

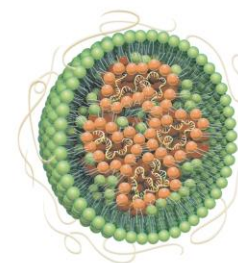
Introduction of CDMO services and platforms for mRNA, LNP

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7 May 2026



Partners for *Life*

FUJIFILM
Value from Innovation

Outline

1. Overview of our mRNA-LNP CDMO services
2. Platforms for mRNA preparation
3. Platforms for LNP formulation

Business Field of FUJIFILM Group

Imaging

- Consumer Imaging
- Professional Imaging



¥ 542.0B 17.0%

¥ 328.0B 61%

¥ 214.0B 39%

Healthcare

- Medical Systems
- Bio CDMO
- LS Solutions



¥ 1,022.6B 32.0%

¥ 693.2B 68%

¥ 219.5B 21%

¥ 109.8B 11%

Business Innovation

- Business Solutions
- Office Solutions
- Graphic Communications



¥ 1,198.5B 37.5%

¥ 330.9B 26%

¥ 522.9B 44%

¥ 344.7B 28%

Electronics

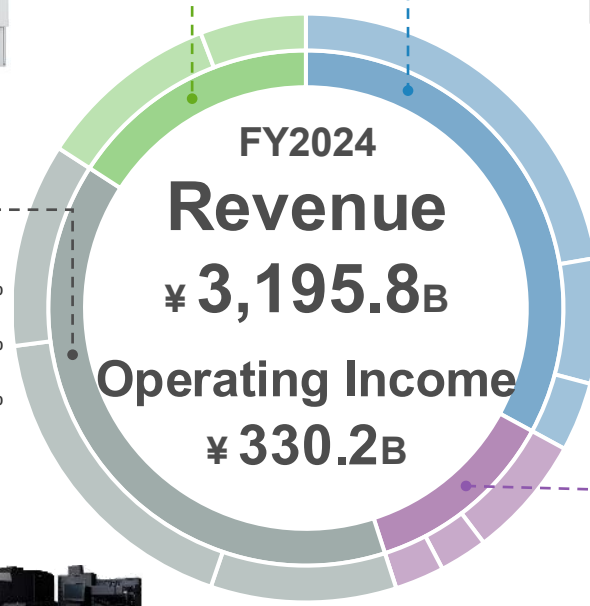
- Semiconductor Materials
- AF Materials
(Advanced Functional Materials)



¥ 432.8B 13.5%

¥ 250.4B 58%

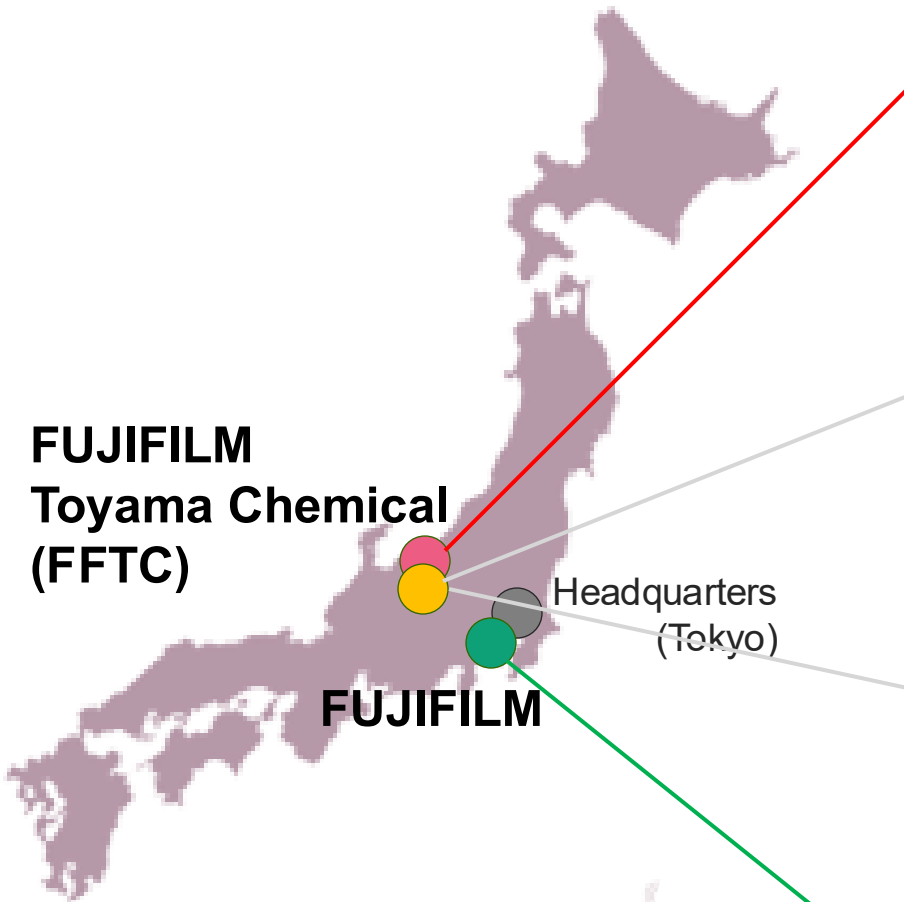
¥ 182.4B 42%



FUJIFILM Group Bio CDMO Network

		North America					Europe		Asia
		CA	TX	WI	NC (RTP)	NC (Holly Springs)	UK	Denmark	Japan
MCC	Large (20kL)					●		●	
	Small & Middle (2k, 5kL)		●		●		●		●
Microbial, DS					●		●		
CGT		●	●	●			●		
ADC									●
mRNA/LNP									●
Fill Finish		●	●			●		●	●
Packaging						●		●	●

Our facilities and functions related to mRNA-LNPs CDMO service



**FUJIFILM
Toyama Chemical
(FFTC)**

FUJIFILM

Headquarters
(Tokyo)



FFTC(Hasumachi-site), 2nd Factory

GMP manufacturing

701F : LNP, liposome, ADC, Fill&Finish

702F : mRNA, QC-Lab

705F : mRNA, LNP, Fill&Finish for commercial
(under construction)



FFTC(Shimookui-site), C-TEC1

GMP manufacturing for early phase CTM

LNP, Fill&Finish 120vials/hr

Start operation in 2026



FFTC(Shimookui-site), T-Lab

R&D for CDMO services

Formulation optimization

Process development

Analytical development



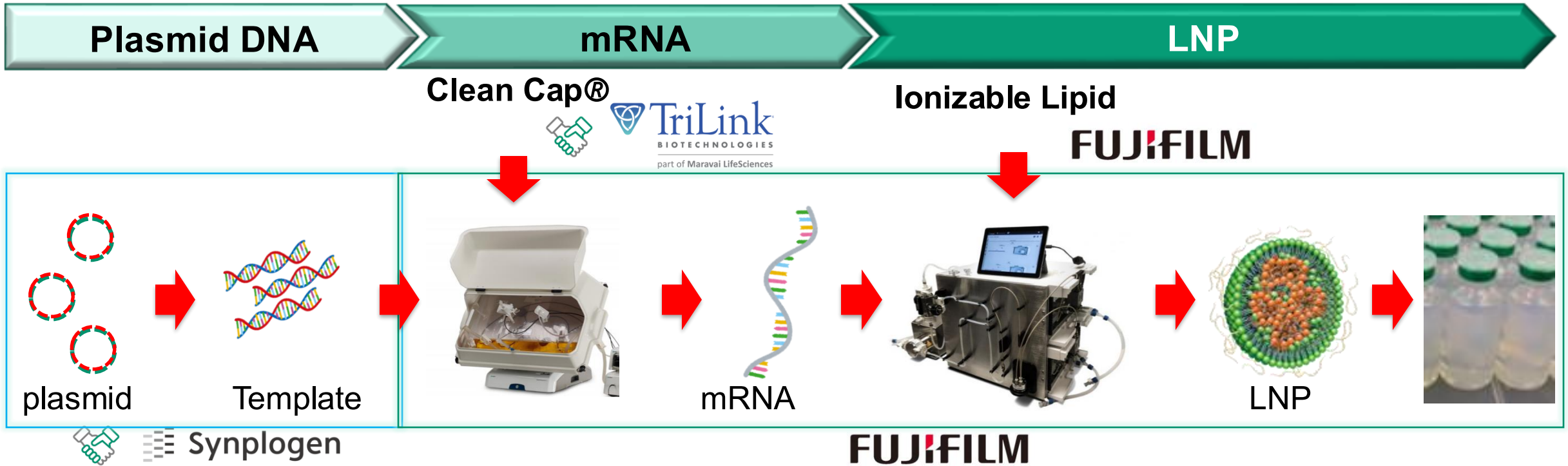
FUJIFILM(Kaisei-site), BSEL

Corporate R&D

Ionizable Lipids

Ready-to-Use LNPs for ex-vivo transfection

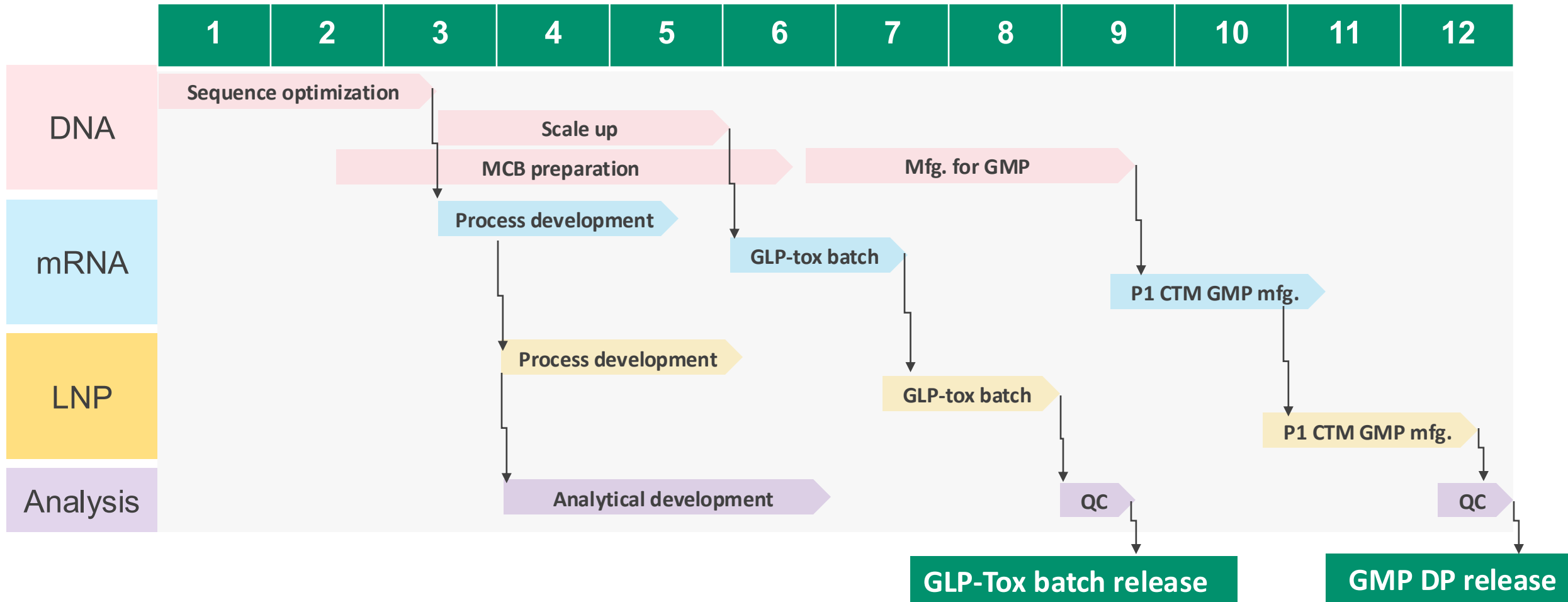
Our mRNA-LNP end-to-end CDMO service



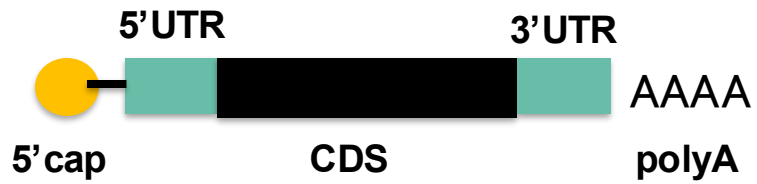
- **For customers at research phase**
 - Optimizing mRNAs and LNPs formulation and manufacturing prototypes
- **For customers at development phase**
 - Developing process and analytical methods
 - Scale-up and GMP manufacturing mRNA-LNPs

Integrated manufacturing from mRNA sequence design to LNP formulation

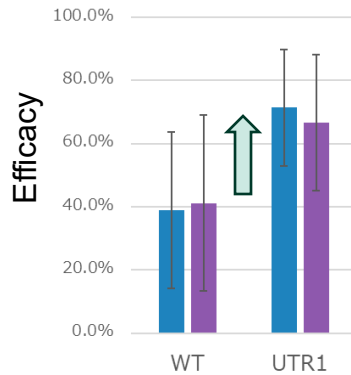
- Collaboration with partner companies for mRNA sequence design to template DNA manufacturing
- Acceleration achieved by performing all processes in-house: from mRNA process development to LNP investigational drug manufacturing, including analytical development



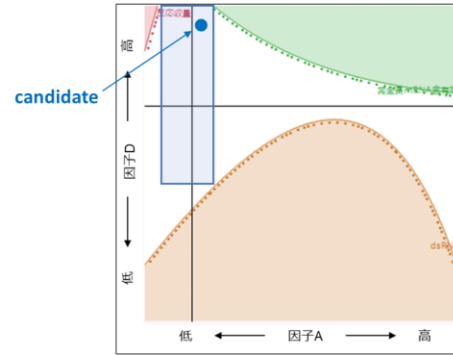
mRNA platform technologies for CDMO services



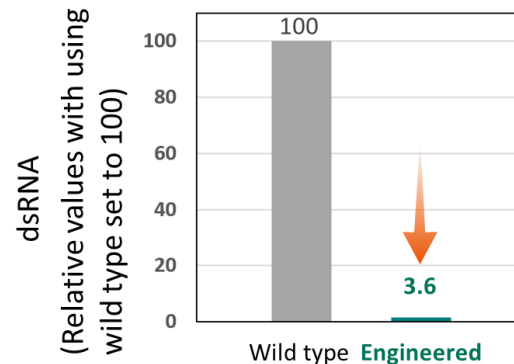
- **Clean Cap technology**
Licensed from TriLink



- **UTR optimization**
By Synplogen



- **Process optimization by DoE**



- **Process for dsRNA reduction**



- **Seamless scale-up**



- **Dedicated facility**

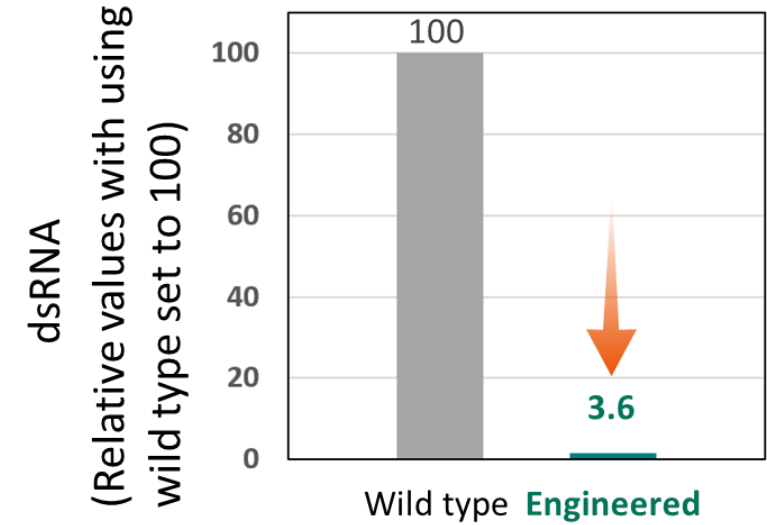
Provide high-quality mRNA by our platform technologies

Development of mRNA manufacturing technology for at dsRNA reduction

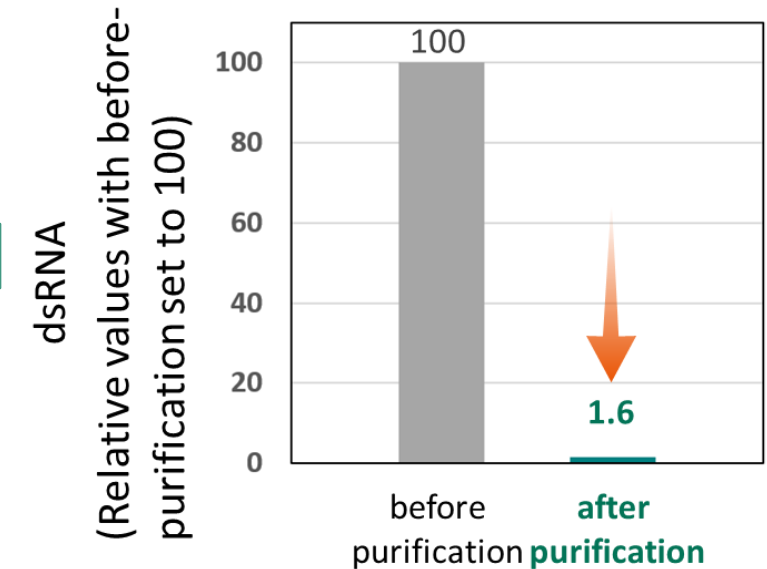
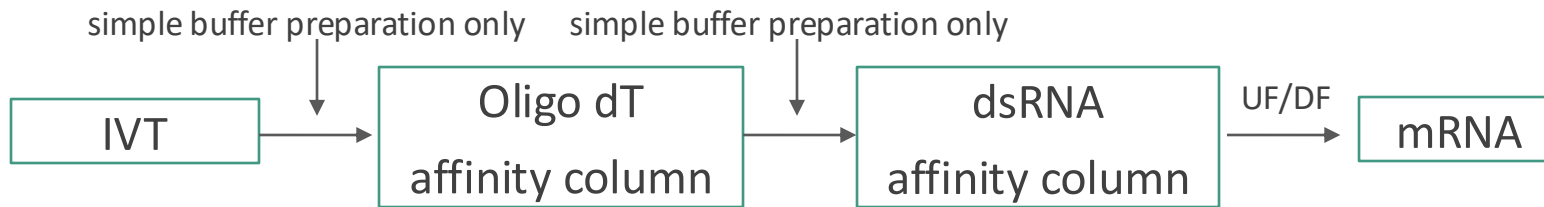
Suppression of dsRNA generation using engineered T7 RNA polymerase



- Engineered T7 RNA polymerase was made by Japanese company



dsRNA removal by column purification



- These technologies have been implemented in our laboratory.
- We have a proven track record of manufacturing mRNA. (2g scale, dsRNA <0.02%)

Analytical Development










✔ Standard

✔ As necessary

Test item	Test method	R&D	GLP-Tox	GMP
Appearance	Visual inspect	✔	✔	✔
Identification (RNA sequence)	RT-PCR / Sanger / LC-MS	✔	✔	✔
Identification (RNA length)	AGE / CE	✔	✔	✔
Identification (poly A length)	PAGE / LC-MS	✔	✔	✔
pH	pH meter	✔	✔	✔
Purity (A260/A280 ratio)	UV spectrum	✔	✔	✔
Purity (capping efficiency)	LC-UV / LC-MS	✔	✔	✔
Purity (mRNA intactness)	CE	✔	✔	✔
Purity (residual protein)	Micro-BCA [total protein] / ELISA [T7 polymerase]	✔	✔	✔
Purity (residual plasmid DNA)	qPCR	✔	✔	✔
Purity (residual NTPs and capping agent)	LC-UV	✔	✔	✔
Purity (dsRNA)	Dot blot / ELISA assay	✔	✔	✔
Assay (mRNA)	UV Absorbance	✔	✔	✔
Endotoxin	Gel / Photometric	✔	✔	✔
Bioburden	Culture method	✔	✔	✔

Conduct quality testing appropriate for each stage of development, including GLP-compliant and GMP-compliant testing

Manufacturing equipment for mRNA

	IVT Reactor	Purification	UF/DF
T-Lab in operation < 1g scale	wonder shaker Wave25 	explorer 10S avant 150 	KrosFlo KR2i 
702F* in operation < 3g scale < 50g scale	Wave25 	AKTA Ready 450 AKTA Ready gradient 	KrosFlo KR2i KrosFlo KMPi 
705F* under planning < 50g scale	Wave25 	AKTA Ready gradient 2 units 	AKTA Readyflux 2units 

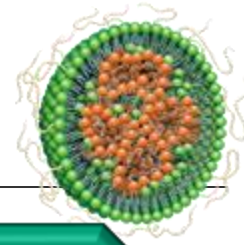
*GMP Facility

Track record : mRNA manufacturing at GMP Facility (ROA)

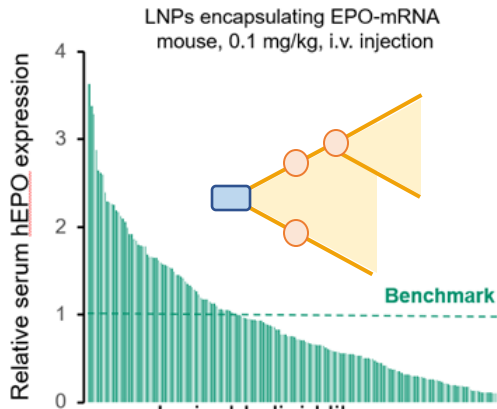
mRNA (4,200 nt), IVT scale = 300 mL

Test items	Acceptance criteria	Results
Appearance	Clear, colorless solution	Clear, colorless solution
pH	5.9~6.9	6.1
Identity	Confirm the band of RT-PCR product around 4000 bp	Confirm the band of RT-PCR product around 4000 bp
Integrity	Report results	83.8%
Purity 5' capping efficiency	Report results	99.4%
Purity 3' poly(A) tail length	Report results	Confirm the band of poly(A) tail around 30 bp and 70 bp
Purity dsRNA	Report results	NMT 0.3%
Purity Residual DNA template	Report results	0.00002%
Purity Residual protein	Report results	NMT 1.7%
Content	0.90~1.10 mg/mL	0.93 mg/mL

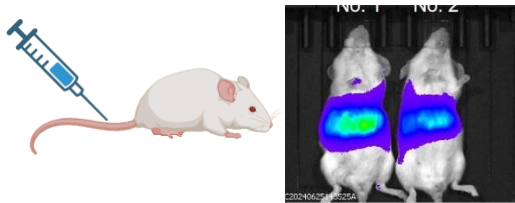
LNP platform technologies for CDMO services



Research



- Formulation by FUJIFILM's ionizable lipid



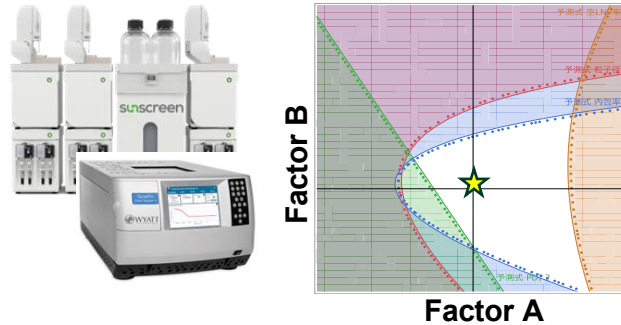
- Biological Assay



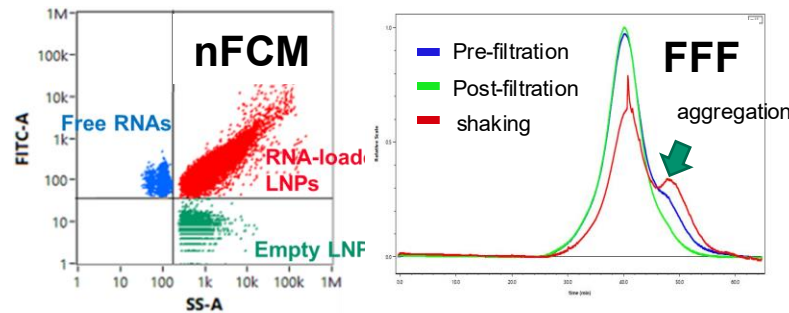
Provide cutting-edge LNP formulation and evaluation technologies

Development

Evaluation system



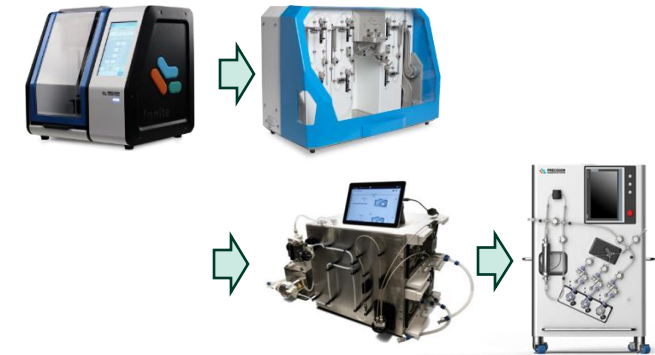
- Formulation and process Optimization by HTS & DoE



- Precise particle Characterization

Manufacturing

Track records on GMP Mfg.

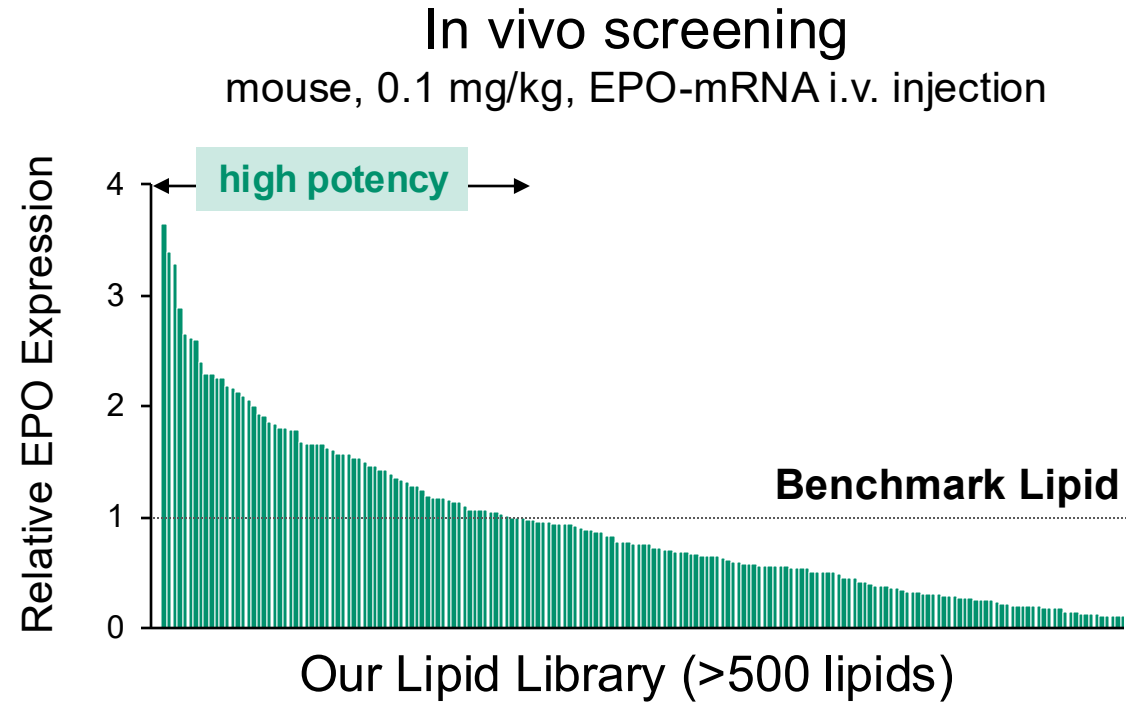
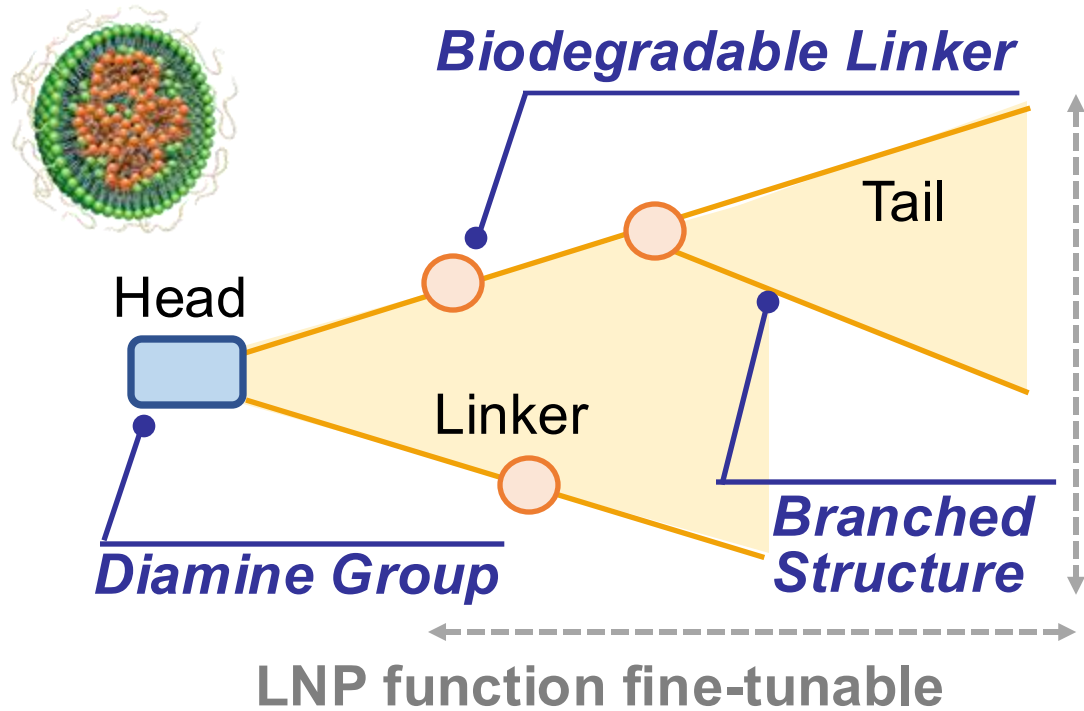


- Seamless scale-up



- Dedicated facility

FUJIFILM Ionizable Lipids | Design concept and list









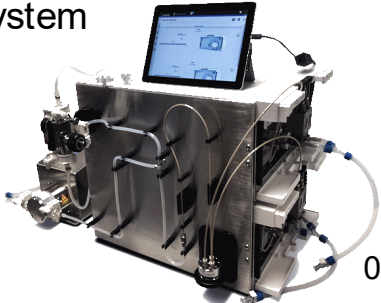
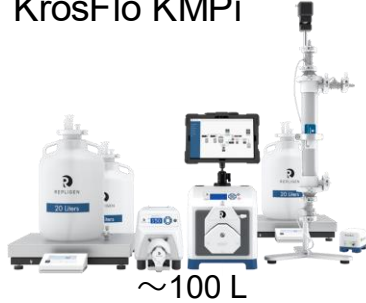





In vivo mRNA-LNP therapy

i.m.(vaccine) FL-0445 GMP	i.v. liver FL-1245T FL-1207T FL-0207T	extra-hepatic FL-1779T
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Ex vivo T cell CAR knock-in

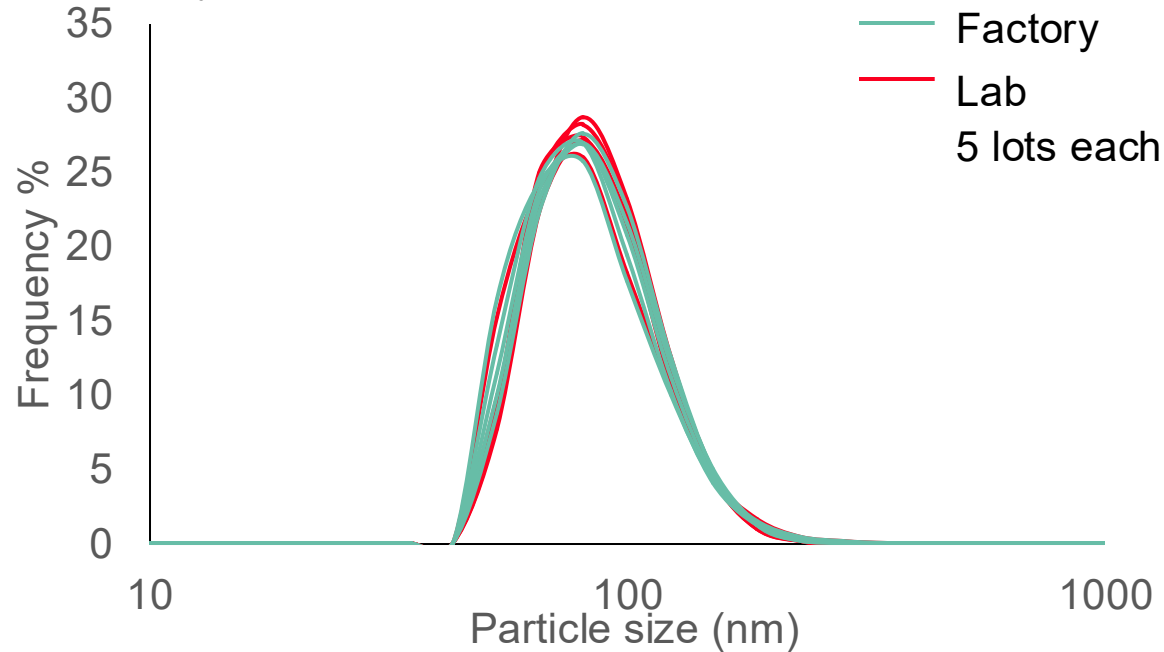
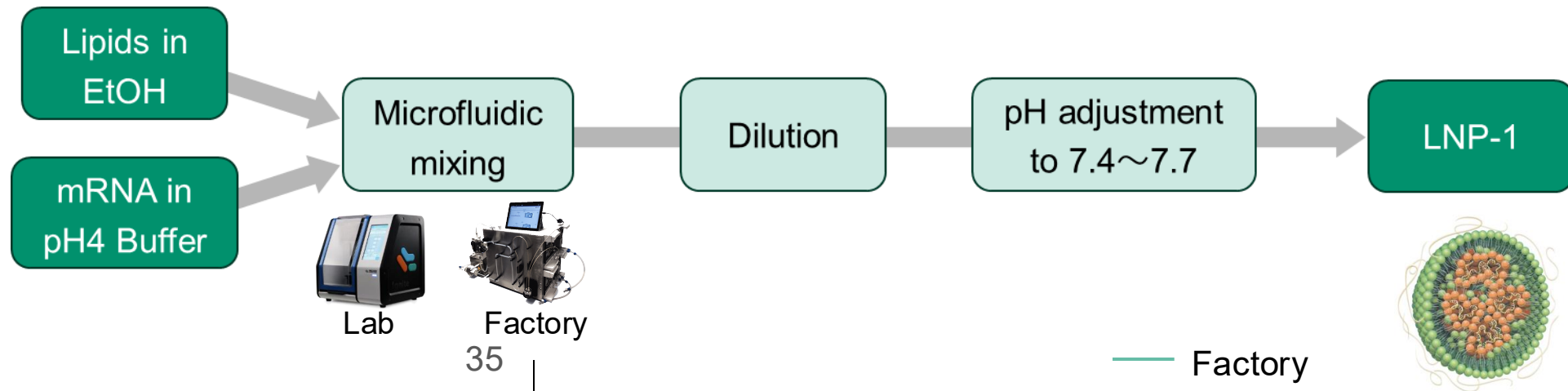
RNA delivery FL-1625T	DNA delivery FL-1779T
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Manufacturing equipment for LNPs

	LNP forming	UF / DF	Filling
T-Lab (in operation) C-TEC1* (2026-)	Ignite+ Blaze+ CFS@C-TEC1    1~60 mL 0.01~10 L ~400 L	KrosFlo KR2i KrosFlo KMPi   0.01~20 L ~100 L	3P Innovation  2~20R、120 vials / hr
701F* (in operation)	GMP System  0.2~100 L	KrosFlo KMPi KrosFlo KTF1600   ~100 L ~5000 L	Shibuya  2~20R、3,000 vials / hr
705F* (2027-)	CFS  ~400 L	ÄKTA readyflux XL 	SYNTEGON  2~20R、18,000 vials / hr

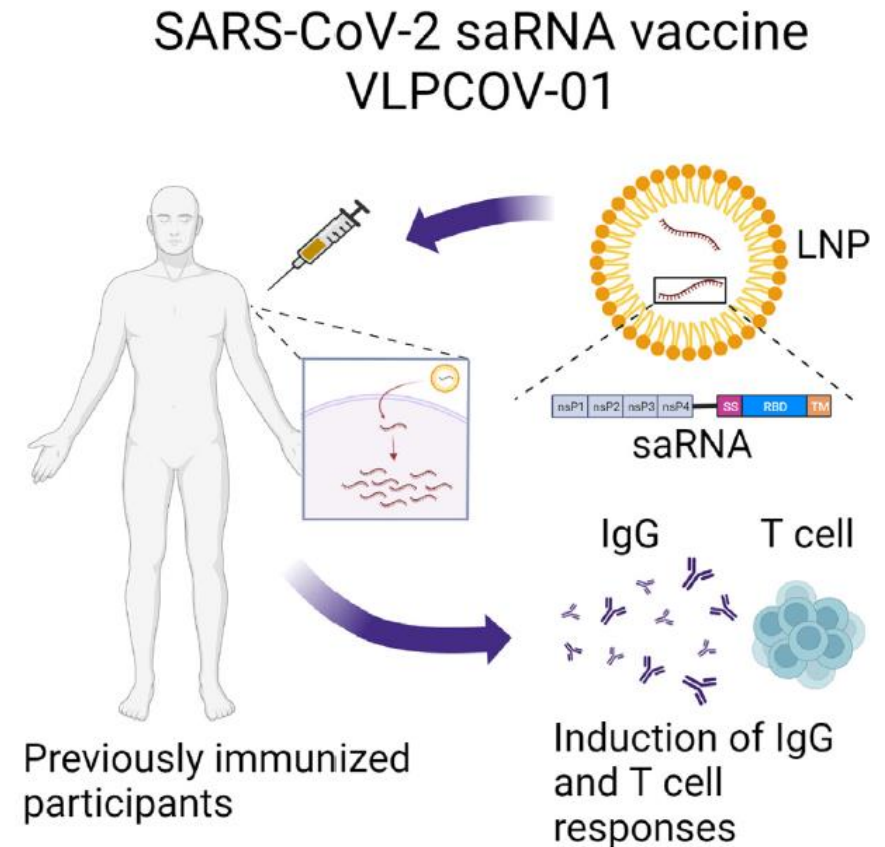
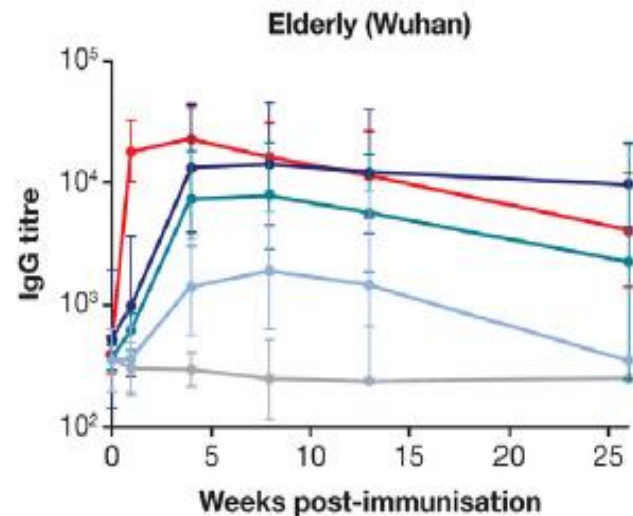
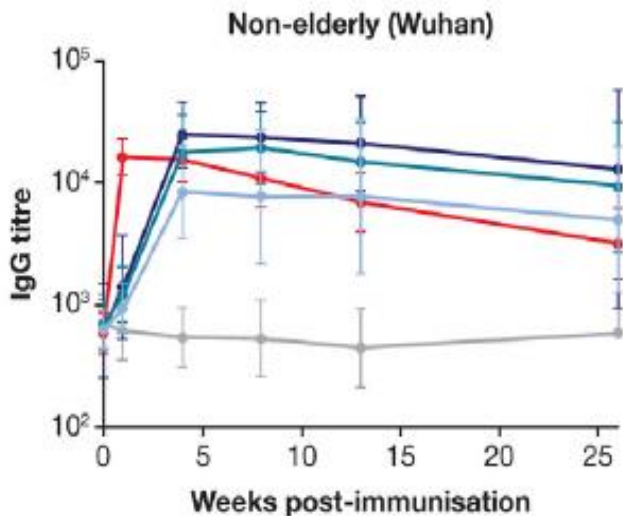
*GMP Facility

Track record : LNPs manufacturing and reproducibility



➤ **High reproducibility of manufacturing from the laboratory to the factory was achieved.**

Safety and immunogenicity of SARS-CoV-2 self-amplifying RNA vaccine expressing an anchored RBD: A randomized, observer-blind phase 1 study



Cell Reports Medicine 4, 101134, 2023

- We completed process development and GMP manufacturing of our LNPs.
- Our LNPs demonstrated IgG titer comparable to FDA-approved mRNA vaccine when combined with saRNA.

Our Experience and track records on mRNA-LNPs

Track Records

100+



Contracted R&D Programs

30+



Lots of GMP mfg. (Lipid based nanoparticles)

10+



Research papers evaluating our LNPs

5000+



Doses in clinical trials (LNPs)

Expertise

15+



Years experience on LNP formulation and analysis

90



Years experience on Pharmaceutical products

FUJIFILM
Value from Innovation