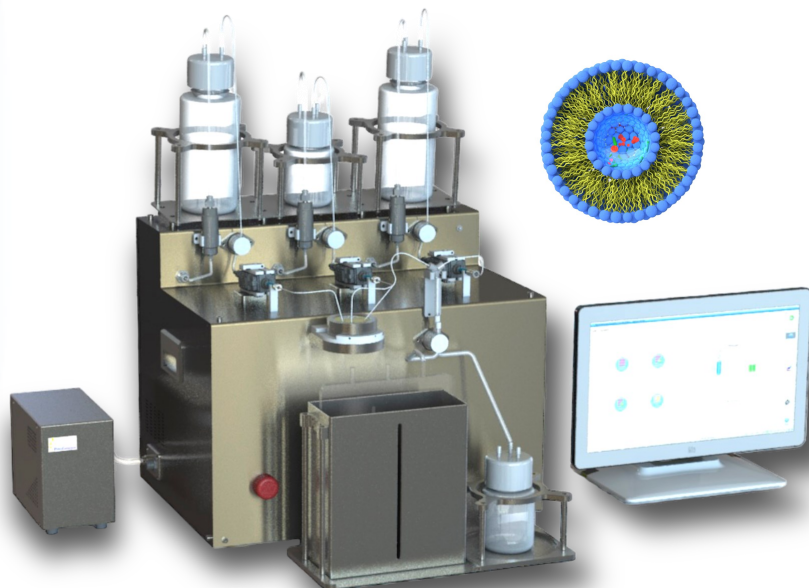
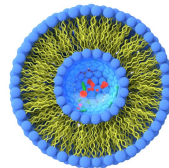
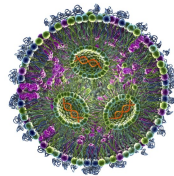
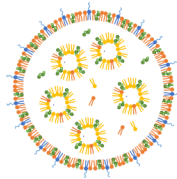


NanoGenerator[®] GMP System

Advanced Microfluidic Technology
for Clinical and Commercial
Nanoparticle Production



NanoGenerator[®] Max Nanoparticle Synthesis System



The NanoGenerator[®] platform ensures consistent critical quality attributes (CQAs) throughout the entire development and manufacturing process. With PreciGenome's microfluidic technology, customers can seamlessly transfer early discovery results (NanoGenerator[®] Flex, Pro) to the late stage production (NanoGenerator[®] Max).

The NanoGenerator[®] Max RUO version can be used for preclinical applications of LNP synthesis, while the NanoGenerator[®] Max GMP version is designed for clinical and commercial production.

System Benefits

High Performance & Efficiency



- Tunable size (40-200nm)
- Low PDI
- High encapsulation efficiency

Regulatory Compliant



- Intuitive software (21 CFR Part 11 compliant)
- Single-use flow kit
- Certificates & reports

Scalable & Reproducible



- Scale-up and minimum process development
- Direct transfer from clinical development to commercial manufacturing
- Reproducible manufacturing

Automation & QC



- Automated workflow
- Real-time flow rate monitoring & recording
- Electronic batch records

Cost Effective



- Affordable system
- Low cost consumables

Custom Design & Service



- On-site 3Q installation & qualification
- Custom design & OEM

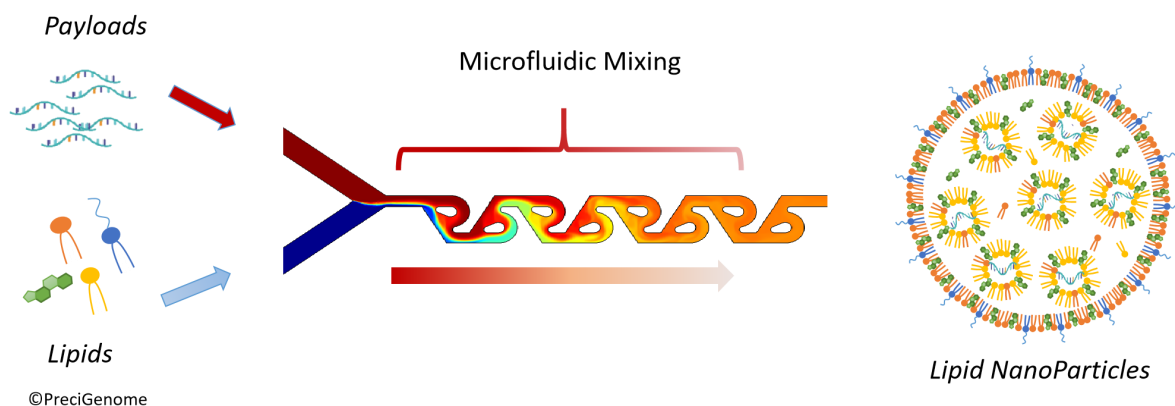
Advanced Microfluidic and Flow Control Technology

Nanoparticle synthesis via microfluidic mixing has superior control of size, homogeneity, and repeatability to conventional batch synthesis methods. Two streams, aqueous and solvent, meet in a narrow mixing channel, forming nanoparticles with payload encapsulated.

PreciGenome's NanoGenerator® platform uses pressure-based microfluidics for reliable nanoparticle synthesis at several production scales. It has been widely used to produce various types of nanoparticles, such as lipid nanoparticles (LNPs), liposomes, PLGA nanoparticles, etc.

Microfluidic Mixing System

- Controllable particle size
- Low PDI
- High encapsulation efficiency
- High reproducibility



System Applications

Nucleic Acid Lipid Nanoparticles

- mRNA vaccines
- Rare genetic diseases
- Gene & cell therapy
- CAR-T therapeutics

Liposomes

- Cancer therapy
- Vaccine adjuvant
- Antimicrobial therapy
- Cosmetics

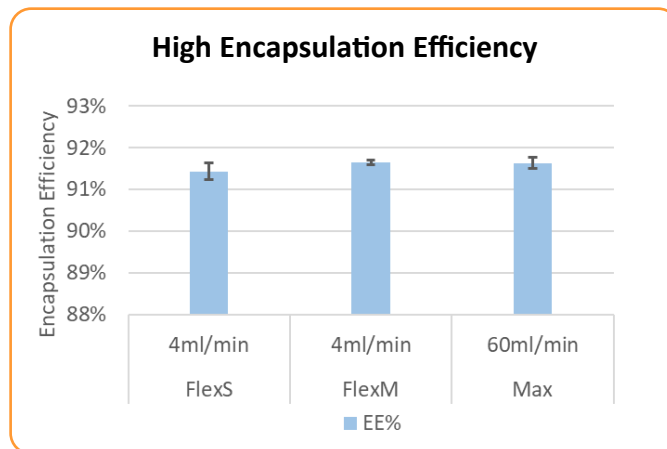
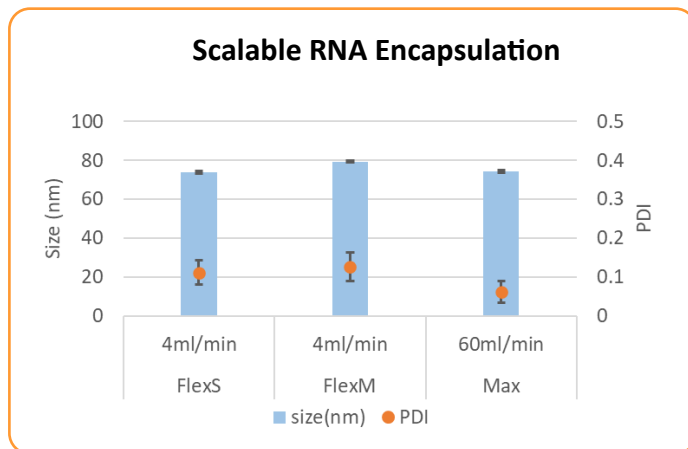
Polymer Nanoparticles

- Cancer chemotherapy
- Immunology & vaccines
- Insulin delivery for diabetes



Scalable and Reproducible Manufacturing with High Performance

Precise control of parameters ensures consistent CQAs, guaranteeing speed, cost-effectiveness, and reliability at every stage of production. Example CQAs include particle size, PDI, and encapsulation efficiency.



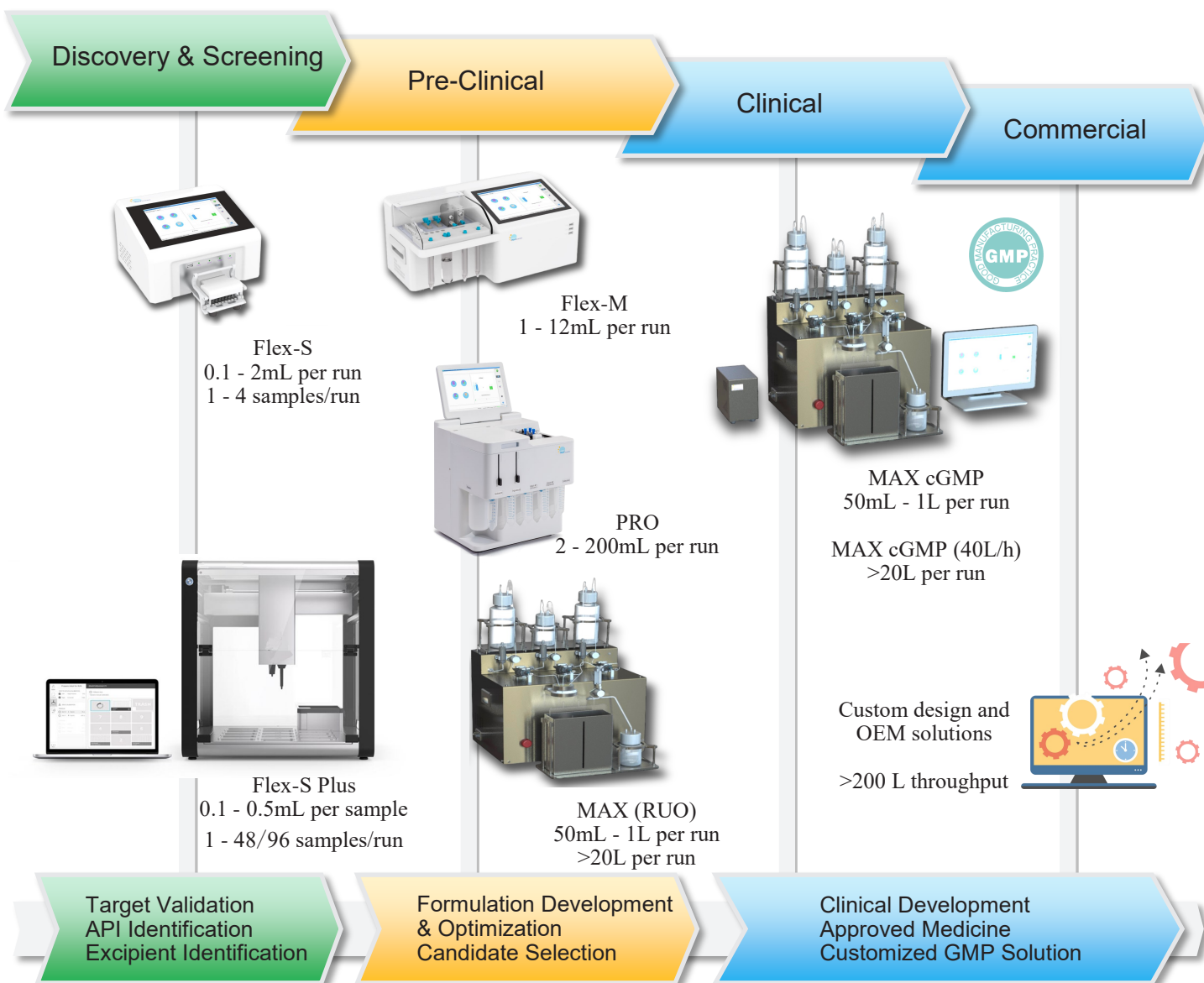
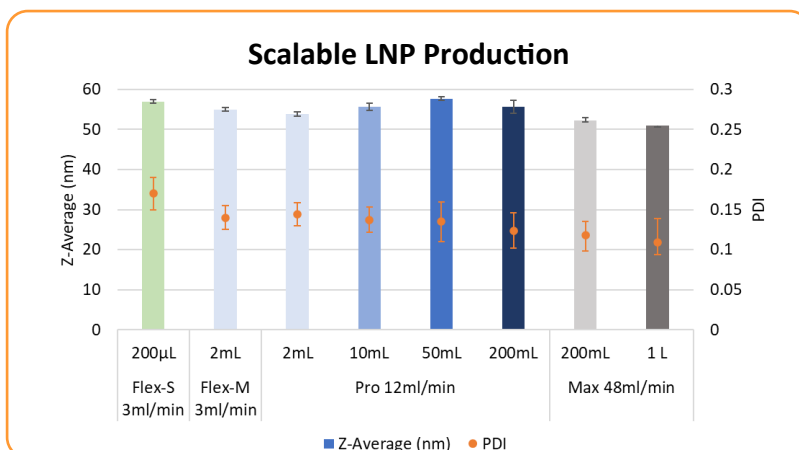
Model	NanoGenerator® MAX			
	RUO flow kit 4.8L/h	GMP flow kit 4.8L/h	RUO flow kit 40L/h	GMP flow kit 40L/h
cGMP compliance	N/A	Yes	N/A	Yes
Software (21 CFR Part 11 compli-	Optional	Yes	Optional	Yes
Throughput	50ml – 1L		> 20L	
Total flow rate	1.2-4.8L/h		Up to 40L/h	
Flow rate ratio	1:1 – 9:1		1:1 – 5:1	
Inline dilution	1:1 – 5:1			
Size range	40 – 200 nm			
PDI	0.05 – 0.2			
Encapsulation efficiency	Up to 99%			
Payload	DNA, mRNA, siRNA, protein, small molecules, etc.			
Dimension (L × W × H)	620 × 380 × 430 mm			
Weight	50 Kg		65Kg	

Email: USSales@precigenome.com
Tel: +1-408-708-4602

Address: 2176 Ringwood Ave., San Jose, CA, USA
Visit us at www.precigenome.com/nanoparticle-synthesis

Path from Discovery to Commercialization

NanoGenerator® offers controllable and reproducible mixing conditions, ensuring the accurate synthesis of LNPs through its scalable architecture found in the entire NanoGenerator® product line. Options are available for all production stages, allowing seamless transfer of crucial process parameters and guaranteeing consistent critical quality attributes (CQAs). LNPs produced from NanoGenerator® may be used for a wide range of applications, such as vaccine development, gene therapy, cell therapy, etc.



The NanoGenerator® MAX GMP System is engineered to facilitate the production of genomic medicines for both clinical and commercial purposes.

Regulatory support files for the single-use mixing flow pack are available including material traceability documentation.

PreciGenome has a proven history of delivering timely support to assist our customers in fulfilling their unique country- or region-specific regulatory requirements. The GMP System is manufactured under a Quality Management System.

cGMP Compliance Documentation

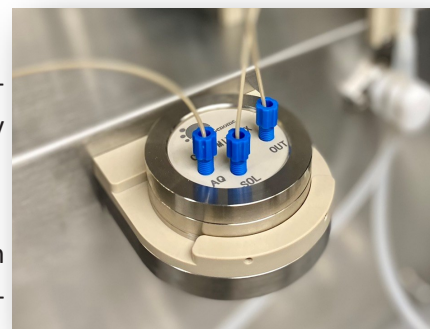
- Installation qualification, operational qualification, performance qualification
- Report of consumable extractables test
- Report of endotoxin test
- Report of RNase/DNase free test
- Report of sterility test
- Report of ethylene oxide residual test
- Report of consumable air tightness test
- Electromagnetic compatibility report
- Safety regulations report



Single-use mixing flow pack

The single-use mixing flow pack is fully documented to support regulatory and quality audits for cGMP production.

It reduces the risk of cross-contamination between batches and campaigns. It also enables multi-product manufacturing in GMP



Software (21 CFR Part 11 compliant) features

- Experimental parameter tuning
- Experimental recipe save/load
- Real-time pressure/flow rate chart
- Historic experimental parameter tracking
- Historic pressure/flow rate tracking
- Self-diagnostic system
- Real-time flow rate diagnostic system
- Warning system
- Manual & automatic emergency stop system
- User management
- Audit trail
- Zero flow calibration
- Flow sensor maintenance & re-calibration (service)



Ordering Information

	Description	Catalog #
Instrument		
NanoGenerator Max System Package		PG-SYN-G
Option 1: Max GMP version	NanoGenerator GMP system , including: NanoGenerator Max GMP Instrument Application software (21 CFR Part 11 compliant), computer, monitor, key board and mouse. GMP documentation Manuals & SOPs On-site installation and training 1 year warranty	
Option 2: Max RUO version	NanoGenerator RUO system , including: NanoGenerator Max Instrument Manuals & SOPs Software , 21 CFR Part 11 compliant (optional) On-site installation and training (optional) 1 year warranty	
Option 3: Max custom design version	NanoGenerator GMP system (custom design for higher throughput and other requirements)	
Cartridges & Consumables		
Mixing cartridge pack for MAX GMP 4.8L/h	NanoGenerator Max mixing cartridge pack, sterilized & GMP compliant, up to 4.8L/h, including: One mixer device Containers, tubing and fittings	CHP-MIX-M1G
Mixing cartridge pack for MAX GMP 40L/h	NanoGenerator Max mixing cartridge pack, up to 40L/h for higher throughput, including: One mixer device Containers, tubing and fittings	CHP-MIX-M2G
Mixing cartridge pack for MAX RUO 4.8L/h	NanoGenerator Max mixing cartridge pack, RUO, up to 4.8L/h including: One mixer device Containers, tubing and fittings	CHP-MIX-M1R
Mixing cartridge pack for MAX RUO 40L/h	NanoGenerator Max mixing cartridge pack, RUO, up to 40L/h including: One mixer device Containers, tubing and fittings	CHP-MIX-M2R
Reagents (optional)		
LipidDemo	Included in the package of the instrument	PG-SYN-LFD
Accessories & Service (optional)		
Software	NanoGenerator software, 21 CFR Part 11 compliant	PG-SYN-SW
Preventive Maintenance Plan	Annual proactive maintenance, that is performed regularly at predetermined intervals to prevent asset failure and unplanned downtime	PG-PMP-1Y
Extended Warranty	Extended Warranty for NanoGenerator Synthesis System, 1 to 3 years	PG-WTY-1Y



PreciGenome is located in the heart of Silicon Valley, San Jose, California, USA. We have been focusing on developing nanoparticle synthesis systems and solutions for our customers. Our technology enables nanoparticle synthesis with high quality and reliable performance for lipid nanoparticles, liposomes, PLGA, etc.

HEADQUARTER

PreciGenome LLC

Tel: 1-408-708-4602

Email: USSales@precigenome.com

Address: 2176 Ringwood Ave. San Jose, California, USA

TAIWAN DISTRIBUTOR

Ding Fong Scientific Co., Ltd

Tel: 886-4-23595717

Email: ding-fong@ding-fong.com.tw

CHINA DISTRIBUTOR

Suzhou Rainsure Biotech Co. Ltd

Tel: 86-512-67503398

Email: info@rainsurebio.com

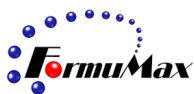
KOREA DISTRIBUTOR

InSung Chroma-Tech Co., Ltd.

Tel: 82-226441991

Email: KRSales@precigenome.com

Some of Our NanoGenerator Customers



Visit us at www.precigenome.com/nanoparticle-synthesis