

# BRING YOUR CGT CANDIDATES FARTHER, FASTER

Advances in technology have reached an inflection point, and cell and gene therapies are taking off. You need a proven partner who can expertly support your research breakthrough, while transcending expectations at every phase of development.

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INCREASING CHALLENGES

SCALING UP

# Rise above the uncertainty and complexity of development

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Rigor and reproducibility are essential as therapies advance toward approval.

#### PROTOCOL AMBIGUITY

Inadequately defined protocols for emerging and existing therapies can lead to roadblocks.

#### SAMPLE MANAGEMENT

Cold chain logistics and storage challenges complicate clinical trials and manufacturing.



ELEVATE YOUR SCIENCE

## **Transcend expectations**

Azenta Life Sciences can help you address these challenges proactively. We have the infrastructure, technologies, and expertise to help you mitigate



#### GLOBAL STORAGE LOCATIONS & LOGISTICS NETWORK

From cell banks to cGMP materials and finished products, our trained staff and certified facilities specialize in cold chain storage, management, and documentation.

#### PROPRIETARY GENOMICS PROTOCOLS

Customers rely on our proprietary hairpin and GC-rich protocols to sequence and synthesize long and difficult DNA sequences with superior results.

#### AUTOMATED SOLUTIONS

Deep application experience and proven technologies protect sample integrity across all temperatures.

#### INDUSTRY EXPERTS

We will guide you through common challenges of advanced therapy development.

# Preparing for scalable CGT solutions

Azenta Life Sciences provides a comprehensive range of solutions across every phase of CGT development. We'll support the rigor of your program all the way from target discovery through scale-out.

	Discovery	Pre-Clinical & Clinical	Manufacturing & Distribution Logistics
	Target Discovery	Vector & Cell Bank Confirmation	← O         O         O         →
	<u>SEE MORE</u>	SEE MORE	<u>SEE MORE</u>
Next-Generation Sequencing	<ul> <li>Transcriptome analysis with RNA-seq (bulk or single-cell)</li> <li>Whole AAV genome sequencing (short- and long-read technologies for AAV or lentivirus)</li> <li>Integration Site Analysis (RUO)</li> </ul>	<ul> <li>Transcriptome analysis with RNA-seq bulk (RUO/CLIA) or single-cell (RUO)</li> <li>Whole AAV genome sequencing (short- and long-read technologies for AAV or lentivirus)</li> <li>Integration Site Analysis (RUO, CLIA)</li> </ul>	
Synthetic DNA Solutions	<ul> <li>Gene synthesis and viral production bundle (AAV packaging, lentivirus, baculovirus)</li> <li>AAV Gene Synthesis (fragments, cloned products)</li> <li>AAV Plasmid Preparation (RUO)</li> <li>CRISPR Synthetic DNA Solutions</li> </ul>	<ul> <li>AAV Gene Synthesis (fragments, cloned products; pre-clinical)</li> </ul>	
Sanger-based Sequencing	• AAV-ITR Sanger Sequencing (RUO)	• AAV-ITR Sanger Sequencing (RUO, GLP)	• AAV-ITR Sanger Sequencing (GLP)
Automated Storage and Cold Chain Products	<ul> <li>Labware and benchtop cold chain instruments</li> <li>Informatics and Data Management solutions</li> </ul>	<ul> <li>21-CFR-11 Data and reporting solutions</li> <li>Automated cryogenic storage and transport</li> <li>Cryopod and Filling station</li> </ul>	<ul> <li>21-CFR-11 Data and reporting solutions</li> <li>Automated cryogenic storage and transport</li> </ul>
Sample and Material Storage Solutions		<ul> <li>Master/Working cell banks, GMP raw materials, critical reagents, QC retains, reference materials, and finished therapeutics</li> <li>Clinical Trials Sample Management</li> </ul>	<ul> <li>Master cell banks, GMP raw materials and other critical reagents, QC retain sample programs</li> <li>Global storage and distribution partner for CGT-related drug materials and finished products</li> </ul>
Digital PCR (dPCR)	• Low-abundance target detection, viral titer, and vector copy number (RUO)	<ul> <li>Low-abundance target detection, viral titer, and vector copy number (CLIA)</li> </ul>	

#### **REDEFINE WHAT'S POSSIBLE**

## Discovery

The shortest route to a breakthrough is rarely a straight line. Azenta's technologies, innovations, and proprietary protocols give you an extra dimension of agility to sequence and confidently characterize your products.



#### TARGET DISCOVERY

Analyze disease samples to find mutations, then validate targets.Services include: RNA Sequencing, Mutation Analysis,Oligo Synthesis, Cell Line Engineering Confirmation, and Digital PCR (dPCR)



#### LEAD GENERATION & OPTIMIZATION

Identify and refine leads; test leads and delivery mechanisms for efficacy. **Services include:** RNA Sequencing, CRISPR Validation Services, gRNA Construct Synthesis, AAV-ITR Sanger Sequencing, Whole AAV Genome Sequencing, Synthetic DNA Solutions, and Viral Production Bundle (AAV Packaging, Lentivirus, Baculosvirus)

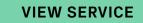


### **AAV Genomics Solutions**

Azenta has developed a suite of proprietary genomics protocols for working with the complexities of AAV.

#### AAV GENOMICS PROTOCOLS

As a global leader in genomics services, Azenta has developed unique AAV-ITR sequencing, AAV plasmid synthesis, and AAV plasmid preparation capabilities to support scientists in their *in vivo* gene therapy research. Azenta's groundbreaking AAV services also include sequence verification and correction of inverted terminal repeat (ITR) regions, which are crucial for rAAV packaging production, and digital PCR (dPCR) for viral titer.







AAV Genome Sequencing



AAV Plasmid

Preparation

AAV

Packaging





Digital PCR (dPCR)

### YOUR VISION IS NOW WITHIN REACH

## **Pre-Clinical & Clinical**

Azenta Life Sciences offers complete sample management and genomic safety testing solutions that enable improved study timelines with increased sample integrity and sample utilization. Our extensive experience in managing clinical trials spans all therapeutic areas, regardless of phase or size, within one global, interconnected platform. Our experts will work with you to customize our suite of services to fit your individual sample management needs.

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#### **VECTOR & CELL BANK CONFIRMATION**

Perform animal safety studies and verify the genetic stability of your master cell and virus banks.

**Services include:** GLP and RUO AAV-ITR Sanger Seqencing, Animal-free Plasmid Preparations, GLP Plasmid Sequencing Confirmation, and Digital PCR (dPCR).



#### CLINICAL TRIALS

Partner with Azenta for sample and critical reagent management for clinical trials. **Services include:** Clinical Trials Sample Management, Patient Safety Testing via CLIA-grade Sanger and NGS sequencing, Drug Products Storage & Logistics, and Integration Site Analysis (RUO, CLIA).



## **Clinical Trials Solutions**

Viral whole genome sequencing (short-read, long-read: RUO; for AAV or lentivirus)

#### CLINICAL TRIALS SOLUTIONS

Clinical Trials are a crucial step in cell and gene therapeutic development, with many logistical challenges. Azenta offers comprehensive solutions to minimize risk and improve sample quality for all clinical trial phases. Our global network of biorepositories and laboratories — in combination with industry-leading cold chain logistics and products — facilitate clinical studies around the world.



#### CLINICAL TRIALS SOLUTIONS





Clinical Trials SampleDrug Product & Critical ReagentManagementStorage & Distribution



Patient Genomic Safety Testing

EXCEED IMPOSSIBLE STANDARDS

# **Manufacturing & Distribution**

Support the integrity of your breakthrough cure from scale-up to scale-out to patient with the most advanced cold chain logistics, automated tools, onsite, offsite, and hybrid services.



#### LOGISTICS AND DISTRIBUTION SCALE-UP

Leverage modular, scalable automated cryogenic storage systems to seamlessly support manufacturing and distribution scale-up, with integrated data management and reporting plus full audit trail tracking. **Solutions Include:** BioStore Cryogenic Automated Storage System.

#### THERAPEUTICS MANAGEMENT

Automated Cryogenic Storage

Flexible pharmaceutical cold chain logistics and distribution solutions to safeguard the integrity and quality of your drug products, critical reagents, and raw materials, while meeting cGMP and regulatory requirements. Services include: Drug Products and Cell Therapies.









**Risk Mitigation** 

Process Control

Data & Reporting

LEARN MORE

materials to the system user.

Empower your team to transcend expectations at https://web.azenta.com/cell-and-gene-therapy

With 10 years and \$100M invested in R&D, Azenta Life Sciences is setting the new world

solution for cellular products and other materials requiring temperatures below glass transition (Tg). The patented cryogenic tank design can locate, lift, and deliver target

standard in cryopreservation. Our -190°C Cryogenic Freezer is the best-in-class automated

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