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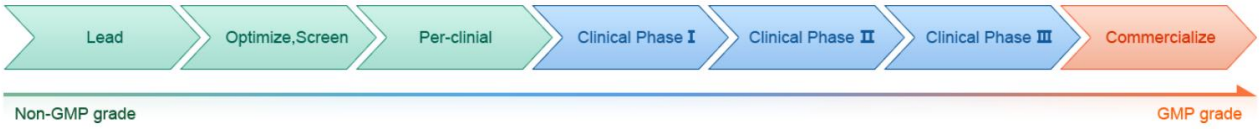
RibobaY

OLIGONUCLEOTIDE MANUFACTURING

The facilities of Ribobay can meet the requirements of cGMP regulations of global authorities. Ribobay can provide Non-GMP grade and GMP grade oligo API production services across all stages of drug development, which is "one-stop" service from drug screening to commercialization.



Drug discovery stage

- **Custom synthesis of candidate molecules for drug screening (nmol - μmol)**

High throughput oligonucleotide library synthesis

- **PCC synthesis in preclinical pre-toxicology stage (mg- grams)**

Pre-clinial stage

- **Customized synthesis of toxicology batch samples**

2 oligo CMC production lines built to meet the needs of toxicology evaluationBatch size up to hundreds of grams

▶ GMP-Like workshop, laboratory, equipment and instrument
▶ Highly customizable, fast delivery

Clinical oligonucleotides API manufacturing

Our facilities and plants at the oligonucleotide manufacturing site are capable of meeting the requirements of cGMP regulations of NMPA, FDA, EMA, etc,and can provide toxicology batch and clinical research grade oligonucleotide API manufacturing services.

We have automated oligonucleotide synthesis, purification and ultrafiltration facilities of various scales and established large-scale manufacturing lines to provide oligonucleotide APIs manufacturing from gram to kilogram, supporting customers in completing Phase I-III clinical studies.

Commercial oligonucleotides API manufacturing

In compliance with GMP requirements, we have established several automatic oligonucleotide API manufacturing lines, which can not only improve the manufacturing efficiency, but also simplify the control system strategy, reduce the production cost, and meet the cGMP manufacturing requirements.

Equipped with a complete set of Cytiva commercial synthesis and purification equipment, with single batch synthesis from 100-1800 mmol, the scale of oligonucleotide synthesis can reach 3.7 mol at the same time, Ribobay meet the commercial needs of oligonucleotides drug and vaccine companies.

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OLIGONUCLEOTIDE PROCESS DEVELOPMENT

Raw material selection

Ribobay has a perfect quality system and strictly follows the "Good Manufacturing Practice" in the procurement of raw and auxiliary materials,classifies incoming materials and sets quality standards.

We test and release the materials to ensure their quality,such as solid-phase support, nucleoside phosphoramidites, anhydrous acetonitrile and other chemical raw materials.

We audits the qualification of suppliers in strict accordance with the supplier audit management procedures,ensuring the quality of supply materials and the stability of supply channels.

Production process development and validation

The process development team of Ribobay possess industry-leading oligonucleotide process development and production service capabilities, have rich experience in analysis of key process control points for oligonucleotides, research on process impurities, quality control, and production scaling up. We can help customers to complete process development, validation and process transfer, and provide final process summary reports.

We have world-class research, development and manufacturing facilities, advanced synthesis processes, offering comprehensive purification solutions consisting of tangential flow filtration, multiple chromatographic fillers.

Scale-up and consistency in manufacturing can be achieved, as well as great flexibility that remove various impurities generated during the preparation of oligonucleotides effectively. Ribobay is a good supplier of commercial oligonucleotides.

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OLIGONUCLEOTIDE PROCESS DEVELOPMENT

Process of Chemical Modification and Conjugation

- Backbone modifications (Phosphate modification, Sugar-phosphate modification)
- Sugar modifications (2'-OMe, 2'-F, 2'-O-MOE, LNA, cET, ENA)
- Base modifications (5-Methylcytosine)
- Conjugates (GalNac, PEG, Cholesterol)