Advancing oligonucleotide therapeutics with cutting-edge bioanalytics

How valuable is your therapeutic development time? Our short lead times, flexible attitude and customized solutions provide you with high quality bioanalytical data in a time and cost-effective manner. Our scientists are client focused, flexible and use their extensive technical and regulatory expertise on to your advantage. We support:

**PK measurements**
- Preclinical discovery
- Preclinical GLP compliant
- Clinical GCP compliant

**PD / biomarker**
- Regulated analysis
- Exploratory analysis

**Immunogenicity assessment**
- Risk based approach
- FDA & EMA guidelines

We can perform your assays on several platforms:

**PK measurements**
- qPCR
- Hybr ELISA
- LC-MS/MS

**PD / biomarker**
- qPCR
- ELISA
- LC-MS/MS
- Flow Cytometry

**Immunogenicity assessment**
- ELISA
- MesoScale Discovery

info@ardena.com
www.ardena.com/bioanalysis
Oligonucleotide Therapeutics: an Integrated Approach

In the past decade, novel oligonucleotide therapeutics have been developed and gene modulating therapies become increasingly important. Ardena has a strong track record of supporting oligonucleotide programs with bioanalytics and understands the unusual CMC regulatory situation.

In an integrated approach, Ardena’s expert teams accelerate your oligonucleotide project from discovery to clinic and smoothly guide you through the complex CMC regulatory landscape.

Nanomedicines
Wide range of nanoparticles: lipid-based nanoparticles (LNPs, liposomes and lipid micelles), polymeric nanoparticles and metal/metal oxide nanoparticles.

Synthesis of building blocks
Process and scale up development
Analytical method development & validation
GMP manufacturing and release testing
Aseptic fill and finish
ICH stability studies
Clinical labelling and supply

CMC Regulatory Support
Extensive experience
Regulatory support in an unusual landscape
IMPD/IND authoring
Nitrosamine risk assessment
CMC report writing

Bioanalysis
PK measurements
PD / biomarkers
Immunogenicity assessment
Pre-clinical discovery to clinical GCP
ICH M10, FDA & EMA guidelines

info@ardena.com
www.ardena.com