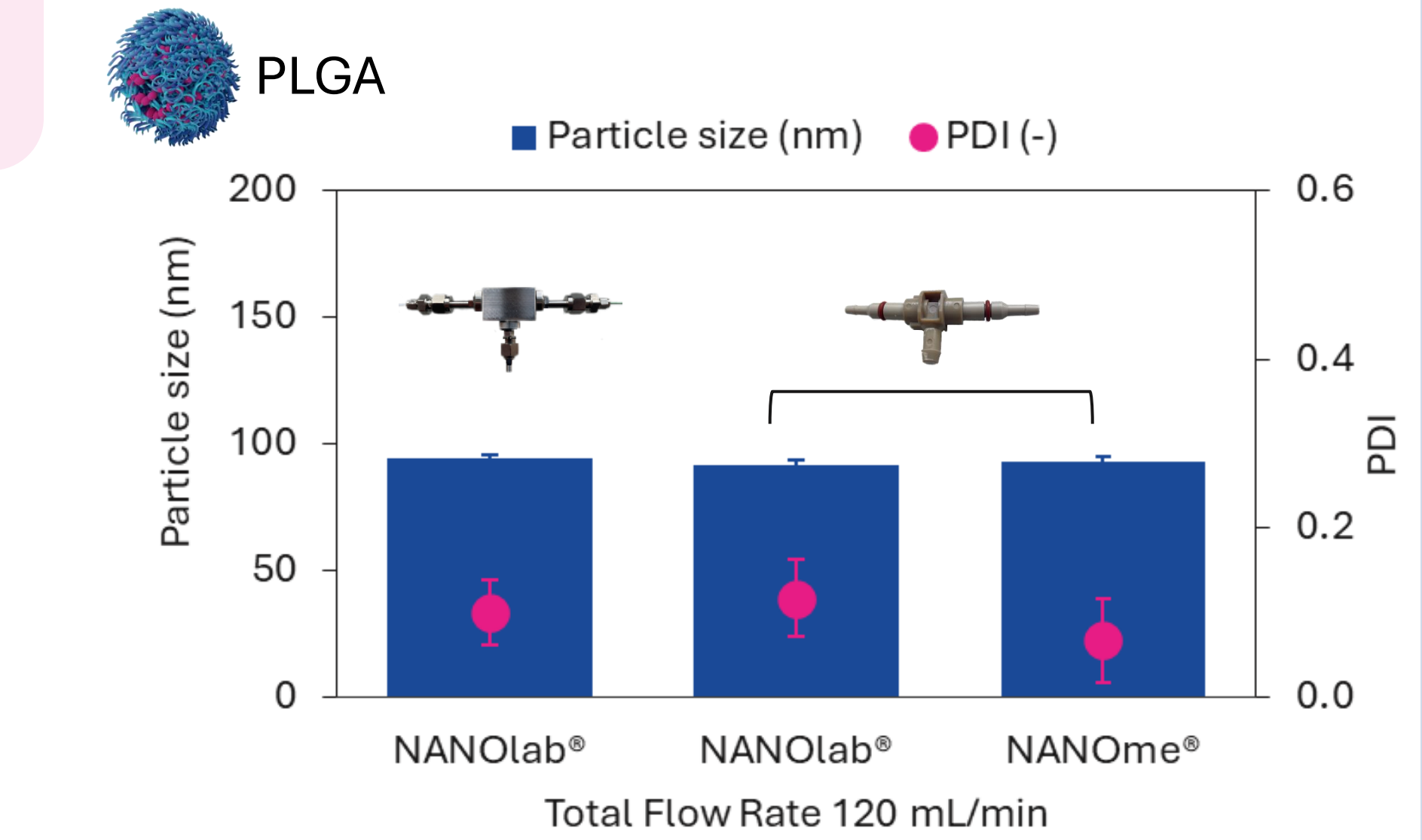
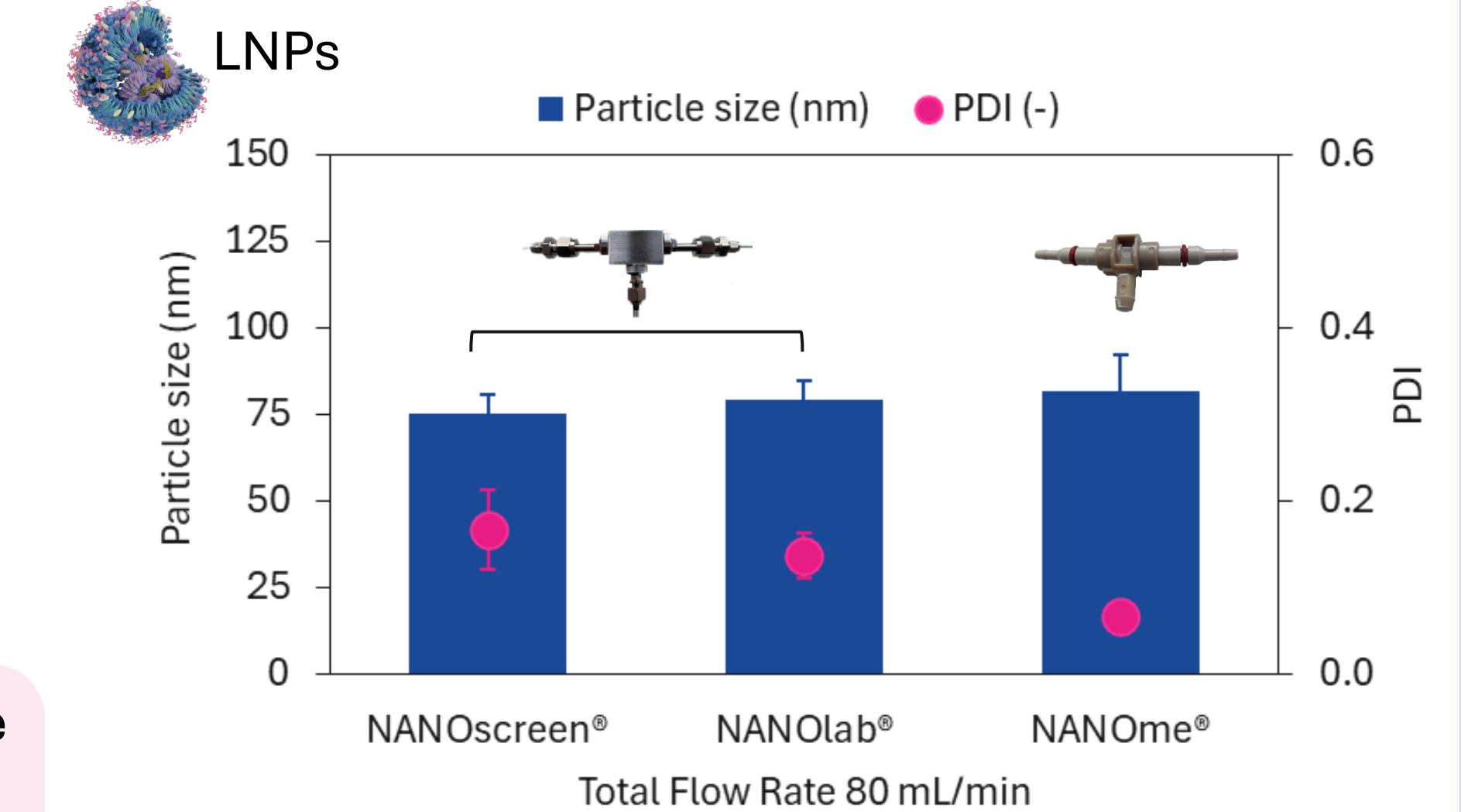
## Enabling Seamless Process Transfer: From Lab to Decentralized GMP Manufacturing — Faster and Closer to the Patient

A critical bottleneck in nanoparticle-based therapy development is the loss of product quality during scale-up and technology transfer. LEON's integrated platform enables a direct, 1-to-1 process transfer from development to GMP manufacturing — without re-optimization at each stage. The data demonstrate seamless scalability across the full workflow: from early-stage screening with the NANOscreen®, through process optimization with the NANOLab®, to aseptic GMP production using the single-use NANOme®. Since the NANOLab® and NANOme® share the same FR-JET® mixer technology, parameters established during development translate directly to the GMP setting — eliminating the iterative re-optimization that typically adds time and cost to scale-up. Both LNPs and PLGA particles show consistent particle size and PDI across all three platforms, confirming robust process transfer. This integrated approach reduces complexity and supports the shift toward decentralized, patient-centric manufacturing.



- ✓ FR-JET® — reusable & single-use version
- ✓ Total flow rate — up to 330 mL/min (FRR 3:1)
- ✓ Batch size — 1 mL to continuous production

- ✓ Total flow rate — up to 200 mL/min (FRR 3:1)
- ✓ Batch size — 30 to 1200 mL (up to 600 mg mRNA)
- ✓ Cycle time — 10 to 20 min (up to 144 batches / day)



## CONCLUSION

The FR-JET® modular mixer and LEON's integrated manufacturing platform represent a significant step forward in addressing the unmet needs of nanoparticle-based therapy development. By combining a Quality-by-Design approach with a fully scalable, modular mixer technology, LEON enables drug developers to maintain precise particle quality from early R&D through to GMP manufacturing — without re-optimization at each stage. The seamless 1-to-1 process transfer across the NANOscreen®, NANOLab®, and NANOme® platforms, demonstrated for both LNPs and PLGA particles, confirms the robustness and versatility of this approach. Together, these tools offer a streamlined, cost-efficient path toward decentralized, patient-centric manufacturing — bringing personalized nanoparticle-based therapies faster and closer to the patient.