Delivering Solutions for Nucleic Acid Therapeutics

Partner with Agilent and benefit from our industry leading nucleic acid experience to efficiently advance your lead oligo candidates from clinic to market with a common goal of patient health and safety.

Agilent's Boulder, Colorado manufacturing site is an FDA inspected facility.
Experience at a Glance

A Strong and Growing Global Presence
- $4.47 billion fiscal year 2017 annual revenue
- 13,500 employees
- Manufacturing and R&D in the U.S., Europe and Asia-Pacific
- Customers in 110 countries
Agilent is a leader in life sciences, diagnostics and applied chemical markets. The company provides laboratories worldwide with instruments, services, consumables, applications and expertise, enabling customers to gain the insights they seek. Agilent’s expertise and trusted collaboration give them the highest confidence in our solutions.

Technology and Market Leader
Our focus is on four life-changing initiatives
- Partner for novel therapeutics & diagnostics
- Fight cancer
- Improve the quality of life
- Enable new discoveries
Agilent’s culture is based on innovation, trust, respect and teamwork, and uncompromising integrity. Added to these are speed, focus and accountability to meet customer needs and create a culture of performance that draws on the full range of people’s skills and aspirations. Agilent is regularly recognized by external organizations for its culture as well as its practices around processes and people.
Nucleic Acid Solutions

Agilent owns two facilities equipped to serve all your oligo API needs. The 77,000 square foot current Good Manufacturing Practices (cGMP) facility located in Boulder, Colorado houses multiple suites enabling the manufacture of several products simultaneously. A broad range of synthesis and purification equipment allows for production of grams for toxicology and pre-clinical use, to 10’s of kilograms for late-stage clinical trials and commercial launch. Agilent’s newest facility, a 135,000 square foot cGMP facility located in Frederick, Colorado will enable the company to more than double its commercial manufacturing capacity for nucleic acid based therapeutics.

Collaboration is important to a successful strategy. Many biotech and pharma companies increase their chances of success by partnering with an experienced development partner, like Agilent, who can help them make decisions, solve technical problems and save money at critical points along the way. Discover how Agilent can help you:

- Reduce your risk with security of supply from grams to kilograms
- Accelerate speed to clinic and scale-up via an efficient approach to chemical development
  - Highest concentration of oligonucleotide scientists at a single manufacturing facility in the world
  - Unparalleled analytical expertise including access to the latest state-of-the-art equipment
- Increase your confidence and understand your molecule better with access to the capabilities and services of the world’s leading analytical company
- Unparalleled commitment to world class innovation
- Dedicated to enabling cost-effective manufacturing of commercial scale quantities of nucleic acids

Accelerate Scale-Up and Speed to Clinic

Extensive knowledge and experience enable Agilent’s nucleic acid experts to do what very few can - taking chemical processes previously run only at very small scales and transforming them into executable processes for significantly larger scales.

Method Development, Qualification and Validation

Method development, qualification and validation are vital to the oligo API manufacturing process. Robust methods developed at the beginning of your program can save you time and money in the long-run. The experts at Agilent can transfer, develop, qualify and validate analytical methods from IND to NDA. We specialize in stability indicating methods for antisense, RNAi, aptamers, conjugates and other complex nucleic acids.

We pride ourselves on finding solutions to difficult analytical problems such as positive identification of impurities and quantitative mass spectrometry for critical impurities. Customers are encouraged to be involved to whatever extent they wish in the development and qualification/validation process.

Rigorous Quality Systems

Agilent is dedicated to cGMP as defined by International Conference on Harmonisation (ICH), Food and Drug Administration (FDA) Code of Federal Regulations and European Medicines Agency (EMA) for providing APIs. Our Quality Policy and robust quality systems incorporate these established standards, enabling us to provide oligo API world-wide. Agilent follows an industry accepted risk-based approach to drug development, utilizing Quality by Design (QbD), and following ICH Q8/Q9 guidance.

Our experienced team of compliance specialists can provide assistance with the Chemistry, Manufacturing and Controls (CMC) for US and international regulatory submissions (DMF, IND, CTA, NDA).

Experience. Innovation.

The Agilent process development team is familiar with compounds including:
- guideRNA (Long-mers)
- siRNA
- miRNA
- Antisense
- Immunostimulatory
- Hairpin RNAs
- Complex Conjugates
- Aptamers
- Ratioed Duplexes
- Highly modified oligos
Your Project Manager will be involved from the very beginning – in fact, working closely with the Business Development team, they are key in helping prepare the initial proposal – this ensures a clear understanding of each customer’s specific requirements. The Project Manager will establish a cross-functional Agilent team, depending on customer need, to ensure successful project completion.

Advance your oligo API through development with the premier CMO providing the analytical expertise, manufacturing capabilities and nucleic acid chemistry knowledge you will need.

Experience does make a difference – contact Agilent today.

Early Stage and Toxicology
Since 2006, the Agilent team has been manufacturing and delivering oligo APIs for clinical trials from our cGMP facility in Boulder, Colorado. Manufacturing capabilities include 11 independent suites that create 4 separate synthesis/purification trains and large scale lyophilization. Agilent’s facility is equipped to provide you with material throughout your development program. Small to intermediate scale quantities are produced for toxicology and early clinical development with appropriately scaled synthesis and purification equipment.

Large Stage Commercialization
The 1 mol cGMP plant in Boulder is now producing multi-kilo lots for late stage and commercial quantities of oligo API. The Frederick facility will begin manufacturing late stage and commercial quantities of oligo API in 2019. Industry leading purification and lyophilization capacity provides accelerated manufacturing options and cost savings to our customers.

Stability
Stability studies are a critical step in the drug development process and are required prior to having a marketed, commercial product.

Agilent stability protocols are designed to support global registration of your oligo API and drug product.

The experts at Agilent have the historical experience to complete your stability studies according to your desired program. We are dedicated to being experts in nucleic acid analytics and we utilize this knowledge to ensure success for your oligo API and drug product stability studies.