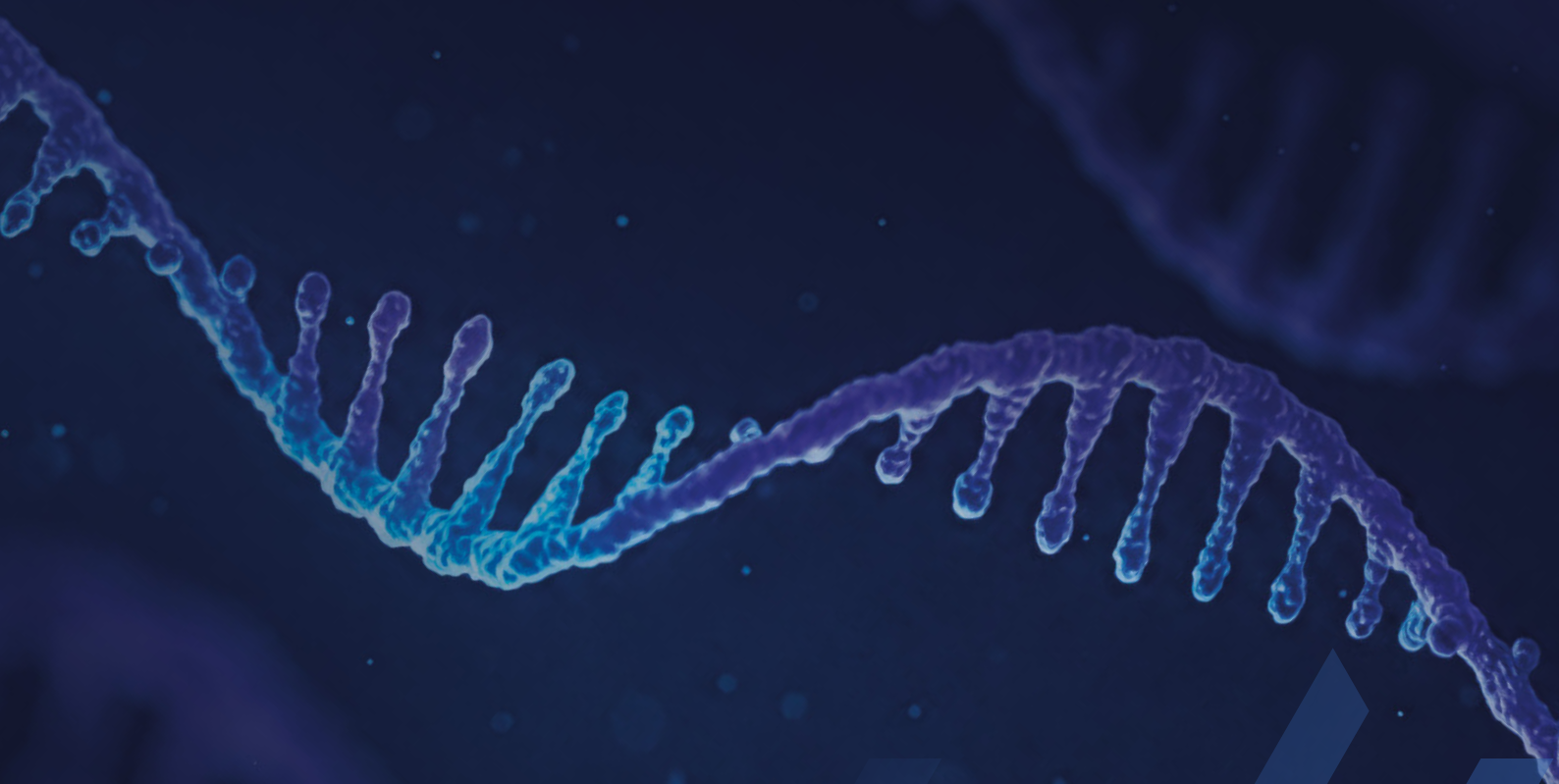
Hongene Biotech

Oligonucleotide CDMO Services

Accelerating Your RNA Therapeutics
With Speed, Precision, and Security



Hongene.com

About Hongene

Founded in 1998, Hongene is a global leader in nucleic acid therapeutics development and manufacturing.

We combine deep expertise in nucleic acid raw materials with integrated CDMO services for oligonucleotide and mRNA therapeutics, providing seamless support from building blocks and starting materials through drug substance and drug product.

With more than 1,600 employees worldwide, Hongene provides end-to-end solutions spanning preclinical development, cGMP clinical supply, and commercial manufacturing. Our vertically integrated model, global footprint, world-leading capacity, and commitment to quality, innovation, and customer service make us a trusted partner for companies advancing the next generation of RNA medicines.

Our Mission

Continuously innovating to make RNA medicines accessible and affordable for patients worldwide.

End-to-End Oligonucleotide CDMO Solutions

From Preclinical Development to Commercial Supply

Hongene provides end-to-end CDMO services for oligonucleotide therapeutics, supporting customers from early development through cGMP clinical supply and commercial manufacturing.

1

Preclinical Development

Establish project feasibility and define the optimal synthetic route.

2

Process Development

Develop efficient, robust manufacturing processes designed for scale up.

3

Analytical Development

Develop analytical methods for product characterization, CQA assessment and regulatory readiness.

4

Drug Substance and Drug Product

Integrated drug substance manufacturing and drug product formulation, with fill-finish support.

5

cGMP Clinical Supply

Deliver high-quality cGMP clinical materials for safe, reliable study execution.

6

Commercial Manufacturing

Large-scale manufacturing capabilities to support market demand.

Why Partner With Hongene?

Differentiated Capabilities for Oligonucleotide Development and Manufacturing

Vertical Integration

Seamless support from building blocks and starting materials through drug substance and drug product, enabling faster, smoother execution.

Supply Chain Control

In-house control over key materials and manufacturing stages reduces risk, improves continuity, and supports faster program execution.

World-Leading Capacity

Large-scale manufacturing capabilities to support seamless progression from clinical supply to commercial launch.

Customer Partnership

Flexible, responsive support tailored to the needs and timelines of each program.

Global cGMP Standards

Robust quality systems supporting regulatory readiness across development, clinical and commercial phases.

Advanced Technology Solutions

Next-generation platforms, including chemoenzymatic ligation, support high-purity, efficient and scalable manufacturing.

Vertical Integration | **World-Leading Capacity** | **Next-Generation Technologies**

Comprehensive Oligonucleotide CDMO Capabilities

An integrated service portfolio designed to support oligonucleotide programs from early development through commercial launch.

1

Proof-of-Concept Studies

Rapid synthesis to support early feasibility assessment and program advancement.

2

Process Development

Process optimization to support robust, scalable, and cost-effectivemanufacturing.

3

Analytical Development

Method development and validation for product characterization, purity assessment, and quality control.

4

cGMP Manufacturing

Clinical and commercial manufacturing under cGMP conditions aligned with global quality standards.

5

Drug Substance and Drug Product Support

Integrated services spanning drug substance manufacturing, formulation, fill-finish and labeling.

6

Scale-Up and Tech Transfer

Efficient transfer from development to pilot and commercial-scale manufacturing.

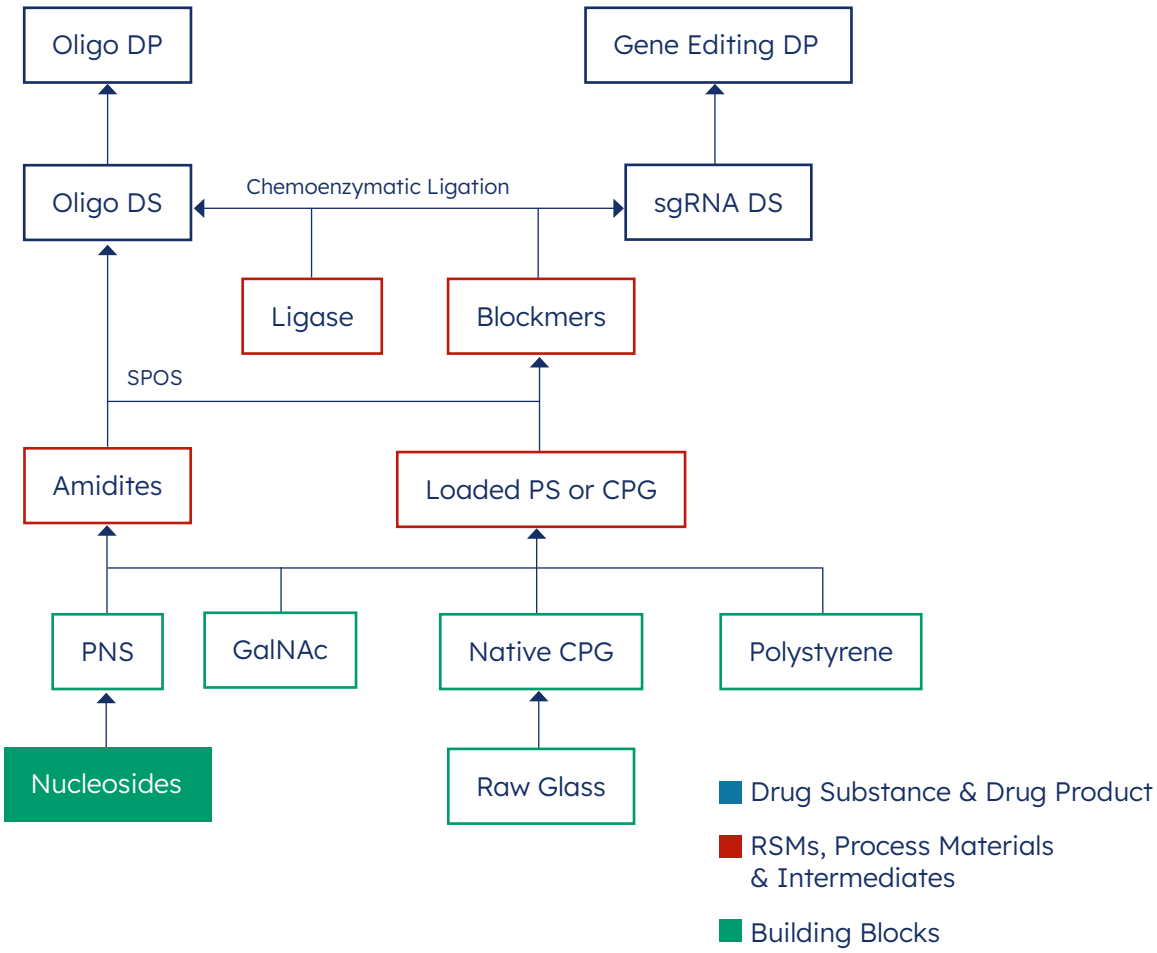
7

Regulatory and CMC Support

Expert technical support for CMC documentation and regulatory submissions across development stages.

Vertical Integration and Supply Chain Control

From building blocks to drug substance and drug product, Hongene's vertically integrated platform reduces handoffs, improves continuity and supports more efficient program execution.



Benefits of Vertical Integration

- **Supply continuity**
- **Fewer vendor handoffs**
- **Stronger traceability**
- **Improved cost efficiency**

Proprietary Technology for Next-generation Oligonucleotide Manufacturing

Chemoenzymatic ligation combines chemical synthesis with enzymatic assembly. Short oligonucleotide fragments are first synthesized chemically, then ligated into a full-length product using ligase.

Hongene's proprietary chemoenzymatic ligation platform, HiPEL™, is designed to support next-generation oligonucleotide therapeutics by improving purity, scalability, and manufacturing efficiency for selected applications.

HiPEL™ vs SPOS

How HiPEL™ Compares With Conventional SPOS

Attribute	HiPEL™	SPOS
Manufacturing efficiency	Higher for large-volume programs	Competitive at smaller volumes
Purity profile	High-purity potential through fragment-based assembly	More susceptible to accumulated synthesis impurities
Long, complex constructs	Well-suited to long, complex constructs	Limited as length and complexity increase
Yield performance	High fragment yield and modular assembly by ligation	Declines exponentially with sequence length
Sustainability	Lower PMI driven by higher overall yield	Higher PMI
Scalability	Well-suited for large-scale manufacturing	More constrained at scales >7 kg

Key Advantages

- Higher yields than conventional SPOS
- Improved purity through fragment-based assembly and enzymatic selectivity
- Improved cost efficiency for high-volume programs
- Compatibility with siRNA, ASOs, and long RNA constructs such as sgRNA and pegRNA

High-Impact Applications

- Large-scale siRNA manufacturing for indications requiring high-volume supply
- High-purity manufacturing for complex constructs such as dual-targeting siRNA and antibody–oligonucleotide conjugates (AOCs)
- High-fidelity manufacturing of long RNA constructs such as sgRNA and pegRNA for gene editing applications

Manufacturing Capacity and Footprint

Manufacturing scale and infrastructure designed to support clinical supply, commercial growth and long-term supply continuity, with continued expansion to meet future demand.

Seamless Scale-Up Capability

From clinical supply to commercial manufacturing

Multi-Ton p.a. Oligonucleotide Capacity

Built to support large-scale global demand

7 kg Batch Size

OligoProcess 1800 mmol synthesizers for large-scale SPOS

58 Ton p.a. Phosphoramidite Capacity

In-house upstream supply security

5 Ton p.a. GalNAc Capacity

Supply continuity for large-volume indications

3 Ton p.a. In-House Loaded Polystyrene

Upstream support for scalable SPOS

Manufacturing Footprint and Expansion

Shanghai Fengxian Site

Current large-scale manufacturing base supporting oligonucleotide CDMO services and commercial supply, opened in January 2025

Hungary Site

European manufacturing expansion under development, targeted to open in early 2028

OperationalAdvantages

- **Reduced scale-up risk**
- **Future-ready capacity expansion**
- **Commercial supply continuity**

Quality, Regulatory, and CMC Support

Our integrated approach combines robust quality systems, cGMP manufacturing and regulatory support help customers advance programs with confidence.

1

Quality Management System

Quality systems designed to support product integrity, traceability, and consistent execution across development and manufacturing.

2

cGMP Manufacturing

Supported by processes and controls aligned with applicable global regulatory expectations.

3

Analytical Development and QC

Analytical method development, product characterization, and release support to enable quality control and regulatory readiness.

4

Regulatory & CMC Support

Technical and documentation support across development stages to help streamline CMC preparation and regulatory interactions.

2025 Fengxian Site Audit and Inspection Track Record

- Extensive customer audits spanning MNC, Big Pharma and biotech companies
- Regulatory visits from NMPA, CDE, and EU QP audits

Hongene Highlights

Hongene is a global nucleic acid CDMO with the capacity, infrastructure and technical depth to support and scale the next generation of oligonucleotide therapeutics.

Nearly three decades of RNA industry experience

1,600 Employees globally
~380 FTEs in R&D

2 R&D Centers: San Francisco & Shanghai

5 tons annual GalNAc production capacity

Extensive impurity reference standard library: Supporting impurity characterization and CMC readiness

2,000+ product SKUs: Phosphoramidites, GalNAc, linkers, solid supports, NTPs, cap analogs, and enzymes

58 tons annual phosphoramidite production capacity

Global footprint across R&D and commercial operations

Together, we can unlock the full potential of oligonucleotide therapeutics and make a difference in the lives of patients worldwide.

We are continuously innovating and advancing oligonucleotide therapeutics to make medicines accessible and affordable for patients worldwide. With our world-leading capacity, unmatched quality and customer-centric approach, we are the ideal partner to support your oligonucleotide journey.

Contact Us for Your Oligonucleotide Projects.

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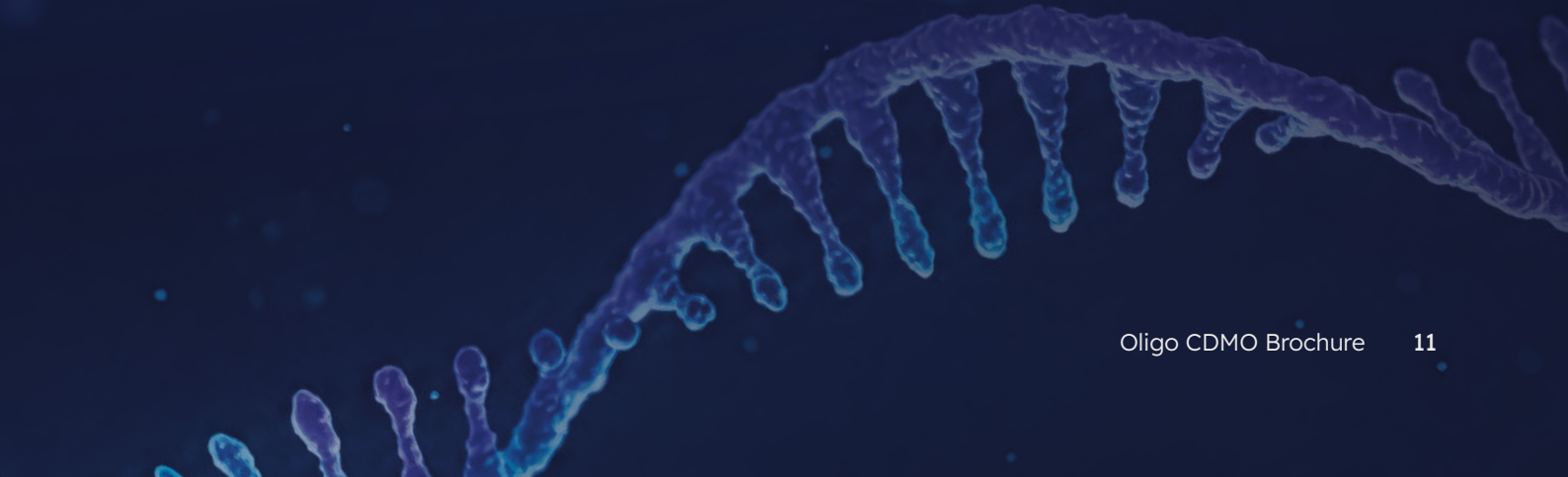

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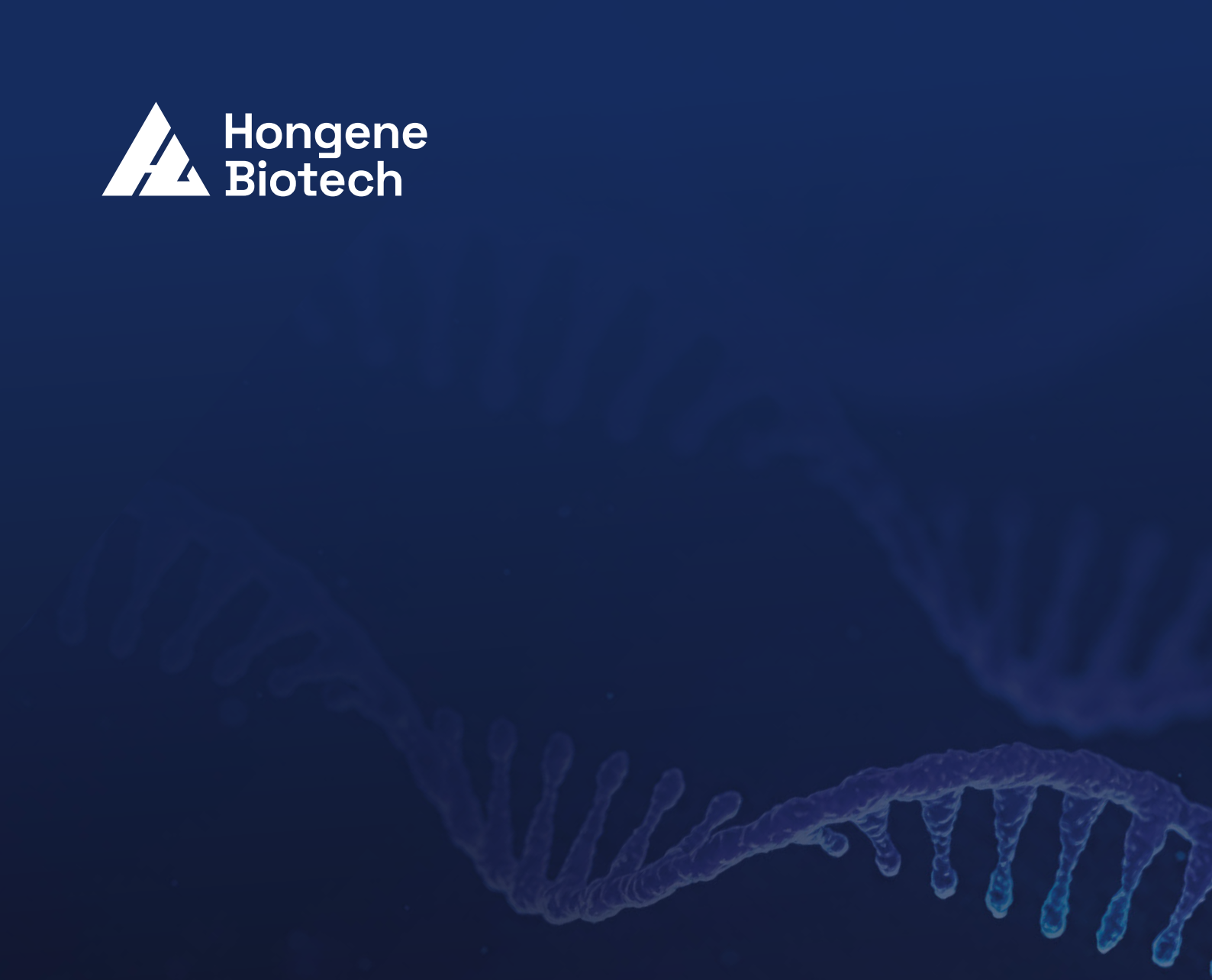

Let's Bring Your RNA to Life.

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