



REFERENCE GUIDE

Plasmid production services for mRNA manufacturing




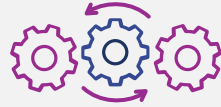

Streamline your start

Seamlessly integrate phase-appropriate, high-quality plasmid DNA templates into the mRNA manufacturing process


Streamline your start

Plasmid DNA, used as an in vitro transcription template, is a critical starting material for mRNA manufacturing programs. Partnering with a single CDMO for plasmid DNA template and mRNA production can help you shorten timelines and simplify your supply chain. Our plasmid production process and release testing procedures are optimized to ensure the quality attributes necessary for downstream mRNA manufacturing. Our comprehensive quality assurance process demonstrates commitment to quality and compliance.

Leverage TriLink's plasmid DNA-to-mRNA pathway to access:

		
Phase-appropriate, high-quality plasmid	Streamlined process and timelines	Expert support for each project
Obtain the preferred DNA template for in vitro transcription with a phase-appropriate plasmid suitable for GMP mRNA manufacturing	Using a single partner for plasmid and mRNA production increases process efficiency and decreases lead time.	A dedicated team of plasmid and mRNA production experts will be assigned to your project.


TriLink's high-quality plasmid production service is an integral part of our overall mRNA manufacturing capabilities. Our plasmid production process has been specifically designed and optimized to support clinical mRNA therapeutic and vaccine programs.



Discovery mRNA (RUO) manufacturing
µg to g scale



High-quality plasmid DNA template



GMP mRNA manufacturing
gram to 100-gram scale

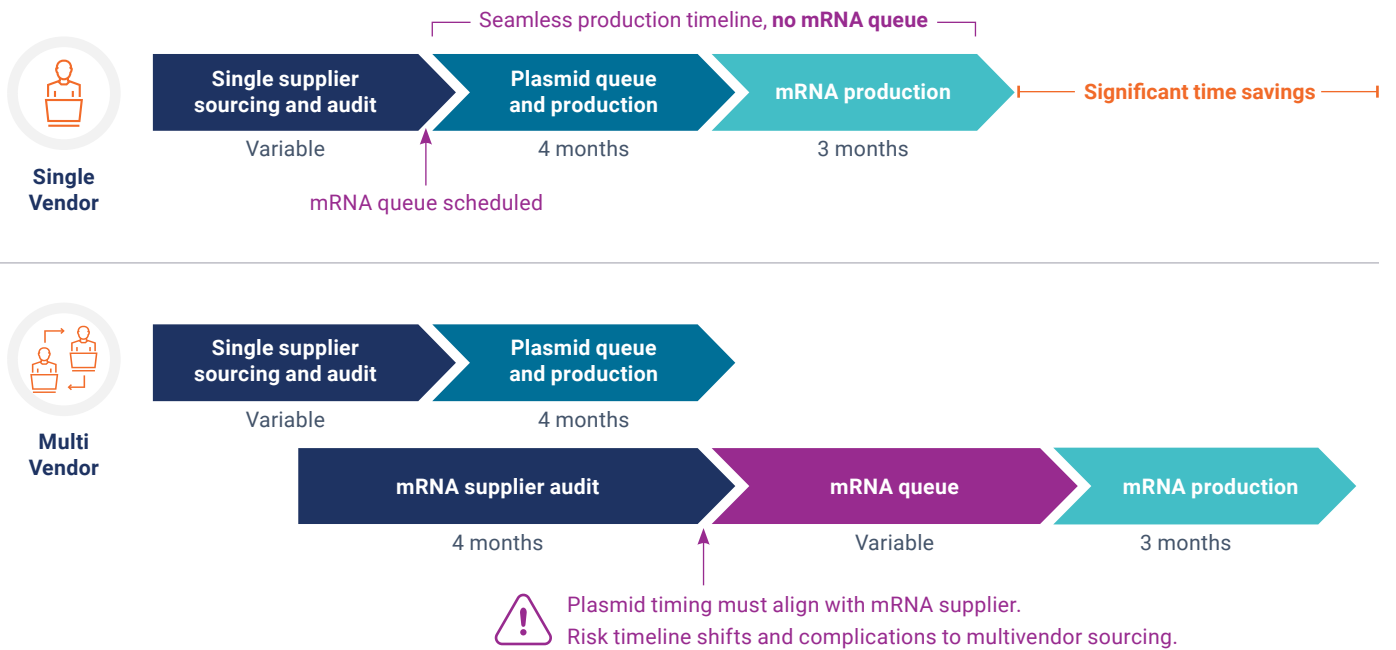
Process development

Analytical services

Consultive and logistical support

Accelerate timelines with our plasmid DNA-to-mRNA pathway

Working with multiple manufacturing partners complicates your supply chain and creates unnecessary roadblocks in coordinating priority, timelines, and quality standards. Our streamlined production process from plasmid DNA through final release testing of mRNA means convenience and time savings for your mRNA manufacturing program. A single partner for plasmid production through in vitro transcription of mRNA can also decrease logistical and regulatory risks with shipping materials.



State-of-the-art facilities

The TriLink headquarters are in the vibrant biotech hub of Sorrento Valley in greater San Diego. Our project management, process development, analytical services, and manufacturing teams are co-located on-site to help streamline plasmid and mRNA production projects from start to finish.

Our plasmid manufacturing suites utilize automated platforms from fermentation through purification.

- ISO 8 cleanrooms
- Single-use systems minimize risk
- ISO Class 6 fill/finish

Scalable production capabilities

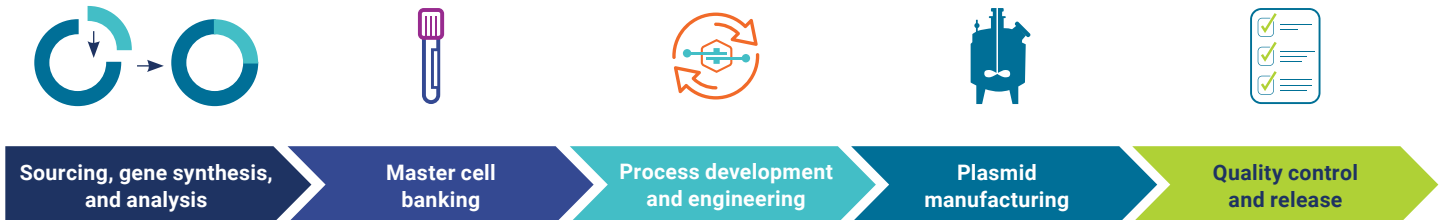
Our plasmid production suites support custom manufacturing with comprehensive quality systems and risk management approaches to deliver high-quality results consistently and predictably. The fermenter capacity and scale are customizable and tailored to each program.



Plasmid production process optimized for mRNA applications

TriLink leverages our process development expertise to optimize plasmid production to create high-quality DNA templates for in vitro transcription.

A team of plasmid and mRNA production experts, including program management, process development, analytical services, quality, and manufacturing, will be assigned to your program. The program manager will provide streamlined project plans with customized milestones and deliverables. An overview of the plasmid production process is summarized below.



TriLink managed production processes, documentation, and manufacturing environment to support plasmid production are summarized in the list below.

Production	<ul style="list-style-type: none"> Gene synthesis Glycerol stock generation Screening for optimal growth conditions E. Coli cell bank generation 	<ul style="list-style-type: none"> Plasmid process development and engineering runs Consistent/platform manufacturing High density fermentation Alkaline lysis Chromatographic purification
Documentation	<ul style="list-style-type: none"> Characterization testing Qualified testing methods 	<ul style="list-style-type: none"> Out-of-specification investigation Customized part number with customized final specifications
Manufacturing environment	<ul style="list-style-type: none"> ISO classified manufacturing suite 	<ul style="list-style-type: none"> ISO classified fill QA oversight and release

Analytical testing and quality control (QC) assays

With more than 20 years of expertise in developing, qualifying, and validating analytical methods, TriLink offers comprehensive and customizable method development and analytical testing solutions to support our plasmid manufacturing services. Our in-house analytical experts perform most of the tests at the facility where the plasmid manufacturing suites are located.

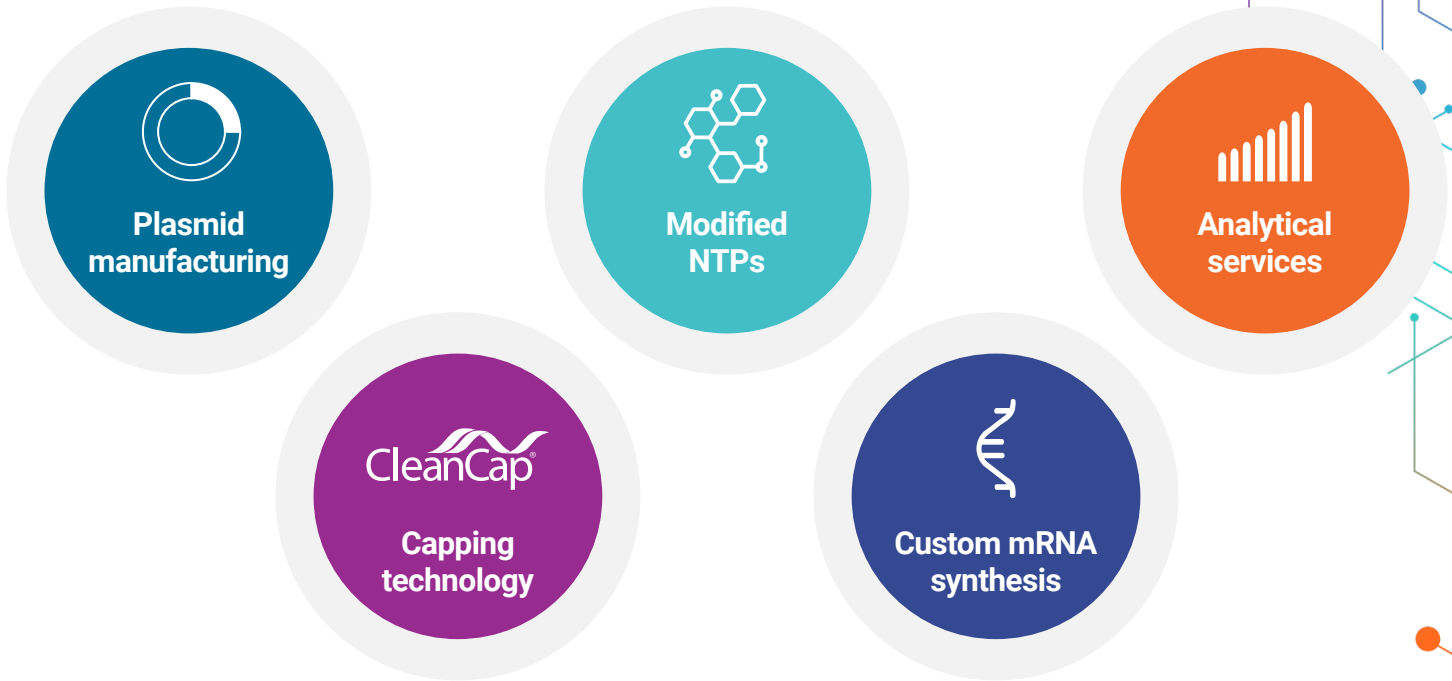
Table Available analytical testing and quality control (QC) assays to support plasmid manufacturing

Attribute	Concentration	Purity	Identification	Safety	Residual impurities	Others or general methods
Method	UV spectroscopy	UV 260/280 % Supercoiled Plasmid isoforms by HPLC - % Total circular, % Supercoiled	Sanger sequencing* NextGen sequencing* Restriction digest pattern	Endotoxin Bioburden*	Residual host cell protein Residual host cell RNA Residual host cell gDNA Residual kanamycin	Appearance pH Conductivity

*Test conducted by outsourced partner

Comprehensive mRNA manufacturing service solution

The TriLink Plasmid DNA-to-mRNA pathway is guided by pioneering knowledge in mRNA, >25 years of experience in process development and scalability, and proven performance as a best-in-class manufacturing partner. This understanding enables us to rapidly respond to customer needs and provide innovative solutions.



Our team is here to discuss your manufacturing needs

To learn more about our plasmid production capabilities and determine if we would be the right partner for your program, contact us by phone or email. One of our business development managers will contact you for a consultation to discuss your project, expectations, and timelines.

Visit our website to learn more at trilinkbiotech.com/plasmid



ISO 9001:2015 certified manufacturing facilities

Contact us at **800.863.6801** or sales@trilinkbiotech.com to speak with an expert regarding our plasmid and mRNA manufacturing services.

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