Navigating the CMC Regulatory Landscape for Oligonucleotide Therapeutics

Getting the CMC regulatory aspects for your oligonucleotide therapeutic right from the outset?

Oligos find themselves in an unusual regulatory situation. Some of the standard ICH guidelines do not fully apply.
Ardena's CMC regulatory team has gained substantial experience in this field and guides you through the regulatory framework to speed up the time to clinic.

Module 3 Writing

- IMPD and IND
- Quality overall summary
- CMC summary

CMC Report Writing

- Criticality analysis
- Nitrosamine risk assessment
- Formulation development

Regulatory Support

- Justification of specification
- Stability study design
- Response to questions

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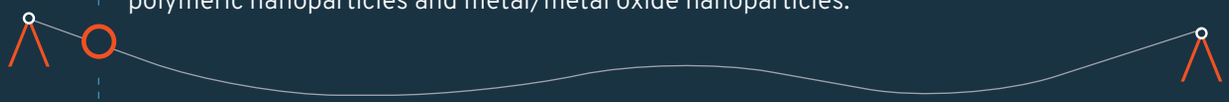
Oligonucleotide Therapeutics: an Integrated Approach

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.

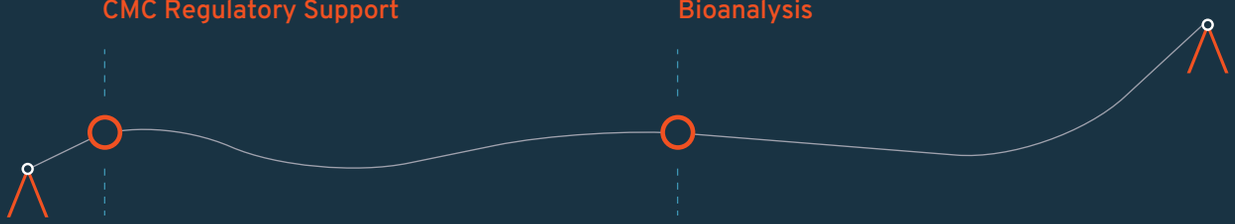
Nanomedicines

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

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