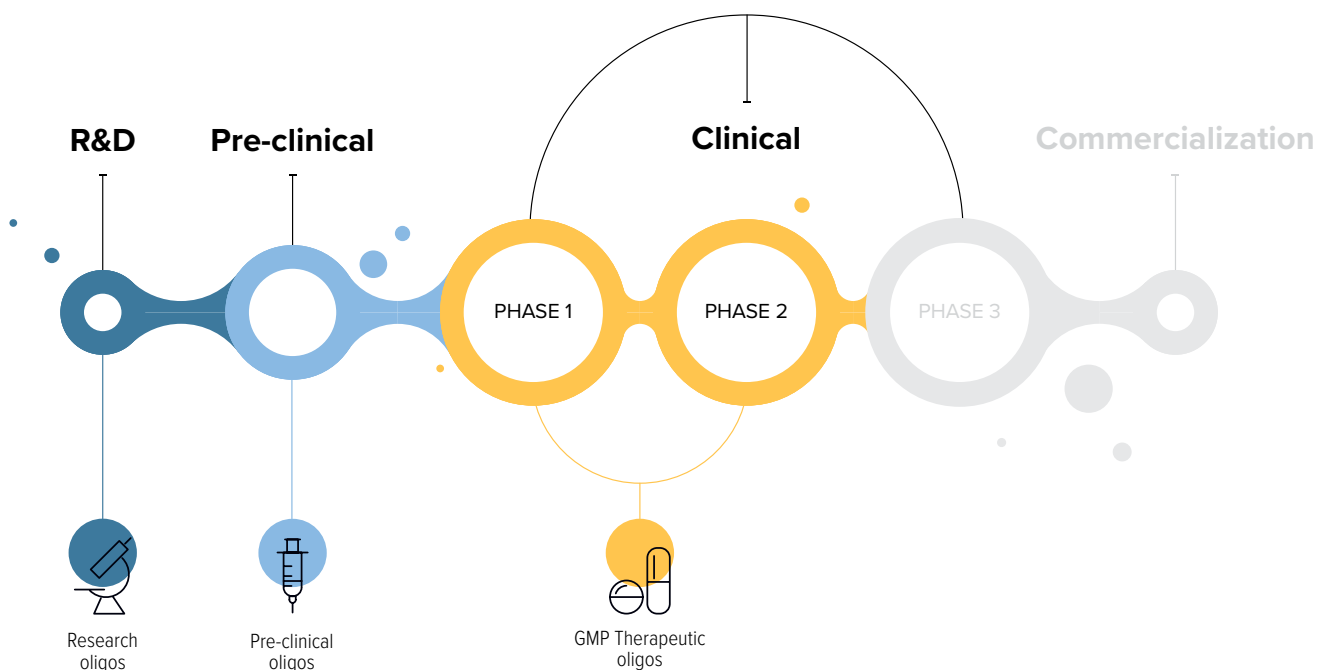




Therapeutic Oligonucleotides

Oligonucleotides manufacturing
from discovery to early clinical phases





ISO7 & 8 Classified Cleanrooms manufacturing environment is used for our production of pre-clinical and clinical Oligonucleotides.

Pre-clinical & GMP Therapeutic manufacturing for early clinical phases

Eurogentec provides custom DNA and RNA oligonucleotides. A broad range of chemistries and modifications are available. Moreover we offer post-synthetic conjugation to different molecules such as Cholesterol or PEG to help drug delivery, stability and efficiency.

Our extensive and technical expertise as well as our flexibility allow us to produce different types of oligonucleotides including siRNA, Antisense, Aptamer, CpG,...

PRE-CLINICAL OLIGONUCLEOTIDES

Thanks to our quality controls and downstream processing developed through our long expertise in the oligonucleotide field, we manufacture high quality pre-clinical oligonucleotides.

Our pre-clinical oligonucleotides are produced using a scalable synthesis and purification methods.

The pre-clinical oligonucleotides include:

- Appropriate QCs and additional controls according to your needs
- Detailed Certificate of Analysis
- Manufacturing Record Summary as support to complete the CMC module for IND/IMPd files.

GMP THERAPEUTIC OLIGONUCLEOTIDES

If you progress into clinical development, we also offer a GMP therapeutic oligonucleotide manufacturing service.

Our rigorous Quality System, the production under classified cleanrooms as well as the optimization of purification and downstream processes allow us to produce oligonucleotides of high and reproducible quality.



Analytical Services

QC analytical methods are qualified for raw material and final product release to meet your specifications.

- Appearance
- Purity by UPLC / HPLC
- Identity by Mass Spectrometry (ESI)
- Endotoxin level
- Bioburden
- Residual solvents
- Residual heavy metals
- pH
- Sodium content
- Osmolality
- Sequencing
- Phosphorothioate - Phosphate content
- Water content

➤ **More on request at**
therapeutic.oligo@eurogentec.com

Quality & Regulatory support

Our Quality Unit is based on 3 departments:

- Quality Assurance (Regulatory support)
- Quality Control
- Validation / Metrology

QA release of the Drug Substance is done according to specifications established between Eurogentec and the customer. It is documented in a full Batch Record containing all production and analytical steps.

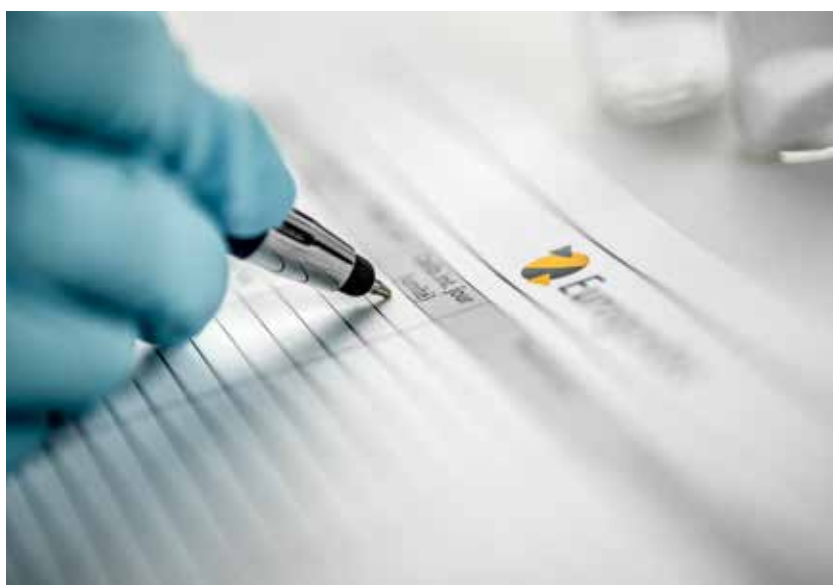
GMP accreditation* by the Belgium Authorities for the manufacturing and quality control of therapeutic oligonucleotides according to ICH Q7.

* Accreditation Q1 2019

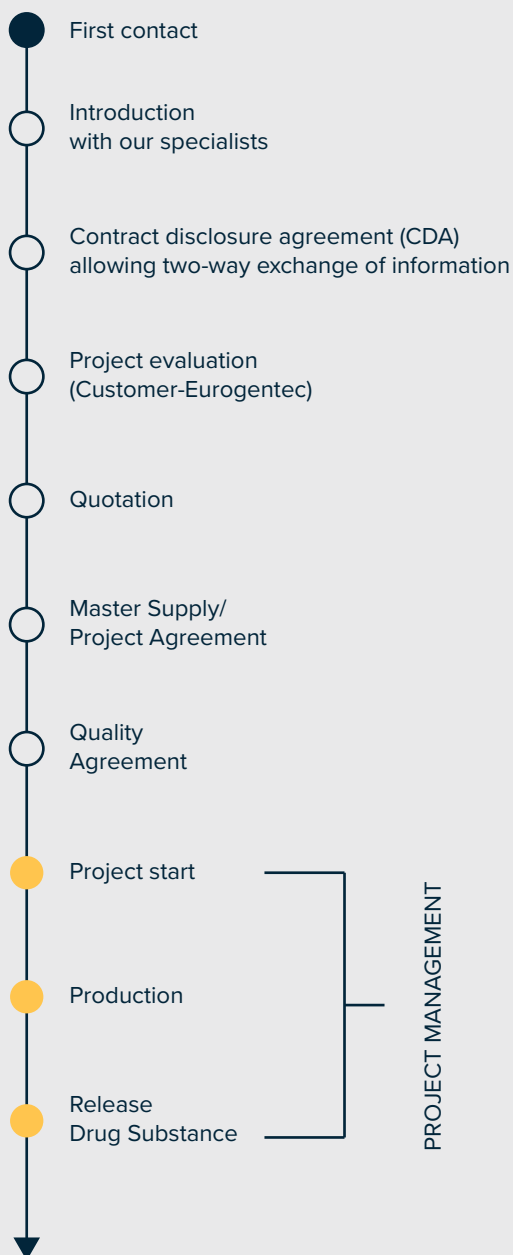
“ UNDERSTANDING YOUR NEEDS AND SUPPORTING YOU ARE THE FOUNDATIONS OF OUR PARTNERSHIP.

We offer support in the writing and review of Chemistry, Manufacturing and Controls (CMC) quality module documentation in CTD for the submission of IND or IMPD files.

QA representatives supervise all projects regarding respect of appropriate regulatory and quality instructions.



Working with Eurogentec



OLIGOS FROM DISCOVERY TO EARLY CLINICAL PHASES



Research & Discovery



Pre-clinical



Therapeutic

30 years of experience

high quality oligonucleotides
for research, commercial and diagnostic field

15 years of experience

multi-grams oligonucleotides
synthesis and purification for pre-clinical market

20 years of experience

injectable GMP manufacturing
of protein and plasmid DNA for pharma companies

EUROGENTEC IS PART OF KANEKA

Kaneka is an innovation-oriented chemical company. Traditionally the company has been active in polymers, fermentation, biotechnology and electronics, as well as other fields. Business activities now span a broad spectrum of markets ranging from plastics, EPS resins, chemicals and foodstuffs to pharmaceuticals, medical devices, electrical and electronic materials and synthetic fibers. The company has been a pioneer among Japanese chemical companies in establishing overseas operations, beginning in 1970 with a subsidiary in Belgium.

www.eurogentec.com

CONTACT US AT

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OUR MANUFACTURING FACILITY IS LOCATED IN THE HEART OF EUROPE, BELGIUM.