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Tech Note

Accelerate LNP Manufacturing with Automated and Templated Process Development Services

Historical Challenges in LNP Formulation and Process Development

Lipid nanoparticle (LNP) formulation has traditionally relied on manual, hands-on operations requiring real-time operator intervention, such as adjusting flow rates to maintain desired process parameters. These manual interventions introduce process variability, increasing the risk to critical quality attributes (CQAs) such as particle size, size distribution, and encapsulation efficiency.

The resulting variability can negatively impact batch yields and overall product quality. For programs using high-value payloads such as nucleic acids, even minor inconsistencies can have major financial impact.

As a program advances, scaling up LNPs from development to clinical manufacturing, requires maintaining CQAs which can be challenging, and failure to do so will prevent a program from reaching the clinic.

Advantages of Automated LNP Process Development Services

Our LNP process development skid replaces manual, variable operations with automated, standardized workflows that improve reproducibility, reduce risk, and accelerate scale-up to GMP manufacturing.

The services incorporate an automated LNP skid that supports small-scale process development, replacing manual adjustments with a fully programmable, feedback loop control system (**Figure 1**). Through the skid's user interface, our operators precisely control flow regulation, mixing, and in-line monitoring to ensure processing parameters are maintained (**Figure 2**).

Figure 1.

Automated process development skid enables controlled and efficient manufacturing of LNPs.

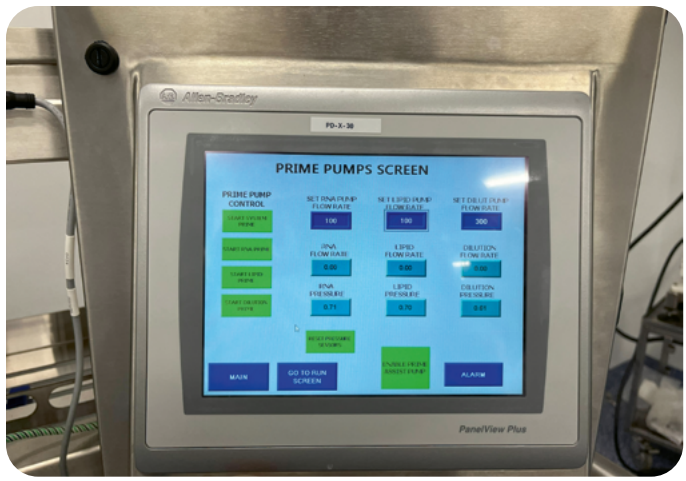

Figure 2.

Automated skid's interface allows real-time monitoring of flow rates, dilution ratios, and pressure for complete control of the LNP manufacturing process.

Automated regulation of flow rates and mixing conditions maintain CQAs such as particle size, polydispersity index (PDI), and encapsulation efficiency. Integrated monitoring systems provide real-time feedback, allowing rapid process tuning and adjustment which protect high value nucleic acid payloads. Together, these capabilities enhance precision, consistency, and efficiency while reducing manual interventions, shortening development timelines, and accelerating the path to optimized process conditions.

Advantages of LNP Process Development – Automated and Templated Services

- Minimize manual intervention
- Improve batch-to-batch reproducibility and maintaining product CQAs
- Faster, more reliable tech transfer
- Applicable for multiple payloads (siRNA, saRNA, mRNA, circRNA, small molecules, proteins, peptides, etc.)

Advantages of Templated Scale-Up and Process Optimization Services

When scaling up an LNP formulation, maintaining product CQAs is critical for the program's success. Our templated methodology bridges the gap between process development and scale-up to GMP manufacturing through standardized, automation-ready protocols and linear process translation.

- **Conversion flexibility:** Enables direct transition from microfluidics-based methods to scalable T-mixing or impingement jet mixing systems.
- **Standardized T-Mixing approach:** A linear scale-up strategy using T-mixing maintains consistent CQAs while minimizing development time and cost.
- **Seamless tech transfer and scale-up:** Lab-scale parameters directly translate to pilot and GMP manufacturing without the need for additional optimization.
- **Reduced risk and faster timelines:** Standardization minimizes scale-up variability and accelerates the path to clinical readiness.

Quantitative results show consistent CQAs, including particle size, PDI, and encapsulation efficiency, across scales from lab development to GMP manufacturing (**Figures 3** and **4**). These results validate the robustness and reproducibility of our templated LNP processes.

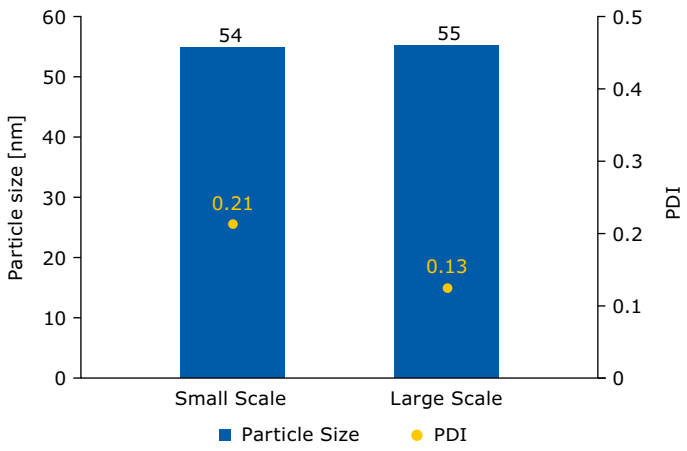

Figure 3.

Comparison of LNP formulations at small and large scale manufacturing. Particle size and polydispersity index (PDI <0.3) remain consistent, demonstrating that the skid's process controls effectively maintain CQAs during scale-up.

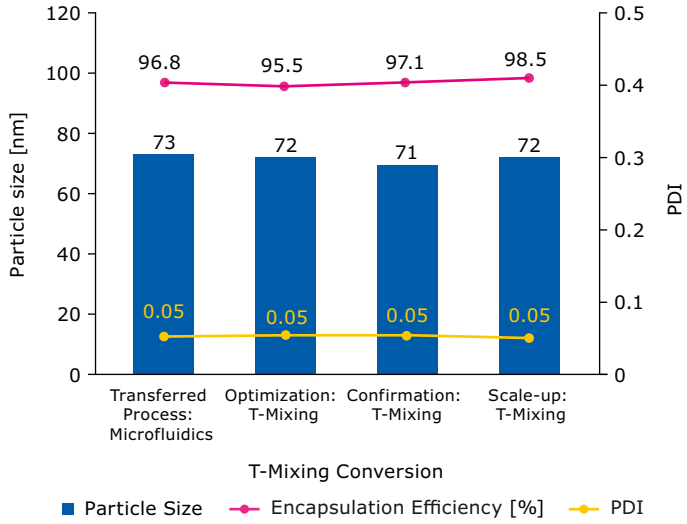

Figure 4.

The microfluidics process can be converted to a T-Mixing process and maintain similar CQAs.

Performance Across Diverse Payloads

Our automated skid and templated scale-up services enable accelerated, reproducible LNP formulations for a broad range of therapeutic modalities, including:

- Nucleic acid payloads such as siRNA, saRNA, circRNA, mRNA, DNA, etc. – for gene therapy, cell therapy, and vaccine applications.
- Small molecules, peptides, proteins, etc.

Conclusion

By integrating automation, process standardization, and scale-up expertise, our templated services for LNP process development streamline the path from discovery to GMP manufacturing. The result is improved reproducibility, reduced product quality risk, and accelerated progression to GMP manufacturing. With over 30 years of experience in LNP and Liposomal formulation process development and 40+ programs executed; we are your trusted partner to bring your product from the lab to the clinic.

For additional information, please visit our **website**.
To place an order or receive technical assistance, please fill out our **webform**.

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Lit. No. MK_TN15093EN Ver. 1.0 01/2026