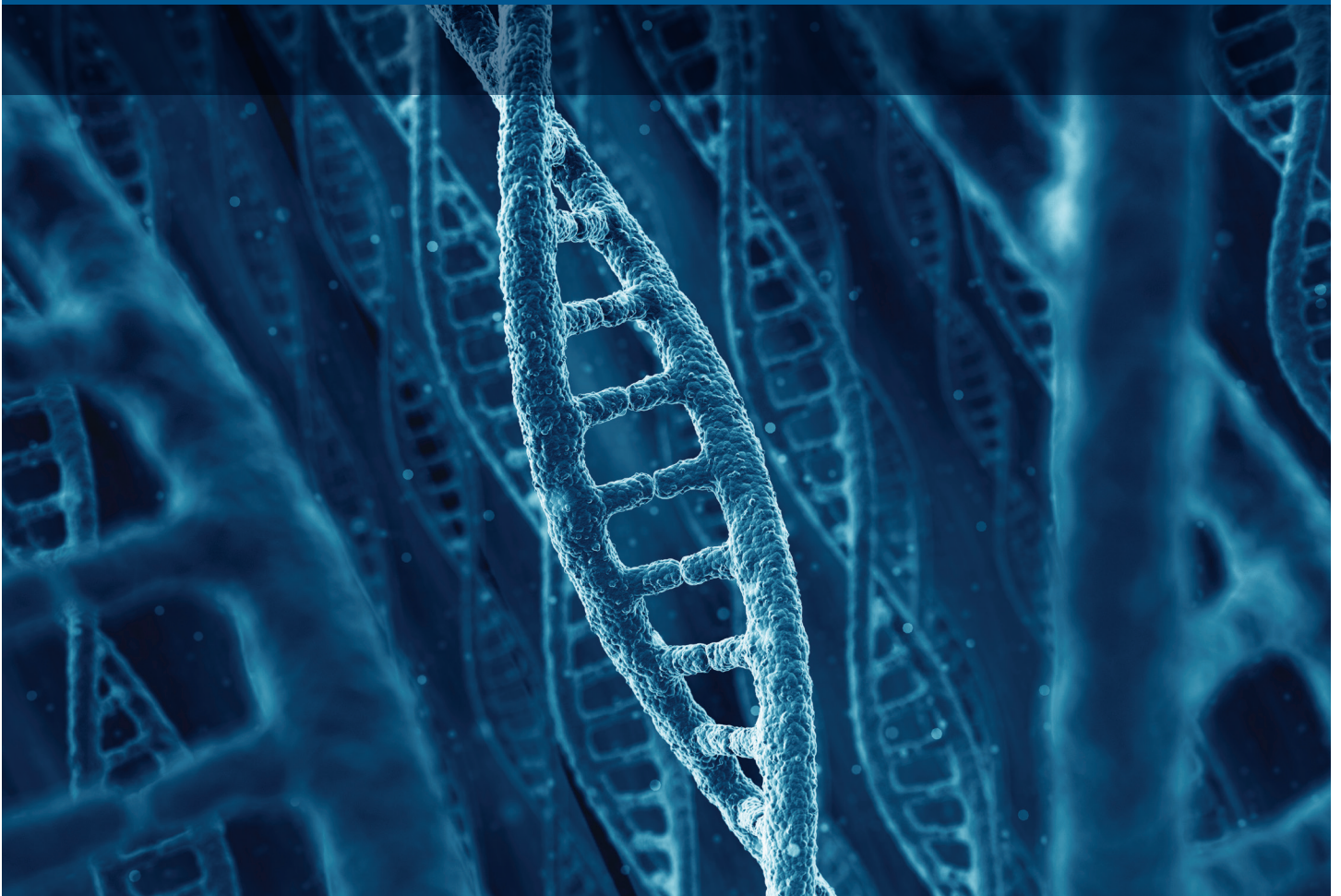




Delivering Solutions for Nucleic Acid Therapeutics

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 and Frederick, Colorado sites are FDA inspected.





Experience at a Glance

A Strong and Growing Global Presence

- \$5.16 billion fiscal year 2019 annual revenue
- 16,300 employees
- Manufacturing and R&D in the U.S., Europe and Asia-Pacific
- Customers in 110 countries
- 265,000 of the world's labs using Agilent solutions

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.



● = Major sites and logistics centers

Nucleic Acid Solutions

Agilent owns two facilities equipped to serve all your oligo active pharmaceutical ingredient (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 of nucleic acid material for toxicology and pre-clinical use, to 10's of kilograms of nucleic acid material for late-stage clinical trials and commercial launch. Agilent's newest facility, a 135,000 square foot cGMP facility located in Frederick, Colorado has enabled 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:

- Produce quality product (low impurity levels)
- Reduce your risk with a partner who can supply grams to kilograms of material
- 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

Agilent provides unparalleled commitment to world class innovation and is dedicated to enabling cost-effective manufacturing of commercial scale quantities of nucleic acids.

Experience. Innovation.



The Agilent process development team is familiar with compounds including:

- guideRNA (ClinGuide)
- siRNA
- miRNA
- Antisense
- Immunostimulatory
- Hairpin RNAs
- Complex Conjugates
- Aptamers
- Ratioed Duplexes
- Highly modified oligos

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 investigational new drug (IND) to new drug application (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).

Focus. Speed. Value.

Manufacturing Excellence from Early Stage
Clinical Development to Commercialization



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 cGMP plants in Boulder and Frederick are now producing multi-kilo lots for late stage and commercial quantities of oligo API. Capacity at the Frederick facility will double again with the latest expansion due to begin design in 2020. 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.

Excellence. Always.

Agilent – Your Extended Team

The Agilent team is truly your partner and is invested in your long-term success. Your Project Manager and Product Quality Engineer are dedicated to your project - they will be responsible for planning, organizing, and managing all the necessary resources to bring about the successful completion of your specific project.



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.

Learn more:

www.agilent.com/chem/nucleicacid

Contact Agilent Today:

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