

Total Solution for mRNA Medicines

G:On RNA

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Contact US 107 Ihyeon-ro 30-beongil, Giheung-gu, Yongin-si, Gyeonggi-do, Korea / www.gcbiopharma.com

CDO winsomey@gccrop.com / +82-31-260-9340

CMO joohyun.jo@gccorp.com / +82-43-906-1940



TOTAL SOLUTION for mRNA Medicines

GCBP

GCBP offers a full range of services for mRNAs based on its experience in developing a wide range of pharmaceutical products, including vaccines and therapeutics.

In the research field, we provide mRNA/LNP design, cell banking, manufacturing process development, GMP production, analytical methods, and quality systems, which can be extended to the licensing and clinical fields through research collaboration.

In terms of services, we are able to collaborate throughout the entire research process, not just with CDMOs, and we will work with our costumers through proactive problem solving and various suggestions rather than simply providing services.

Based on this, GCBP will become the best partner to provide total solutions for mRNA-based drug development.

SERVICE AREA overview

Scope	Capacity	
mRNA construct design	pDNA	LNP
pDNA/mRNA manufacturing	<i>E. coli</i> ~ 20 L Fermentation	~8 g scale [single batch] (plan up to 50 g)
LNP formulation	mRNA	DP fill & finish
DP formulation/Fill&Finish	~ 1 L IVT scale [single-use] (plan up to 10 L)	5 L-1,000 L
Quality system		
Site	Type	
R&D Center[Yongin]	CRO, CDO, CMO Collaboration	
Pilot plant (GMP)[Hwasun]		



The one and only GCBP Technology

Through our mRNA platform technology research, we have secured GCBP's proprietary UTR sequence and artificial intelligence-based codon optimization software. We have also secured GCBP's LNPs for vaccines and therapeutics that can target specific organs.



We deliver quality at scale and on time

GCBP provides optimal solutions based on process development know-how such as cell culture, purification, and formulation acquired through various projects. Our facilities range from research scale to manufacturing scale for clinical trials, enabling rapid response and development.



Beyond CDMO, as your partner

More than just a CMO service, we provide process development services optimized for your products and proactively respond to issues. We can also collaborate with you based on your needs.



One stop solution for all analytical test

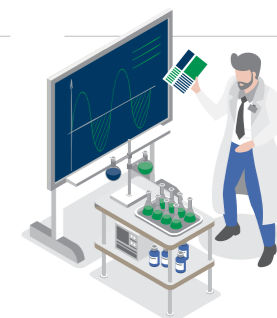
GCBP has expertise in a variety of pharmaceutical analytical methods and experience with domestic and international INDs and NDAs, enabling us to proactively prepare for regulatory requests.

GC Biopharma SERVICE AREA

mRNA CONSTRUCT DESIGN

GCBP's superior and unique mRNA design technology

- Proprietary UTR sequence
- AI-based codon optimization software



pDNA/mRNA MANUFACTURING

One-stop process (Lab-to-Production, CDMO)

- CDMO: Sequence to pilot scale Production in 84 days
- Pilot plant GMP facility: up to 1 liter IVT (1 kg mRNA/year)[Scalable to 10 liter IVT]
- Major equipment: BioFlo® 320 / ÄKTA Ready™



LNP FORMULATION

Proprietary LNP delivery technology for vaccine and therapeutics

- Portfolio of proprietary ionizable lipids by GCBP
- LNP component/composition optimization
- Process development and multigram scale production (GMP facility)
- Major equipment: IJM SingleCore NanoProducer



DP FORMULATION FILL AND FINISH

High-throughput formulation and High-quality aseptic fill & finish

- High-throughput molecule characterization and construct screening
- Fill & Finish in clinical and commercial scales (5 L – 1,000 L)
(vial/PFS, Liquid/Freeze/Lyophilized)



QUALITY SYSTEM

One stop solution for all customer's analytical testing needs

- Analytical method development and characterization
- Qualification and validation of QC methods
- Stability test for pre-clinical/clinical study

