TriLink BioTechnologies
GMP Manufacturing

A CDMO with over 20 years of development and manufacturing experience, facilitating your clear path to the clinic.

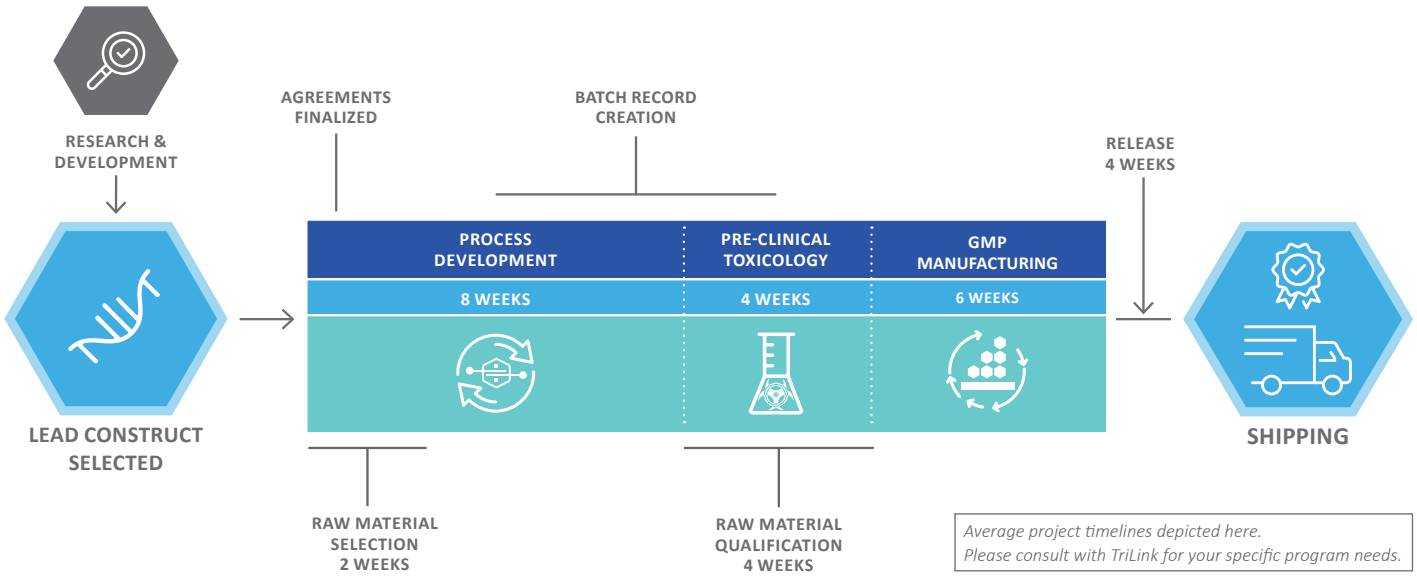
TriLink BIOTECHNOLOGIES
part of Maravai LifeSciences

A Clear Path to the Clinic

Your Manufacturing Partner from Discovery to GMP

TriLink BioTechnologies is an industry leader in modified nucleic acid chemistry, methods development, and manufacturing. With over 20 years of experience manufacturing custom molecules, the TriLink level of expertise in manufacturing complex modified oligos, mRNAs, and small molecules is unsurpassed. From research to clinical development, we are your trusted reagent supplier and technology partner.

TriLink provides a streamlined path for the clinical success of your therapeutic program.



Our process is seamless and efficient, and that is why our products are used in research, diagnostics, therapeutics, vaccines, and OEM applications all over the world. When you partner with TriLink as your trusted supplier, you maximize your budget and resources, while benefitting from our dedication to innovation and continuous improvement.

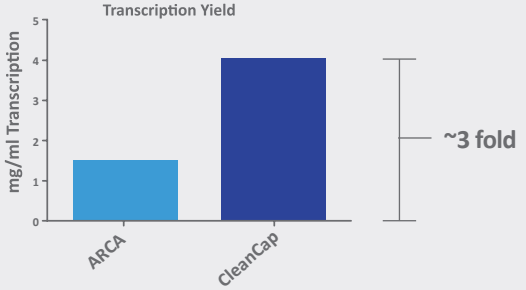
Extensive Range of Products

TriLink manufactures a broad range of custom therapeutic-grade materials, including end-to-end mRNA solutions and nucleic acids:

mRNA	CRISPR guide strands (sgRNA)	Nucleotides (NTPs)
CleanCap®	Long RNA	Nucleosides
Plasmid	Oligonucleotides	Small molecule custom chemistry
	Aptamers	

Manufacturing Feature: CleanCap®

CleanCap a is proprietary, co-transcriptional 5′ capping solution that can streamline mRNA manufacturing by reducing steps in the capping process. It achieves three times the yield of mRNA when compared to traditional methods. Integrating CleanCap technology early in your mRNA program is optimal for seamless scale-up, improved yields, and lower GMP costs.



A GMP Partner that Delivers

Steps to the clinic, shaped by experience

TriLink supplies quality and documentation tailored to your program needs. We understand the importance of time and cost-savings in your clinical path, and we are dedicated to providing streamlined project plans to create milestones and deliverables that pave the way for a successful IND filing.

Phase 1: Intake and Approval

STEP 1

PROPOSAL AND CONTRACT SIGNING

- Project requirements determined
- Review & approval of scope
- Establish timelines
- Proposal

STEP 2

PROJECT INITIATION

- Kick-off meeting
- Assign program manager
- Establish communication plan
- Assign start date

STEP 3

AGREEMENT AND DOCUMENTATION

- Master service agreement
- Quality agreement
- Statement of work
- Batch records

Phase 2: Production and Shipment

STEP 1

PRE-CLINICAL PRODUCTION

- Toxicology material
- Raw material qualification
- Analytical assay qualification

STEP 2

GMP PRODUCT

- Manufacturing
- QC testing
- Stability studies

STEP 3

QA BATCH RELEASE & DELIVERY

- Certificate of Analysis (CoA)
- Certificate of Origin (CoO)
- TSE/BSE statements
- Executed batch records
- Support of Chemistry Manufacturing and Control (CMC) Information
- Certificate of GMP Release (CoR)

Quality Matters

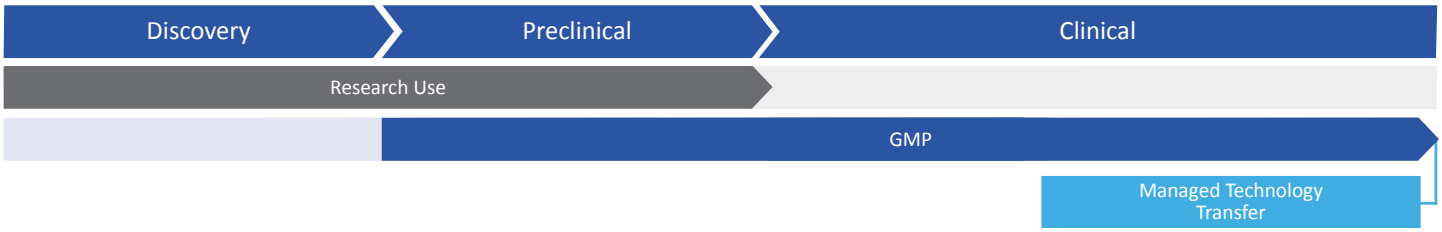
Current Good Manufacturing Practice (cGMP) refers to regulations of product quality and compliance detailed in the ICH Q7, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients (Section 19) and European Community, Part II, Basic Requirements for Active Substances Used as Starting Materials (Section 19). cGMP regulations help ensure that active pharmaceutical ingredients (APIs) meet the purported requirements for identity, strength, quality, and purity. These regulations provide guidance about good manufacturing practices for APIs under a system for managing quality and operations. Our stringent quality systems and a dedicated team of quality experts ensure the highest level of consistency, purity, and comprehensive documentation.

As a trusted GMP product supplier, we adhere to the following:

- Documented processes and impurity profiles
- Qualified test methods
- Stability testing
- Quality Assurance (QA)
- Quality Control (QC)
- cGMP training for all employees
- Packaging, handling, storage, and distribution, and a rapid response system to enable product recalls when necessary
- Traceability of raw materials
- Yearly internal and external quality audits
- Product sample retention system
- Calibrated instrumentation with maintenance logs for critical quality parameters
- Comprehensive documentation

A Customized and Flexible Program

The appropriate manufacturing grade for your development pipeline.



		Research	GMP
Compliance	ISO 9001:2015	✓	✓
	ICH Q7: Section 19		✓
Quality Control	Characterization Testing	✓	✓
	Qualified Testing Methods		✓
	Out-of-Specification Investigation		✓
	Customized Part Number with Customized Final Specifications		✓
Certificates	Certificate of Analysis	✓	✓
	Certificate of Origin		✓
	Certificate of Release		✓
Batch Record	Traceable	✓	✓
	Custom		✓
	QA Review and Release	✓	✓
	Batch Record Transfer to Client		✓
Raw Materials	Traceable	✓	✓
	Inspection and Release by CoA (Risk-Based QC Testing)	✓	✓
	Identity Testing		✓
	RM CoAs Transferred to Client		✓
Environment	Temperature and Humidity Controls	✓	✓
	ISO Class 7 or 8 Clean Room		✓
	Environmental Monitoring and Alarm		✓
	ISO Class 5 Fill		✓
	Dedicated Laboratory Suite During Manufacturing		✓

Products are to be used in accordance with all labeling provided by TriLink included but not limited to: **Research**: For research only, not for use in diagnostic or therapeutic procedures. Not for use in humans. **GMP**: cGMP compliance for clinical investigational use only.

State-of-the-Art Facility

TriLink headquarters is located in the vibrant biotech hub of Sorrento Valley in greater San Diego, and includes a cGMP facility with cutting-edge capabilities to meet your needs. Virtual and onsite site tours are available for audit ease and accessibility.

TriLink operates cGMP laboratories with an environment that includes:

- ISO Class 7 and ISO Class 8 engineered GMP customer suites. Class 5 finish/fill hoods.
- ISO 9001:2015 certification
- Comprehensive Quality programs and Quality systems for document control
- Compliance with ICH Q7, section 19
- Analytical and functional support laboratories to support product testing
- A single-pass, HEPA-filtered air system
- Routine monitoring of temperature, pressure, humidity, and particle count

121,000
square feet
and growing

cGMP
manufacturing
since 2016,
with **over**
100 program runs

Managing Scale-Up

We successfully manage the scale-up of research projects through early clinical needs. Our custom pilot manufacturing facility and team of technical experts guide the successful scale-up and development of methods.

Unparalleled Expertise, Extensive Range

TriLink manufacturing is guided by experience in synthetic organic chemistry and pioneering knowledge in mRNA. This understanding enables us to continually respond to customer needs and provide innovative solutions. Our technical expertise spans experimental design, chemistry, processing, and manufacturing of modified nucleic acids with a remarkably high success rate in synthesizing complex compounds. Our global reputation precedes us – our technical understanding, on-time product delivery and adherence to your program timelines make us an ideal partner to help you achieve your clinical goals and improving overall speed to market.

Get in Touch

Speak with our team today to learn more about how TriLink can support your program. Our technical experts are available to guide your team at every step of the way. Engage with us early on to streamline your clinical and commercial timelines.

Working with TriLink early on in your program enables us to strategically optimize your project for future scale-up and quality requirements, enabling our expert team to seamlessly guide your therapeutic discovery into clinical programs. We are here to help you meet your program goals and timelines. For more information visit us online at **trilinkbiotech.com/gmp**

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