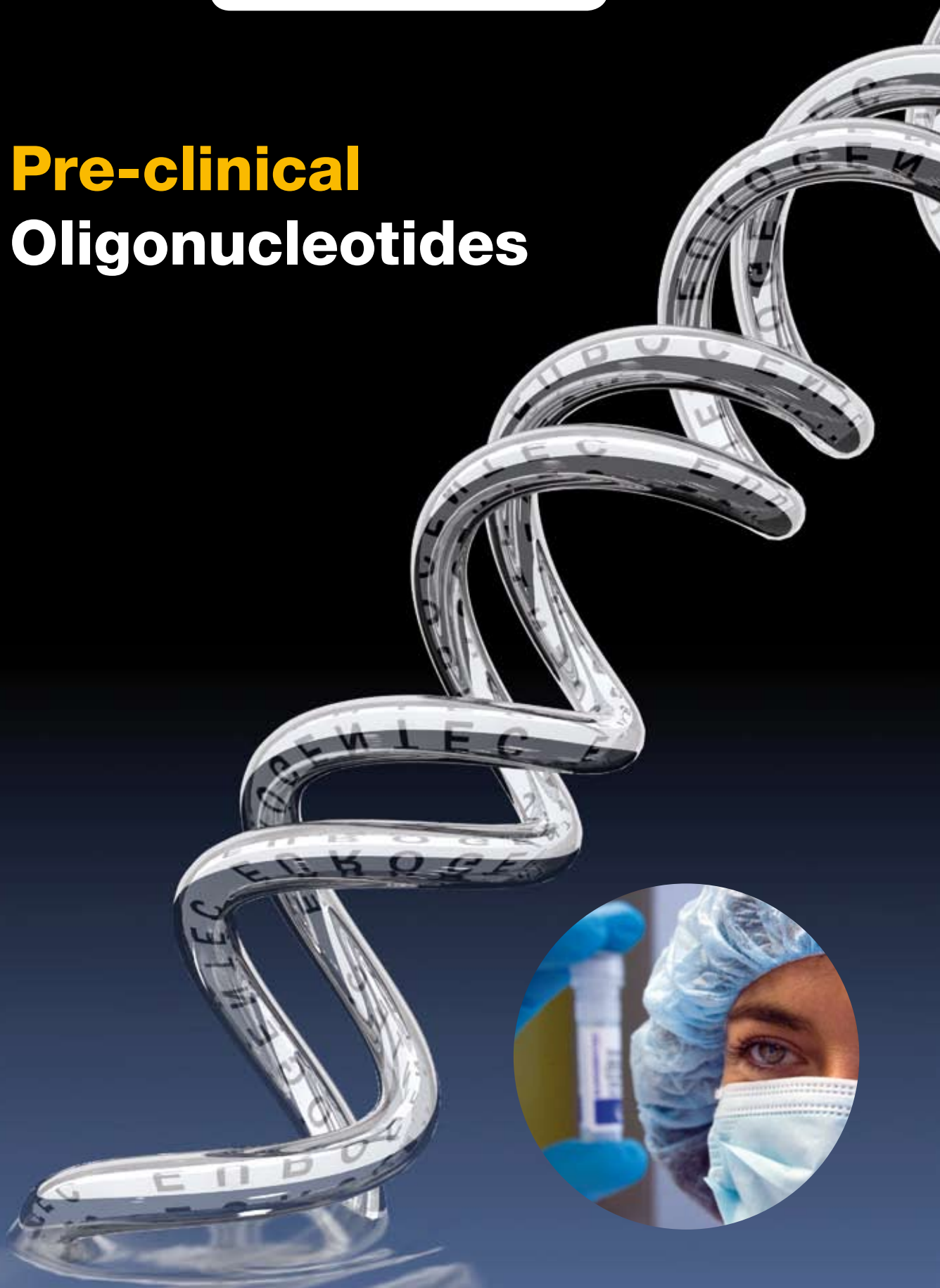


# **Pre-clinical** **Oligonucleotides**



**cGMP manufacturing**  
**for (pre-)clinical studies**

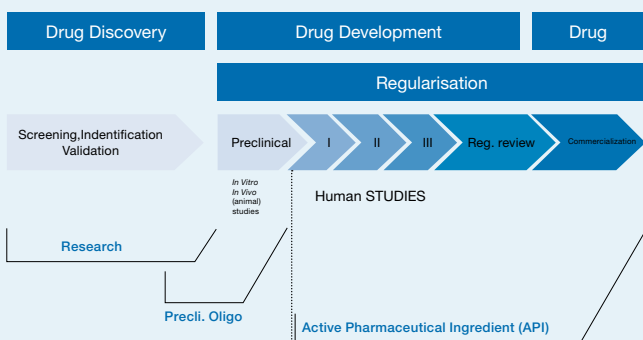
## Oligonucleotide Therapeutics

In the interim years since the FDA approved the first oligonucleotide-based therapeutic in 1998<sup>1</sup>, compounds based on synthetic oligos have established themselves as critically important tools for life scientists. Recent scientific progress in the field of RNA interference (RNAi) has stimulated increased interest in this field. A growing number of companies are developing oligonucleotide-based pharmaceutical products which are in various stages of pre-clinical testing. Proposed clinical applications include the use of antisense-, aptamer-, immunostimulatory CpG- and RNAi-related therapeutics. Many of these compounds hold the promise of treating life-threatening and previously untreatable or incurable diseases.

As a result of this increasing activity, the requirement for GMP manufactured synthetic oligonucleotides for pre-clinical testing and eventual *in vivo* use is becoming increasingly important.

## Pre-clinical Oligonucleotide Manufacturing

For over 20 years Eurogentec has been a leading provider of high quality oligonucleotides and related products for R&D applications, complementing our R&D capability, Eurogentec maintains a separate state-of-the-art GMP facility for the manufacture of oligos for use in *in vitro* and molecular diagnostic applications. Eurogentec now brings this level of GMP manufacturing expertise to the synthesis and purification of oligonucleotides for use in pre-clinical studies.



In addition to pharmacological documentation, detailed records of the compound's manufacture must be generated and saved for future review. Upon request, results of pharmacological testing and compound manufacture may be required for review by governmental regulatory agencies as part of the drug approval process.

EUROGENTEC understands that compounds destined for pre-clinical and therapeutic applications require a level of manufacturing traceability that becomes more rigorous and comprehensive as the compound progresses from discovery and development to pre-clinical studies to *in vivo* clinical trials. Although not requiring full API (Active Pharmaceutical Ingredient) work-up, oligos manufactured for pre-clinical study phases are provided with documentation detail between the levels required for R&D and API's.

Our Pre-clinical Oligo service offers the optimal solution for pre-clinical studies. Our quality management system is ISO13485:2003 certified. Our GMP manufacturing facility incorporates a card-key system for access to the manufacturing floor and permits full segregation of synthesis, cleavage/deprotection, purification and fill & finish processes. Access to the various clean rooms (customer can choose between class 100,000 or 10,000 rooms with class 100 working zones) requires entry through a pass-through airlock and a strict gowning policy is enforced.

In partnership with our customers, we offer a large selection of standard and customized QC release methods any of which can be incorporated into customized documentation.

Special QC tests testing for heavy metals, residual solvents, endotoxins and bioburden, assuring performance equivalence to the API's that would eventually be manufactured for use in human *in vivo* clinical trials.

Every aspect of the manufacturing process is monitored and documented with a formal Certificate of Analysis detailing final release of the compound based on its detailed batch record as signed by a QC authorized person.

Eurogentec offers its customers a very cost-effective manufacturing solution for oligos for pre-clinical use. Attractively priced between Research oligos and API's, pre-clinical oligos are manufactured to the highest standards in dedicated clean rooms in our GMP facility with processes and documentation that can be customized to satisfy client-specific requirements.

<sup>1</sup>The first FDA-approved oligonucleotide therapeutic was the antisense antiviral molecule Vitravene® (fomivirsen) developed by Isis Pharmaceuticals for the treatment of cytomegalovirus retinitis, an eye infection affecting immunocompromised patients. Fomivirsen is a phosphorothioate oligonucleotide, twenty-one nucleotides in length, with the following sequence: 5'-GCG TTT GCT CTT CTT CTT GCG-3'.

**Eurogentec your manufacturing partner of choice**

For more information or to request a quotation, please contact us at [therapeutic.oligo@eurogentec.com](mailto:therapeutic.oligo@eurogentec.com)

