PRECISION NANOSYSTEMS

Create Transformative Medicines™

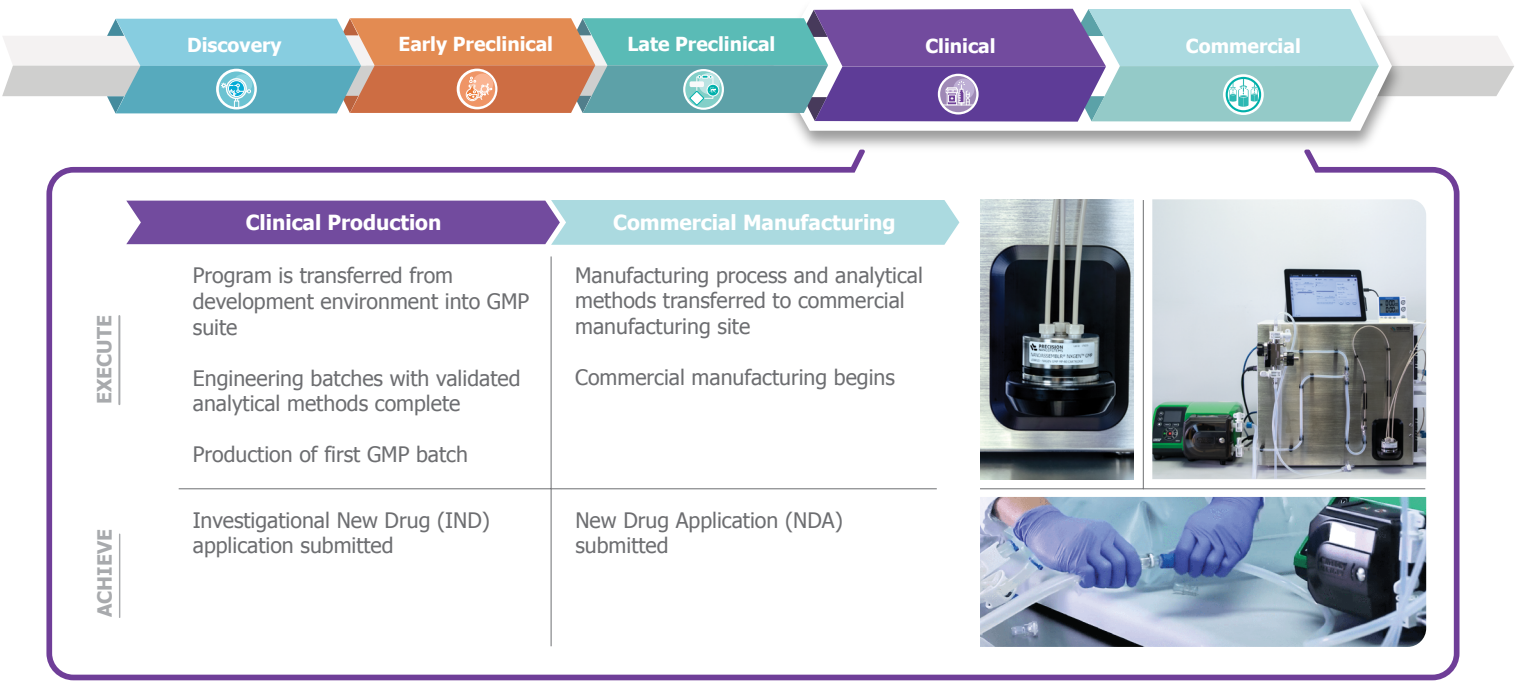
NanoAssemblr® GMP System

with NXGen™ Technology

Power to Commercialize

Accelerate the Path to Manufacturing

Built upon our revolutionary NxGen™ microfluidic technology, the NanoAssemblr® GMP System enables you to go from concept to clinic with speed and confidence. NxGen models unit operations at scale for precise nanoparticle assembly under non-turbulent conditions across our NanoAssemblr family of instruments. Combined with Precision NanoSystems' comprehensive technical expertise in genomic medicines, we accelerate the clinical and commercial development of nanomedicine drug products.



Maximum Delivery. Minimal Risk.

The NanoAssemblr GMP System expedites drug development timelines through a seamless scale-up process across our platform. This minimizes engineering batches and de-risks manufacturing under cGMP conditions for robust and reproducible results.

Precise control of nanomedicine self-assembly allows for simplified scale-up of formulations for getting drugs to clinic faster.

All necessary traceability documentation and vendor qualification of critical components and consumables support equipment qualification for regulatory compliance.

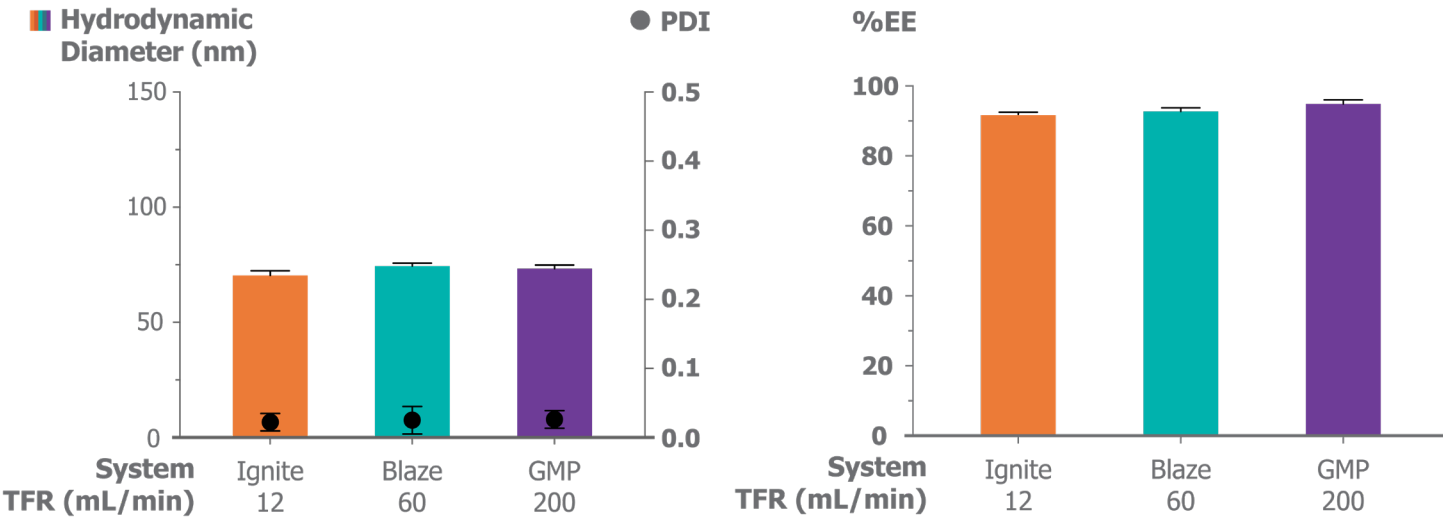
Quick and simple installation, qualification and operator training and full service packages enable ease of setup with minimal downtime.

Clinical to Commercial. Confidently Covered.

The NanoAssemblr GMP System is a complete, ready-to-use instrument for clinical and commercial nanomedicine drug development. Its intuitive, easy-to-use technology minimizes operator training, error and variability, resulting in a reproducible, automated manufacturing process for a broad range of applications, including vaccine development and cell and gene therapy. The GMP System and its single-use fluid path are fully documented to support regulatory and quality audits for cGMP production of genomic medicines.

Robust Scalability. Trusted Performance.

Precisely controlled parameters for consistent critical quality attributes including particle size across the NanoAssemblr platform means that each step in the development and manufacturing process is quick, cost-effective and dependable.



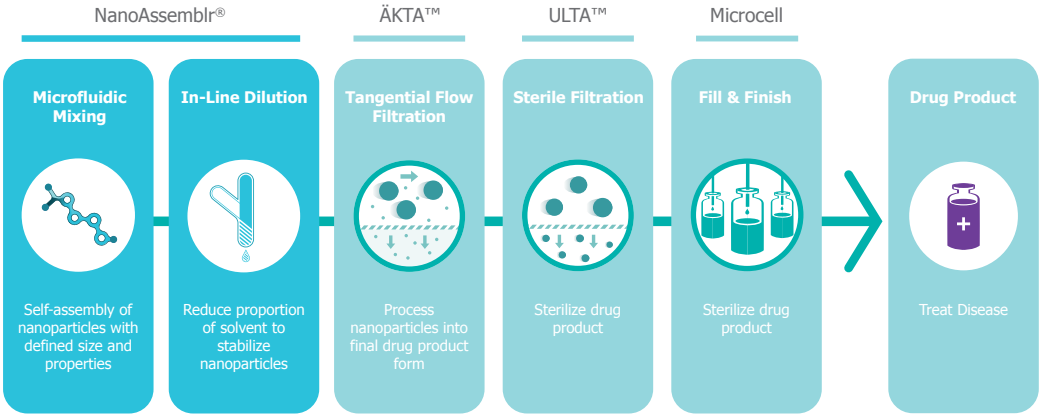
Particle size, polydispersity and RNA encapsulation efficiency are consistent as production of epo-encoded mRNA-lipid nanoparticles (LNPs) was scaled using the NanoAssemblr platform.

Customized cGMP Manufacturing Solutions

With decades of LNP formulation and manufacturing experience, our Biopharmaceutical Services team helps you optimize process development and execute technology transfer in order to scale across NanoAssemblr instruments. The GMP System can also be customized for specific user requirements, including heating of solutions or different types of dilution, and to support scale-out manufacturing through parallelization of the NxGen mixer. This enables the rapid production and manufacturing of Phase I and II nanomedicine drug products, accelerating the time to commercialization.

Manufacturing Made Easy

Our NanoAssemblr family of products empowers you to model the full unit operations of the nanomedicine workflow, translating smaller scale parameters onto the NanoAssemblr GMP System. This reproducibility translates into fewer large-scale experiments, accelerating timelines and preserving costly reagents.



PRECISION NANOSYSTEMS | cytiva | PALL

The NanoAssemblr GMP System plays a critical role in producing high-quality nanoparticles with the necessary quality documentation to help you advance to the clinic with confidence. This versatile solution for commercial manufacturing of genomic medicines leverages the combined support, supply, quality and technical expertise of Precision NanoSystems, Pall and Cytiva to provide an end-to-end manufacturing workflow that maximizes efficiency with centralized processes. The result is a reproducible, automated process for cGMP manufacturing of genomic medicines with upstream and downstream integration capabilities.

Sirnaomics Case Study

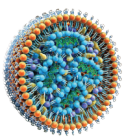
Precision NanoSystems' complete solution of innovative platforms accelerates the entire commercialization process. A recent study from Sirnaomics shows a less than 6-month timeframe for formulation development ready for GMP manufacturing.

> *The scalability and reproducibility of Precision NanoSystems' NanoAssemblr platform allowed us to move into GMP manufacturing with greater control over the process and increased precision in the final product compared to our previous macromixing process, allowing acceleration of our time to commercialization.*

David Evans, Ph.D., CSO, Sirnaomics

October 2018
Proof of concept study Benchtop purchase

June 2019
Formulation development and scale-up initiated



November 2019
License and Supply Agreement executed

December 2019
Tech transfer of formulation and GMP System to CMO

December 2019
GMP Manufacturing run

January 2020
Engineering batch run

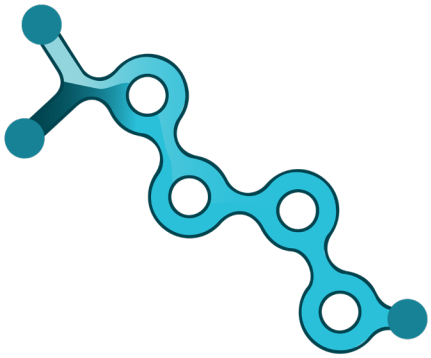
NXGen™ Microfluidics

A disruptive technology enabling accelerated transformative medicine development

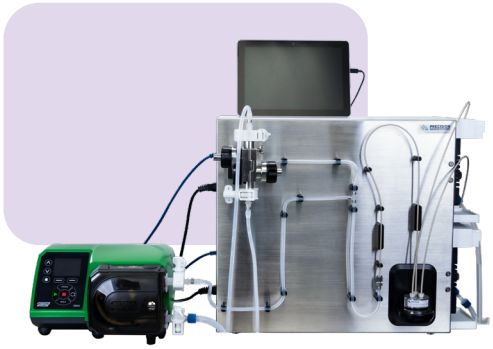
Precise - Non-turbulent particle formation ensures the most reproducible results for a wide range of nanoparticle types

Scalable - More than 25X throughput in a single mixer simplifies scaling up while maintaining particle quality and reproducibility compared to a classic mixer

Innovative - Platform designed to rapidly take ideas to the clinic



The GMP System utilizes the same revolutionary microfluidic technology as the Ignite™ and Blaze™ instruments to de-risk and expedite technology transfer as production is scaled. This also enables you to scale down to continuously optimize formulation and process parameters to achieve greater efficiencies. The GMP cartridge is a part of a fully documented, single-use fluid path, which reduces cleaning between batches or products and minimizes the risk of contamination. The GMP System comes with full warranty, installation qualification/operational qualification (IQ/OQ) and service packages, ensuring ease of setup and minimizing potential downtime.



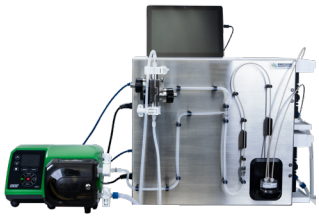
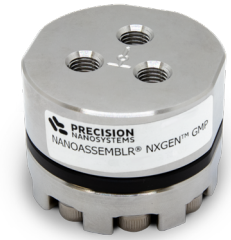
Regulatory Compliance

The NanoAssemblr GMP System was designed to enable the clinical and commercial manufacturing of genomic medicines. Regulatory support files including material traceability documentation of the single-use, animal component-free fluid path are available. The GMP System is manufactured under a Quality Management System certified to ISO9001 and Precsion NanoSystems has an established track record of providing timely support to help our customers meet country- or region-specific regulatory requirements needs.

Regulatory Compliance Documentation

NAME	CONTENTS	
NanoAssemblr GMP System	Primary Materials of Construction (Non-product Contacting)	
NanoAssemblr GMP Fluid Path	Materials of Construction	Passivation Records
	Certificates of Conformance	Specifications
	Certificates of Analysis	BSE/TSE Statements
	Gamma Processing Certificates	

Ordering Information

INSTRUMENT AND CARTRIDGES		PRODUCT CODE	INCLUDES
	**NanoAssemblr GMP System Package**	1000453	NanoAssemblr GMP Instrument Bioprocessing bags Calibration tool GMP documentation including manuals, certificates and SOPs On-site installation and training 1 year warranty
	**NanoAssemblr RUO Fluid Path:** NxGen 400D NxGen 500D	1000442 1000441	NxGen 400D or NxGen 500D cartridge Connective tubing elements
	**NanoAssemblr GMP Fluid Path:** NxGen 400D NxGen 500D	1000438 1000440	NxGen 400D or NxGen 500D cartridge Connective tubing elements Pump head consumables and accessories Fluid path traceability and material report

About Precision NanoSystems

Precision NanoSystems is a global leader ushering in the next wave of genomic medicines in infectious diseases, cancer and rare diseases. We work with the world's leading drug developers to understand disease and create the therapeutics and vaccines that will define the future of medicine. Precision NanoSystems offers proprietary technology platforms and comprehensive expertise to enable researchers to translate disease biology insights into non-viral genomic medicines.

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