

Hongene Biotech: Your Partner for End-to-End mRNA Solutions



One-Stop mRNA Development and Manufacturing Services



Accelerated mRNA Development: From plasmid to vialed drug product, we offer a fully integrated service to streamline your project, ensuring efficient and timely delivery



25+ Years of RNA Expertise: Benefit from our extensive experience in mRNA synthesis, backed by a seasoned team, cutting-edge technology, and a streamlined workflow



On-Site Analytical Services: We employ rigorous testing protocols supported by advanced technology and instruments, ensuring your mRNA meets the highest standards of purity, potency, and safety



Fully Integrated Supply Chain:

Our comprehensive range of in-house manufactured raw materials guarantees exceptional quality from the very beginning

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State-of-the-Art Facilities:

Our advanced laboratories and GMP manufacturing spaces, exceeding 30,000 sq ft, leverage cutting-edge technologies and processes to meet the growing demands of mRNA development



Advanced mRNA Technologies & Expertise

mRNA Synthesis & Purification

- **Comprehensive Process:** In vitro transcription (IVT), co- or post-transcriptional capping and poly(A) tailing, DNA template removal, mRNA purification, and sterile filtration
- Quality from the Start: The full range of key raw materials for mRNA manufacturing adheres to GMP regulations, ensuring quality control right from the beginning
- Streamlined Production: One-pot synthesis combines plasmid linearization and transcription, eliminating the need for intermediate separation
- Scalable mRNA Synthesis:
 - Flexible scale: 1 mg-100 g mRNA/batch
- High-Quality mRNA:
 - High integrity: greater than 98% full-length mRNA
 - Ultra-low impurity (dsRNA < 0.01%)
 - High capping efficiency (95%-99%)
- **Platform Versatility:** Proven technology platforms for linear RNA and mRNA, circular RNA (circRNA), and self-amplifying RNA (saRNA)
- Additional Services: Sequence optimization, receptor binding domain (RBD) construction, and plasmid preparation for use as template DNA in mRNA IVT

Analytical Platform & Quality Control

- **State-of-the-Art:** All equipment is sourced from top global suppliers
- Stringent Standards: Analytical and QC methodologies follow ChP, USP, and Ph.Eur
- **Comprehensive Stability Studies:** Platform for long-term stability, accelerated stability, and stress stability assessments

Fill & Finish Platform

- **Globally Compliant:** Fully automatic aseptic filling line in an isolator, meeting Chinese, US, and EU GMP standards
- Versatile: Suitable for both liquid and lyophilized products
- Flexible Batch Sizes:
 - 9,000 vials of 2 mL/batch/week
 - 4,000 vials of 6 mL/batch/week

mRNA Encapsulation & LNP Manufacturing

- cGMP mRNA-LNP Production: Supporting studies from early R&D to preclinical up to commercialization
- Advanced Encapsulation: Utilization of Knauer[®] encapsulation systems
- High-Quality LNP Products:
 - High encapsulation efficiency (~99%)
 - Controlled particle size
 - Polydispersity index (PDI) < 0.04
- Scalable Production: Encapsulation scale from 1 mg to 50 g mRNA per batch
- **Specialized Formulation:** Expertise in well-established lyophilization techniques and multivalent vaccine development



Bring your RNA to life.

- · Hongene is your dedicated partner in nucleic acid development and manufacturing. We specialize in providing high-quality, high-value products with best-in-class lead times.
- As a true end-to-end partner, we guide you through every step of your journey to create transformative treatments for patients - from product synthesis to commercial distribution.
- Our integrated supply chain, world-renowned expertise, and specialized capabilities ensure your project is delivered on time, in full, and on budget.

Contact our expert team today to discuss your project

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