Working with

Lipid Nanoparticle-Based Drugs (LNPs) and Other Complex Formulations

LNPs are increasingly being used to deliver highly specialized therapeutic molecules, such as oligonucleotides, which themselves are seeing heightened attention in drug development, owing to their ability to tackle disease on the genetic level.

LNPs and other complex formulations require a high level of technical expertise, combined with customizable technology solutions, process integration, and collaborative, comprehensive tech transfer.

If you are considering an LNP-based formulation or another complex drug, here are several points to consider to make the process more efficient.

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1 TIMELINES

Be aware of the time needed for:

- Material
- Test method development
- Test method verification
- Studies including filtration, mixing, or formulation.

2 CONTRACT DEVELOPMENT AND MANUFACTURING ORGANIZATION (CDMO EXPERTISE AND CAPABILITIES)

A qualified CDMO should offer LNP capabilities including:

- Ability to manufacture cGMP complex formulations for clinical through commercial applications.

Good communication to:
Agree on the scope of work including project boundaries in terms of: raw material supply, final product presentation, batch size, product specifications, and client or supplier responsibilities.

3 ESTABLISH MODULES OF INFORMATION

The CDMO and Sponsor should establish information modules to define the scope of the project. The modules can include:

- Contact Information
- Terminal Sterilization
- Program Information
- Inspection
- Target Drug Product Profile
- Bulk Drug Product Packaging and Labeling
- API/BDS Safety Info
- Production Components
- API/BDS General Information and Profile
- Required Excipients
- Formulation
- Labeling and Packaging
- Filtration
- Final Product Shipping Information

4 TECHNICAL FORMULATION EXPERTISE

A CDMO should offer audited and qualified systems to support:

- Pre-clinical formulation
- Analytical process development
- Process development and scale-up from the milligram to gram scale
  - Protocol drafting as master batch record precursor
  - Process verification/robustness
  - Prepare product-specific batch records
  - Use Multi-Compendial raw material
- Process optimization
  - Downstream processing steps (e.g. UF/DF, sterile filtration)
  - Equipment development and troubleshooting
  - Process-specific training/user familiarization
  - Configure GMP T-mixing system to meet customer requirements
- Sample generation for GLP-Tox pre- stability testing
- Specialty filtration and handling for viscous processes
- Single-use technology throughout
- Formulation specializations to include: Microfluidization, nanoparticles, and other highly complex modalities.