



Oligonucleotide



Company Introduction

RiboBio is Asia's largest oligonucleotide-based drug manufacturer. Over the years, RiboBio has developed many novel nucleic-acid based technologies utilizing its world-class R&D team equipped with state-of-the-art tools and facilities. Currently, RiboBio develops and supplies innovative RNAi, lncRNA and miRNA products and offers a diverse line of oligonucleotide-based services including CRO, Synthesis and CDMO services from small to commercial scales. Our customers represent thousands from academia, medical, pharmaceutical, industrial and government organizations, both domestic and international.

RiboBio was the first licensed cGMP manufacturing facility in China specializing in Oligonucleotide Manufacturing. In its facilities, RiboBio offers a wide-range synthesis of synthesis scales for oligonucleotides, from milligram to multi-kilogram, with diverse modifications and chemistries. RiboBio manufactures oligonucleotides for various purposes including; pre-clinical research and toxicology studies, to clinical trials from Phase I to Phase III, and marketed-product commercialization of final API, diagnostic or cosmetic ingredient. To assure the success of our manufacturing projects, we work closely with our clients: from the definition of the projects initial goals through development, including analytical methods development, tox and stability studies, through commercialization and beyond.

Environment, Methods, Materials and Validation

RiboBio's cGMP manufacturing facility meets or exceeds current IS08 (synthesis, purification), IS07 (lyophilization) and IS05 (product packaging) requirements as well as ICH Q7(cGMP) and CFDA Title 21 part 210(cGMP) requirements. To ensure RiboBio continues to meet or exceed these requirements, RiboBio conducts continuous and systematic on-going testing of facilities, water and air supplies, major equipment and in-coming raw materials.

- Validated procedures for the strict qualification of raw materials from reliable, industry-leading suppliers
- Centralized gas supply with on-site purification systems for air and water
- Operating procedures for equipment cleaning, sanitization and validation.



Oligonucleotide Synthesis Expertise

Experienced Team

- 15+years of experience synthesizing and manufacturing oligonucleotides
- Manufactured 1,000, 000+ molecules, with a variety of modifications
- Recognized as top supplier of specialty oligonucleotides
- Highly trained personnel (Bs, MS, PhD), [th experienced project managers
- Successfully completed Many projects requiring regulatory agency approval

Advanced Equipment

Ribobio manufactures oligonucleotides using comprehensive, most advanced and updated synthesis, purification and analytical equipment.

- Synthesis: ÄKTA Onigoplot 100 ÄKTA Oigoplot 400, 1.8M Oligo Process Instrument
- Purification: ÄKTAexplorer, ÄKTApilot and ÄKTAprocess, Kiloprep
- Desalting: ultra-filtration skids
- Lyophilization: CGMP freeze-drying equipment
- Sterile Fill and Finish

We provide effective scale-up solutions for oligonucleotide synthesis under internationally accepted GMP standards and practices.



Process Development

Your oligonucleotide manufacturing project is considered unique requiring an individual approach. Therefore, we work closely with you to optimize your process, before starting full scale production. Process optimization assures you an oligonucleotide manufactured with the highest yield and purity while minimizing costs.

Project Management

Ribobio's utmost goal is Customer's satisfaction. To achieve this goal we make all reasonable efforts to establish mutually acceptable and achievable project goals with timelines and milestones and success metrics.

- Strict timelines
- Unsurpassed recovery, high purity, low cost
- Consistent, Scalable, Performance from research to production
- Process reliability and reproducibility
- Protocol and Process developed according to ICH standards

	≤1 mg	10 mg	100 mg	1 g	10 g	100 g	1 kg	10+ kg*
Discovery	■							
Research	■	■						
Pre-Clinical		■	■	■	■	■		
Clinical Trials					■	■	■	
Commercial						■	■	■

* Construction of additional large-scale synthesis facility is in progress

Quality and Efficiency

RiboBio is dedicated to making oligonucleotides that comply with the strictest internationally accepted standards. We have extensive knowledge of and possess in our arsenal versatile approaches and state-of-the-art instrumentation for handling quality analysis and control of oligonucleotide raw materials, intermediates and final products.

Analytical Method Development

- Impurity identification and qualification
- LC/MS, ICP-MS, UPLC, GC, Other
- Manufacturing process development and optimization
- Customized methods development

Product Properties

- Physicochemical (T_m, water content, Mw)
- Molecular structure and sequence
- Salt content
- Reference standards development and qualification
- cGMP Manufacturing

Quality Assessment

- Raw materials
- Process validation
- Finished products

Quality Assessment

- ICH storage conditions
- Real-time data collection and analysis
- Systematic report generation
- On-demand stability tests



Cost-Efficient Business Models

Each oligonucleotide cGMP manufacturing project is a major undertaking and requires significant resources from a drug developer. Ribobio recognizes and acknowledges this. In addition to conventional financing models, our business team is willing to consider creative compensation schemes, including partial risk-sharing. Such alternatives might be particularly attractive for younger sponsoring organizations and drug developers in transitional financial stages.