Agilent

Trusted Answers

Accelerate Your Journey from Clinic to Market

Produce high-quality oligo APIs and efficiently advance from clinic to market, delivering therapeutics to patients with unmet medical needs

Full-service oligo contract development and manufacturing organization

Partnering with Agilent, a contract development and manufacturing organization (CDMO) with more than 20 years of nucleic acid experience, will ensure that your active pharmaceutical ingredients (APIs) meet appropriate specifications, and quality and purity requirements. We scale processes from grams to tens of kilograms, ensuring safety and robustness.

Two locations

Since 2006, we have produced oligonucleotides in Colorado, U.S., strictly adhering to current Good Manufacturing Practices (cGMP).

In Boulder, we produce grams of material for toxicology and pre-clinical use, and tens of kilograms for mid- to late-stage clinical trials and commercial launch.

Our large-scale state-of-the art facility in Frederick opened in 2019. It is producing multi-kilo lots for late stage and commercial quantities of oligo API. In 2023, we launched the second manufacturing train in Frederick, doubling our clinical and commercial manufacturing capacity.

Our broad range of synthesis and purification equipment and independent operating suites provide maximum manufacturing flexibility.

Investing $725 million to double manufacturing capacity

We are expanding to take on more programs faster and increase batch sizes.

In 2023, we announced a $725 Million investment into further expansion.

With two new manufacturing lines in Frederick to go online in 2027, we will double our capacity again and meet the growing demand for siRNA, antisense, and CRISPR guide RNA.

Scale from early stage clinical development to commercialization

We are equipped to provide you with material throughout your oligo API development program, from toxicology and early stage clinical trials through to Phase III and commercial supply.

FDA inspected

Both the Boulder and Frederick facilities have been regularly inspected by the U.S. Food & Drug Administration (FDA) since 2015.

Our customers from platform biotech and big pharma companies have performed successful audits in both sites.

Development, quality, and stability support

Our experts will transfer, develop, qualify, and validate analytical methods from investigational new drug (IND) to new drug application (NDA) and biologics license application (BLA). We find solutions to difficult analytical problems such as positive identification of impurities and quantitative mass spectrometry for critical impurities.

Our testing covers all aspects of the supply chain and manufacturing process, from raw materials through to in-process testing and final release. We provide comprehensive stability studies throughout the oligonucleotide drug development cycle.

cGMP compliance

Our manufacturing, quality policy, and systems incorporate cGMP standards as defined by the International Conference on Harmonisation (ICH), U.S. Food and Drug Administration (FDA), and the European Medicines Agency (EMA).

An employee of the ultrafiltration suite documents the manufacturing process according to cGMP standards.

Global commercialization

Agilent manufactures six commercially approved oligo therapeutics, more than any other oligo CDMO. Our commercial portfolio includes APIs for treatments of common conditions like hypercholesterolaemia.

We support many clinical siRNA programs and help advance them from early clinical phases through to approved marketed therapies. Agilent is the listed API manufacturer on over 100 INDs including material for Phase I, II, and III clinical studies.

We have used a platform approach to help our partners with speed and scalability, and our partners rely on our industry leading experience in qualification and validation to support them on their journey to commercialization.

Approval timeline for commercial APIs manufactured by Agilent. The latest approval was received in 2023.

Oligo conjugates for targeted delivery

Supporting the next wave of drug conjugates

Agilent supports customers who use N-acetylgalactosamine (GalNAc) ligands and other bioconjugates to overcome delivery hurdles of the negatively charged oligonucleotide molecules. Our expertise includes incorporation during and after solid-phase synthesis. We have experience with conjugating under cGMP glycol polymers, lipids, peptides, and other moieties.

Our development team will support you with analytical method development and validation, process optimization, process scaling, and process validation, optimizing the conjugation, synthesis, and downstream purification of your conjugated molecule to deliver high quality material and array technology.

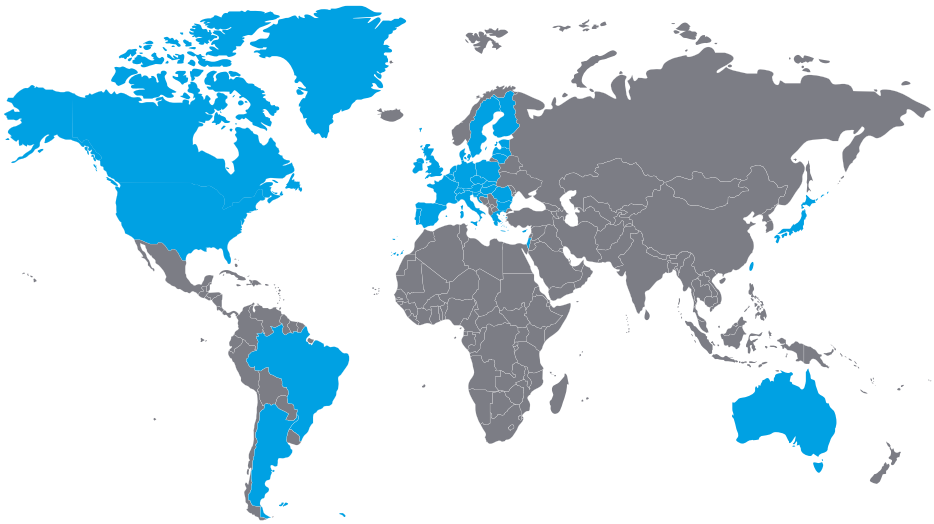
Our oligonucleotide compound portfolio

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

Global authorization

Commercial APIs made at Agilent have been used in market-authorized therapies in geographies around the world. We follow global standards, work with regulatory bodies, and keep growing the list of geographies to ensure that your oligo API is ready for global commercialization.

We adhere to the international cGMP standards in manufacturing and quality systems, and quality control. Our stability protocols are designed to make the API ready for registration and commercialization. Our compliance team assists with international regulatory submissions (IND, CTA, NDA, BLA) and we have extensive experience supporting inquiries from international health authorities. This makes Agilent the perfect partner to launch your API internationally.



Commercial API manufactured by Agilent are used in

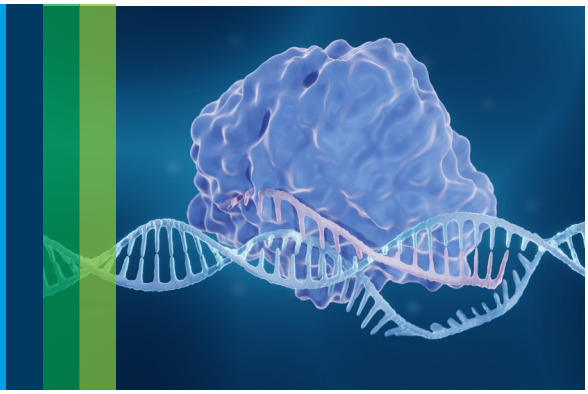
- Argentina
- Australia
- Brazil
- Canada
- EU
- Israel
- Japan
- Switzerland
- Taiwan
- UK
- US

Our team is invested in your success

The nucleic acid solutions team consists of people from various disciplines—now over 450 strong. In a collaborative cross-functional environment, we draw on the full range of expert skill and knowledge. This allows us to address challenges quickly, complete projects on time, and achieve the highest quality.

Agilent ClinGuide CRISPR sgRNAs for Human Therapeutics

Accelerate the clinical success of therapeutic gene editing programs



ClinGuide CRISPR sgRNAs delivers the high-quality cGMP material that you need to meet the rigorous requirements of human clinical trials

Agilent is here to support you during the advancement of your lead single guide RNA (sgRNA) oligonucleotide therapeutic candidates through clinical trials to commercialization.

We understand the importance of high-quality cGMP manufacturing, timely delivery of material, and the need for robust support throughout your program.

Our team is uniquely qualified to develop analytical methods and RNA synthesis manufacturing processes that optimize purity and yield for your specific guide RNA.

Produce cGMP material at scale

Confidently produce chemically modified guide RNA for human therapeutic use with Agilent. We have consistently demonstrated manufacturing success across a large range of scales and adhere to strict cGMP practices for robust, scalable, efficient, and safe sgRNA manufacturing—such as documentation, traceability, and quality standards.

Move seamlessly to manufacturing

As a CDMO, we have two cGMP facilities in Colorado that are equipped for multiple products and projects. We are continuing to expand our sgRNA manufacturing capacities and capabilities.

Ensure high purity of your CRISPR molecule

Our rigorous phase-appropriate quality systems incorporate cGMP standards and Quality by Design approach. Agilent utilizes highly resolving impurity methods compatible with mass spectrometry to ensure high quality of your guide.

ClinGuide capabilities

- Lightly to heavily modified sequences
- Highly scalable manufacturing
- High-resolution purity testing
- cGMP expertise from clinical to commercial

Learn more at:
www.agilent.com/chem/clinguide

Agilent LC-MS instruments are used to identify and control impurities.

Agilent at a Glance

A strong and growing global leader in life science, diagnostic, and applied chemical markets

Agilent Technologies Inc. (NYSE: A) is a global leader in the life science, diagnostic, and applied chemical markets, delivering insight and innovation that advance the quality of life.

Agilent's full range of solutions includes instruments, software, services, and expertise that provide trusted answers to our customers' most challenging questions.

- $6.83 billion in fiscal year 2023
- 18,000 people employed worldwide
- Manufacturing and R&D in U.S., Europe, and Asia Pacific
- Customers in 110 countries

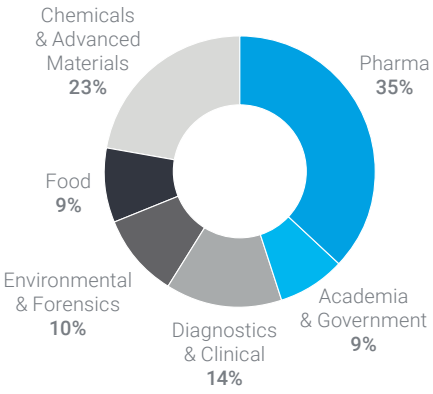
Key platforms

- Liquid and gas chromatography
- Mass spectrometry
- Spectroscopy
- Cell analysis
- Genomics and diagnostics
- Consumables, services, and software

Key growth drivers

- Biopharma
- Oligonucleotides for therapeutics
- Cell analysis
- Cancer diagnostics

Agilent revenue by end market[1]



1) % of Q4'23 Agilent revenue.

R&D and/or Manufacturing Sites

Logistics Centers

Learn more:
www.agilent.com/chem/nucleicacid
www.agilent.com/chem/clinguide

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