

# Leon-nanodrugs: Enabling decentralized GMP manufacturing of RNA-LNP therapies



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## INTRODUCTION

The NANOME® platform is a benchtop, fully closed, single-use cassette system designed for aseptic RNA-LNP production. At its core, the FR-JET® modular mixer employs a jet-impingement technology to achieve precise and reproducible nanoencapsulation of RNA and other nucleic acids. The system supports highly flexible batch sizes, from individualized therapies (n=1) of 50–1200 mL produced in 10–20 minutes to larger-scale runs yielding up to 100,000 vaccine doses (for an saRNA dose of 6 µg). Designed for use in Grade C clean rooms, the fully CFR 21 Part 11 compliant NANOME® enables modular, decentralized, and point-of-care GMP manufacturing.

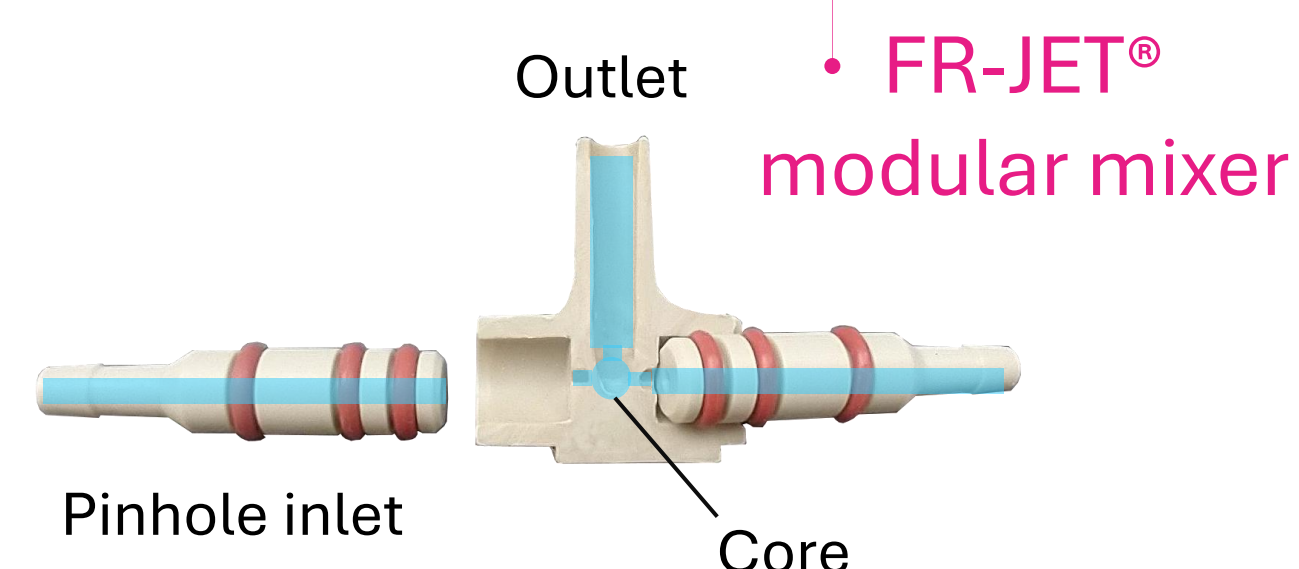
The NANOME® system enables aseptic processing of the encapsulating of RNA under grade C

### Benchtop system



- Completely closed and Single-Use system:**
- ✓ Ensures product integrity
  - ✓ Minimizes risk of cross-contamination
  - ✓ Eliminates cleaning between products

### Disposable cassette



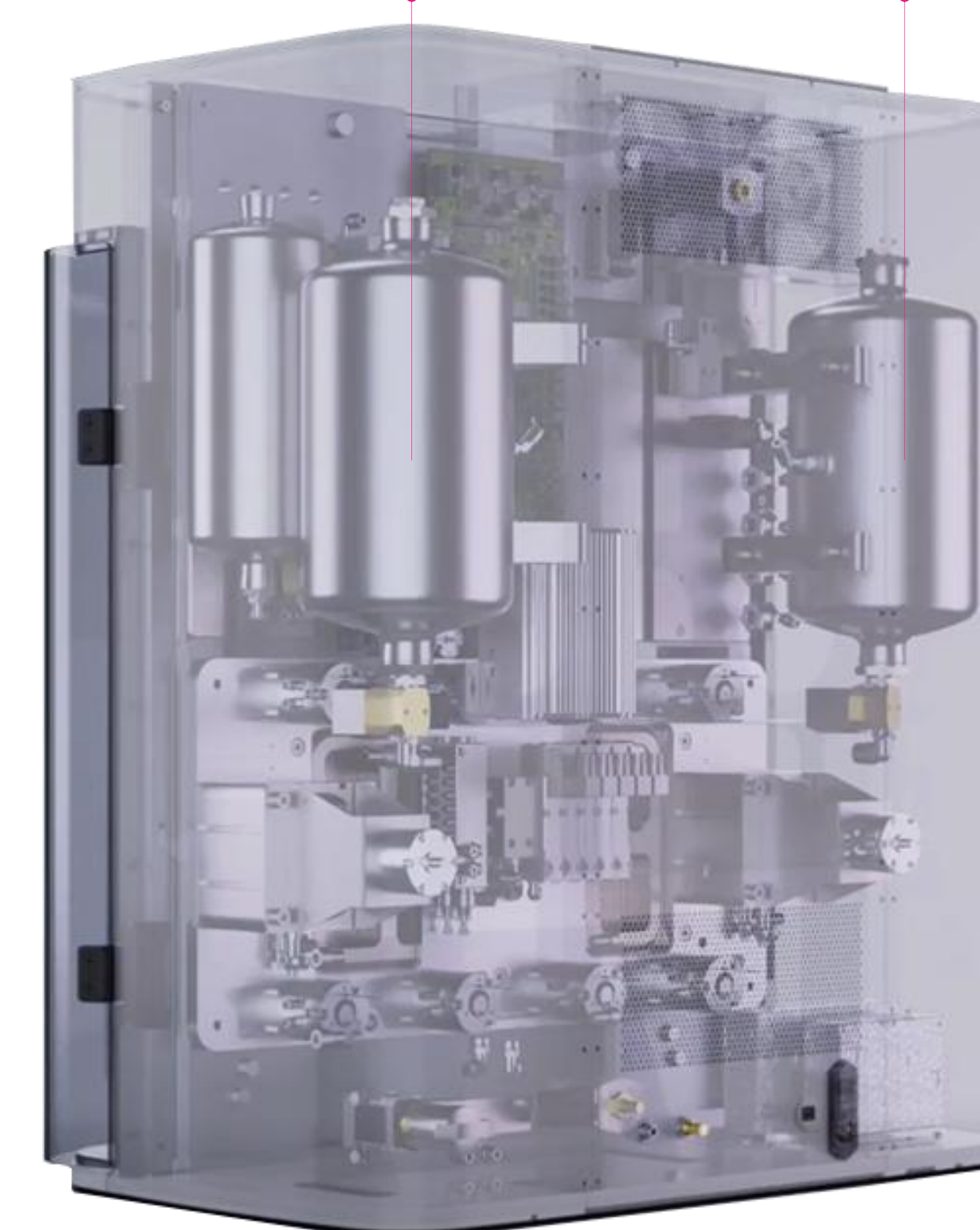
Aseptic pinch pipe disconnector



MicroCNX™ aseptic connector or tube welding to TFF

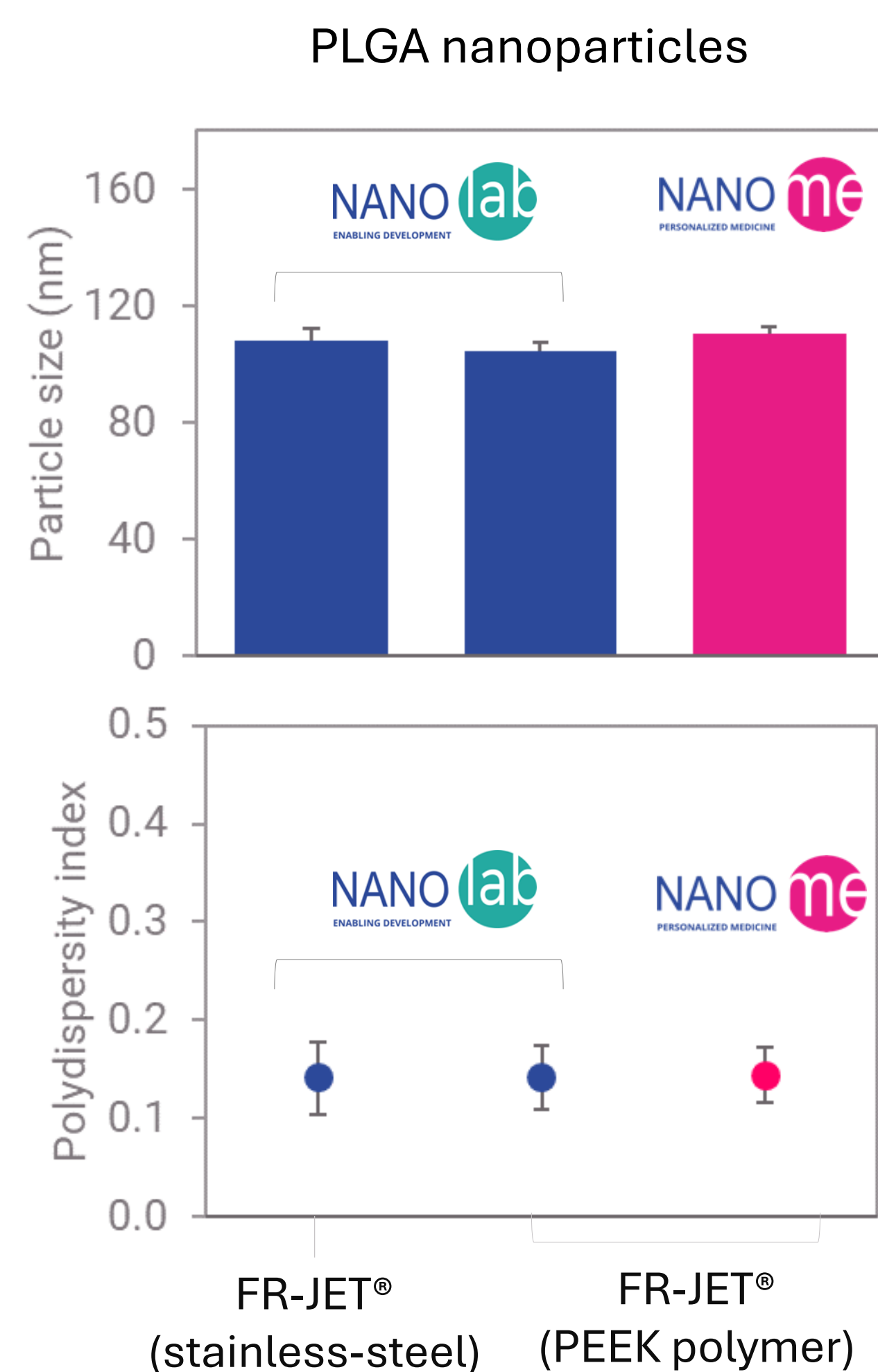
Sterile QC sampler

### Pressure chambers



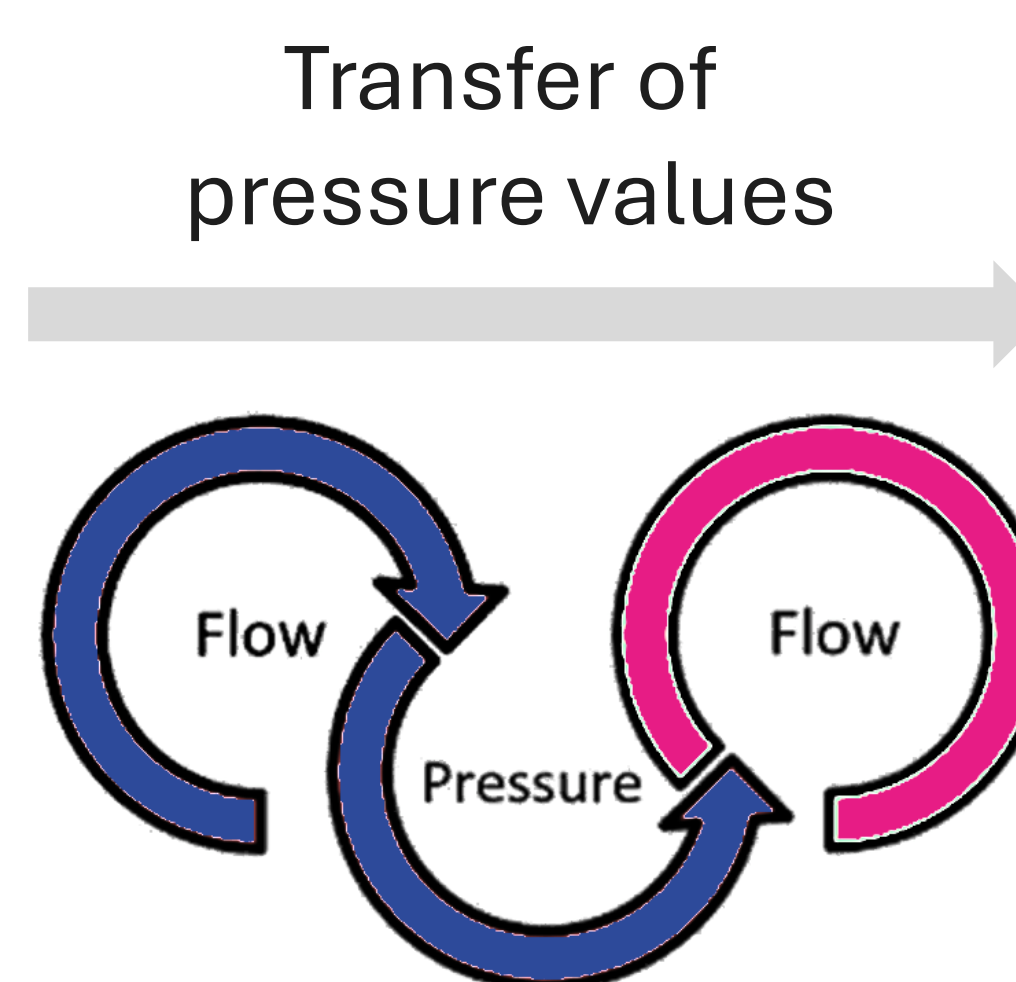
- ✓ Minimal hold-up volume
- ✓ Non-invasive & Contactless
- ✓ No pump pulsation (no-pumps!)

Easy process transfer from development with the NANOLab® to GMP manufacturing with the NANOME®



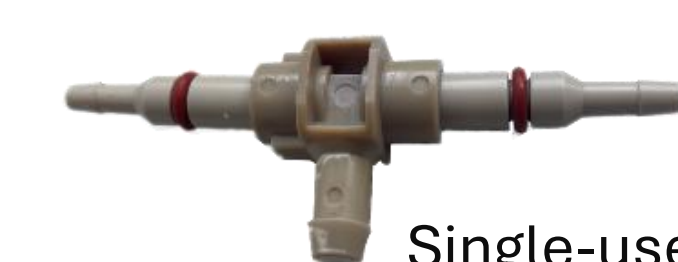
Process Development

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



GMP manufacturing

- ✓ Total flow rate — up to 200 mL/min (FRR 3:1)
- ✓ Batch size — 50 to 1200 mL (up to 600 mg mRNA)
- ✓ Cycle time — 10 to 20 min (up to 144 batches / day)



Single-use FR-JET® (PEEK polymer)

- Single-use cassette**
- Pre-assembled
  - Triple packaged
  - Closed & sterilized

## CONCLUSION

With no pumps required, the NANOME® system uses pressurized air to move liquids smoothly and precisely, ensuring high efficiency, minimal waste, and fast setup. Its fully closed, single-use design eliminates cleaning between product changeovers and prevents cross-contamination, enabling rapid, back-to-back production of up to 140 aseptic batches per day. Together, these features make NANOME® a transformative solution for flexible, scalable, and contamination-free RNA-LNP manufacturing—democratizing access to advanced therapeutics globally.