LEON
ENABLING NANO NOW

NANO REVOLUTION

The ultimate nanoformulation manufacturing platform

FR-JET
technology

OUR PROPRIETARY CORE

The FR-JET technology is based on jet-impinging principles and features a modular design with interchangeable parts. This innovative approach provides the flexibility to fine-tune process parameters from the early development stages through to large-scale production.

THE UNDERLYING PRINCIPLE

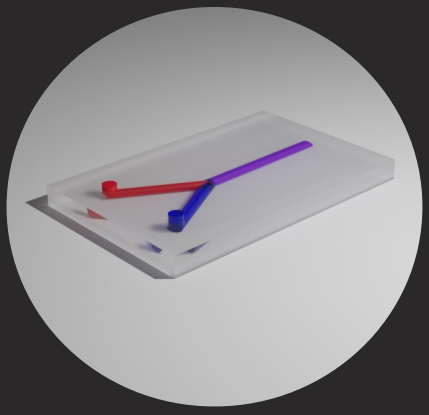
Two liquids are injected into the reactor under pressure through two nozzles. This process establishes a highly turbulent yet stable mixing process, in which the liquids mix in a very short period of time within the mixing chamber. The unique internal geometry of our mixer core maximizes the turbulent mixing efficiency by minimizing the surface area-to-volume ratio and reduces deviations from ideal reactors by eliminating stagnant or dead volumes.

UNPRECENDENTED REPRODUCIBILITY & PROCESS CONTROL

The pharmaceutical development of nanoparticle-based products, which encapsulate small molecules or large biomolecules, is a complex operation that has been met with various hurdles. From designing stable formulations to the critical task of scaling up to GMP-compliant manufacturing processes requires a holistic solution that can be relied upon.

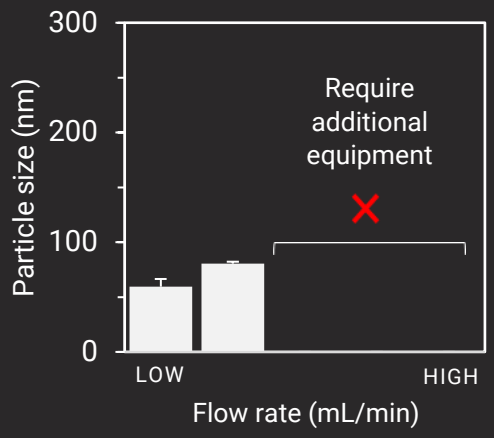
Current conventional technologies, such as microfluidics and T-mixing, fall short in addressing critical challenges in mitigating the risk of aseptic manufacturing, suboptimal product CQAs, high batch-to-batch variability, and steep production costs.

Recognizing the complexity of the emerging drug modalities and their associated high manufacturing costs, LEON has introduced the FR-JET technology.



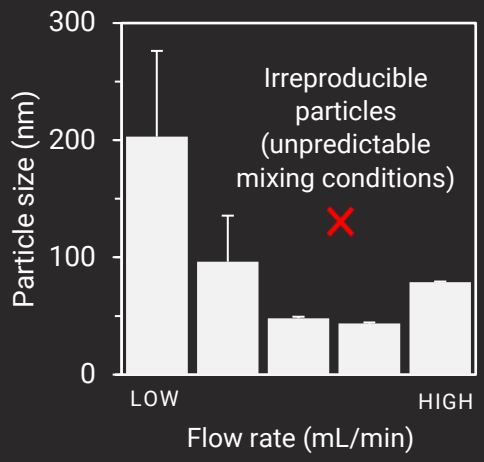
MICROFLUIDICS

- Short process development time
- Poor volume throughput
- Complex scale up
- Batch-to-batch variability
- High material loss
- Poor versatility



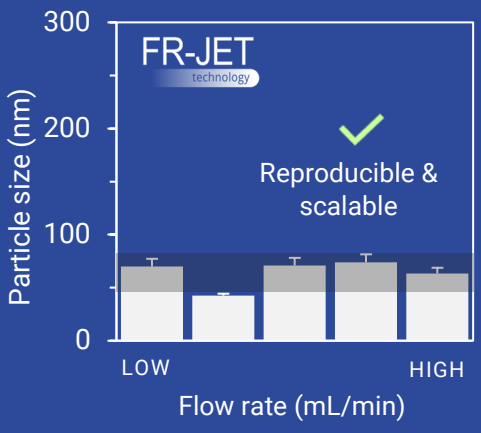
CONVENTIONAL JET IMPINGEMENT

- Long process development time
- Large volume throughput
- Complex scale up
- High batch-to-batch variability
- High-to-medium material loss
- High versatility



FR-JET TECHNOLOGY

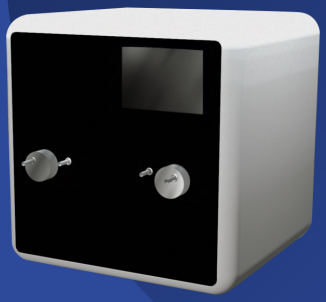
- Short process development time
- Large volume throughput
- Effortless scale up
- Consistent interbatch quality
- Low material loss
- High versatility



Our manufacturing systems have been developed keeping GMP-compliant designs in mind. This is why they can meet the demanding need for a cost-effective aseptic manufacturing process while ensuring batch-to-batch reproducibility at the same time, whether producing low or high product volumes.

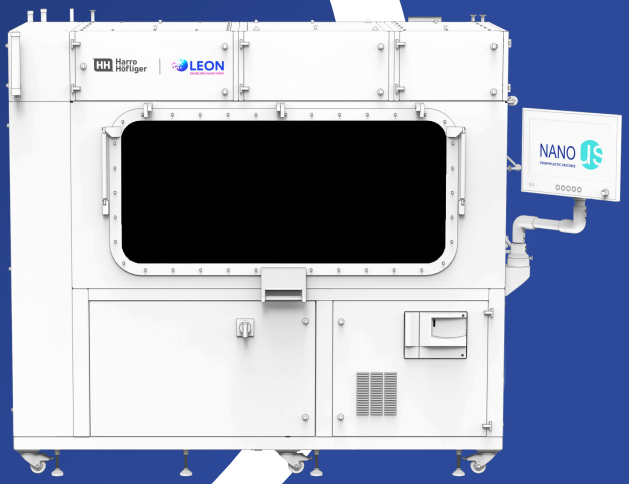
OUR EQUIPMENT PORTFOLIO

NANO lab
ENABLING DEVELOPMENT



NANO me
PERSONALIZED MEDICINE

NANO JS
PROPHYLACTIC VACCINES



NANO lab
ENABLING DEVELOPMENT

SIMPLIFIED PROCESS DEVELOPMENT

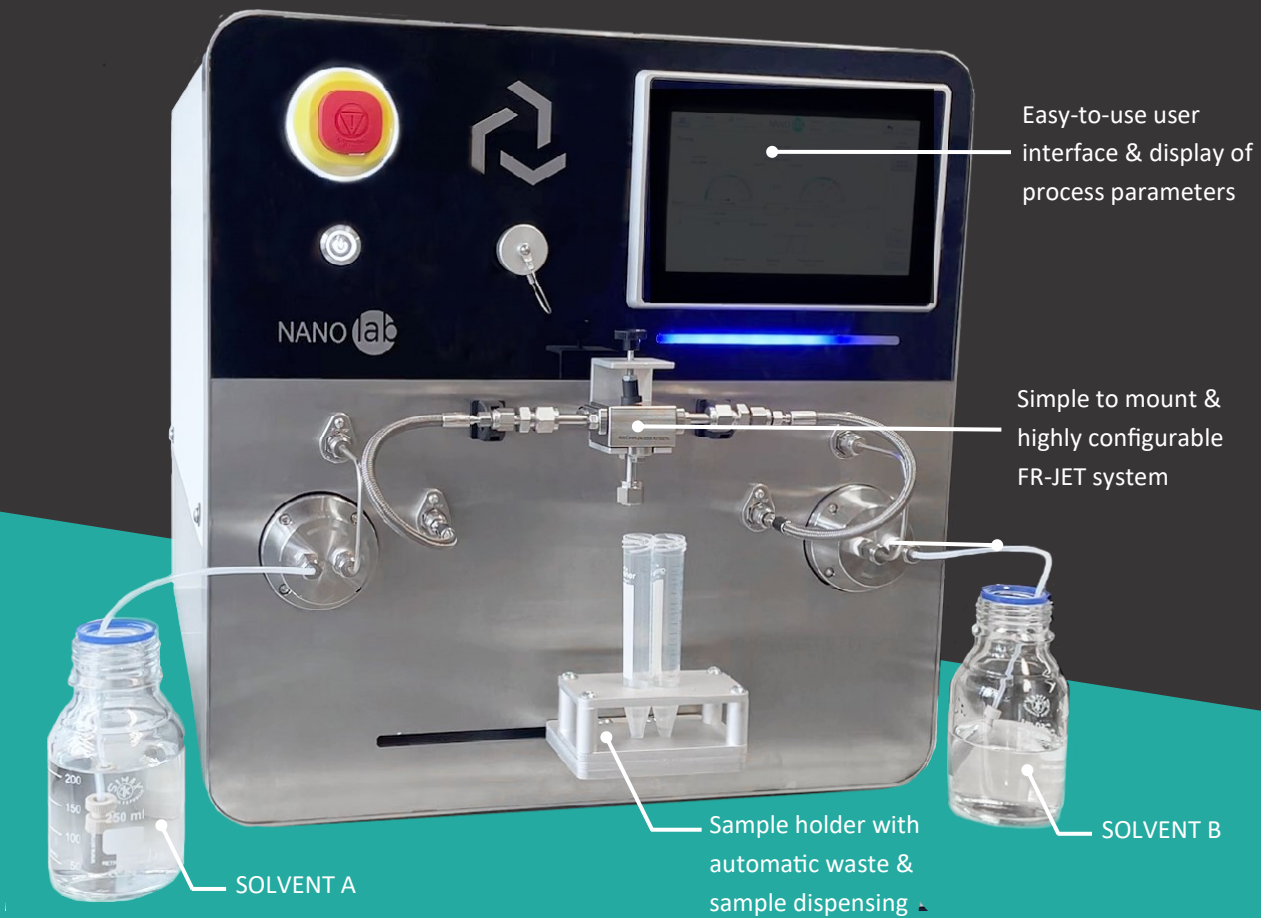
The NANOlab® features a broad operational window (e.g. flow rate) combined with the modular design of the FR-JET system, enabling precise control over nanoparticle properties.

DELIVER YOUR TARGET SPECIFICATIONS

A highly configurable system makes it easy to screen and identify the right process parameters to achieve particle properties that meet your needs.

DIRECT ONE-STEP PROCESS TRANSFER TO GMP

The process parameters can be scaled up directly to our GMP NANOme® or NANOus® devices without the need for intermediate steps or additional equipment.



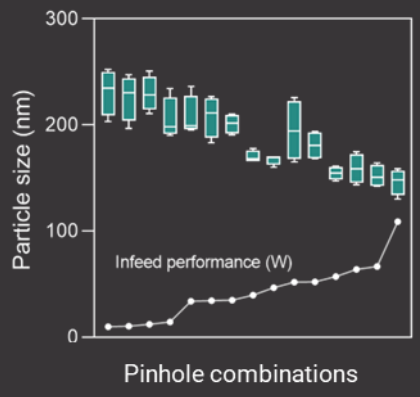
TECHNICAL DETAILS

System description	NANOlab® bench-top device for nanoparticle formulation process development
Scope	Non-clinical pharmaceutical nanoparticle formulations
Dimensions	45 cm × 45 cm × 60 cm (approximate)
Weight	25 kg
Features	• FR-JET reactor (included) for mixing two solutions • FR-JET system offers combination of pinholes, cores and outlets to tune process • Flow-controlled feed of educt streams using micro-gear pumps with a low internal volume • Manual operation mode for protocol development • Customizable protocols for automated process runs • Export function for process parameter logs (flow rates, total flow rates or TFR, pressure)
Operation parameters	• Flow rate of single pump: 3-250 mL/min • Total flow rate: 6-500 mL/min (FRR 1:1) • Pressure rating ≤ 40 bar • Samples can be dispensed automatically (≤1 mL applicable at low TFRs only)
Output	• Minimum product volume: starting at 1 mL (for 10 second run at lowest TFR, FRR 1:1) • Maximum product volume: N/A (continuous operation mode)

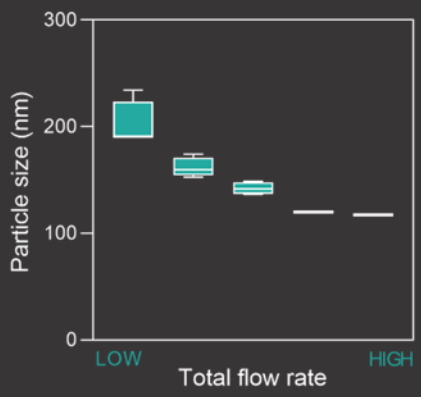
EXAMPLE WORKFLOW TO OPTIMIZE PROCESS

Representative data shown with model PLGA nanoparticles. Data for other nanoparticles, including LNPs, available.

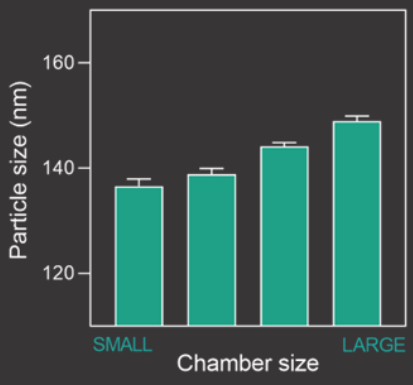
1. SCREEN SIZE RANGE



2. MODULATE



3. FINE TUNE



EFFORTLESS SMALL-SCALE GMP STERILE BATCHES

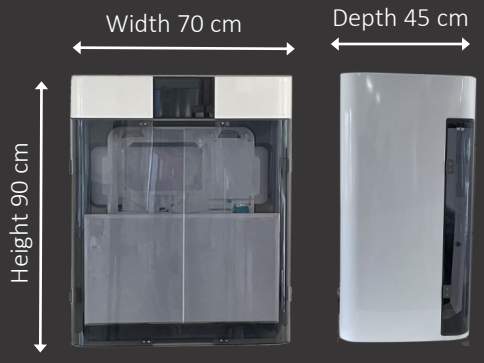
Our bencthtop NANOme® GMP equipment redefines back-to-back aseptic manufacturing intended for clinical trials and individualised doses for personalized medicine.

FULLY CLOSED AUTOMATED SYSTEM FOR SMALL FORMULATION BATCHES

The only system offering a fully-closed single-use sterile fluid path with zero contact between product and reusable parts for high sterility assurance.

DIRECT PROCESS TRANSFER FROM NANOlab®

The process established on the NANOlab® can be transferred directly to the GMP NANOme® device without the need for intermediate scale up equipment or steps.



TECHNICAL DETAILS

System: NANOme® benchtop device for GMP nanoparticle production

PART I

Description	Apparatus for processing fluids in disposable kits for nanoparticle formulation manufacturing
Scope	Aseptic manufacturing of pharmaceutical nanoparticle formulations intended for clinical use
Dimensions	45 cm × 70 cm × 90 cm (130 kg)
Features	• Automated system with touchscreen operation • Export function via USB outlet for process parameter logs • Storage of pre-written formulation protocols and process data tables • 21 CFR Part 11 compliant software (option for remote software updates) • Designed for sterile production in Grade C cleanrooms • No need for cleaning between batches (including product changeover)
Operation parameters	• Flow rates - inlet A: 10 - 90 mL/min, inlet B: 5 - 45 mL/min (flow stabilizes in <4 seconds) • Reactor configuration optimized for lipid nanoparticles • Pressure rating ≤ 16 bar
Output	• Maximum total flow rate: 120 mL/min (assuming typical FRR 3:1 for LNPs) • Maximum product volume: approx. 1.2 L • Typical batch size: 200-1000 mL

PART II

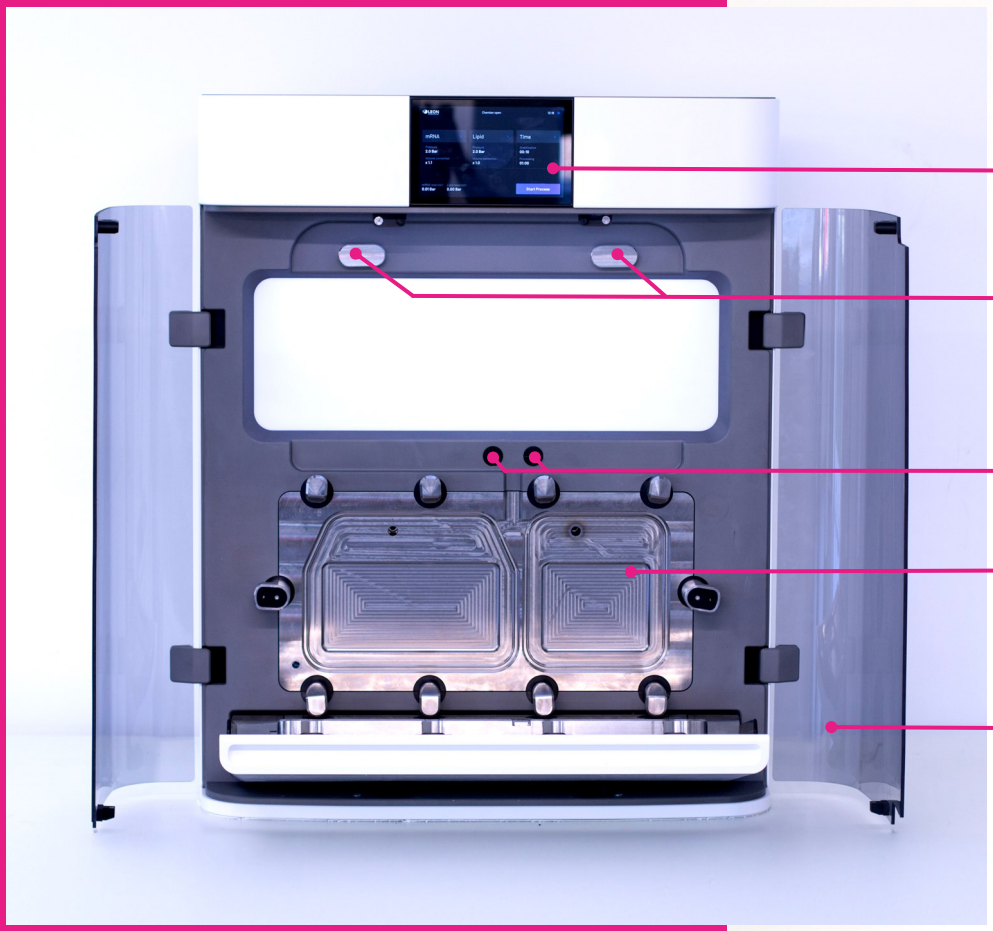
Description	Disposable kit to be used with the NANOme® apparatus
Features	• Preassembled, triple-packaged & sterilized disposable reactor included • Kit includes container bags, with easily detachable product bag for downstream processing • In-built sterile connectors & disconnectors for maintaining a closed-loop workflow • Sterile fluid path with closed design for GMP aseptic manufacturing • Filling aid prop for easy handling during filling operation (included) • In-built sterile sampling feature for Quality Control • Easy handling, secure transport, and risk-free mounting and unmounting within seconds • Minimal internal dead volume to minimize material loss • Customization of reactor configuration for non LNPs (not included) • Option to select between in-line or pre-filled in-bag dilution of nanoparticles

Note: Filling of single-use bags requires external pump, syringes, or similar equipment and in-line dilution requires an external pump (not included)

NANO me
PERSONALIZED MEDICINE

NANO me
PERSONALIZED MEDICINE

A CLOSER LOOK AT THE NANOme® APPARATUS



HMI (touchscreen panel) for easy-to-use device operation

Attachment point for connection & auto-alignment of disposable kit

Disposable kit with closed design for easy aseptic processing

Valve actuators for automated flow direction control

Chamber for housing bags with starting solutions for formulation with automatic mechanical clamps

Device cover with pneumatic door locks ensures user safety

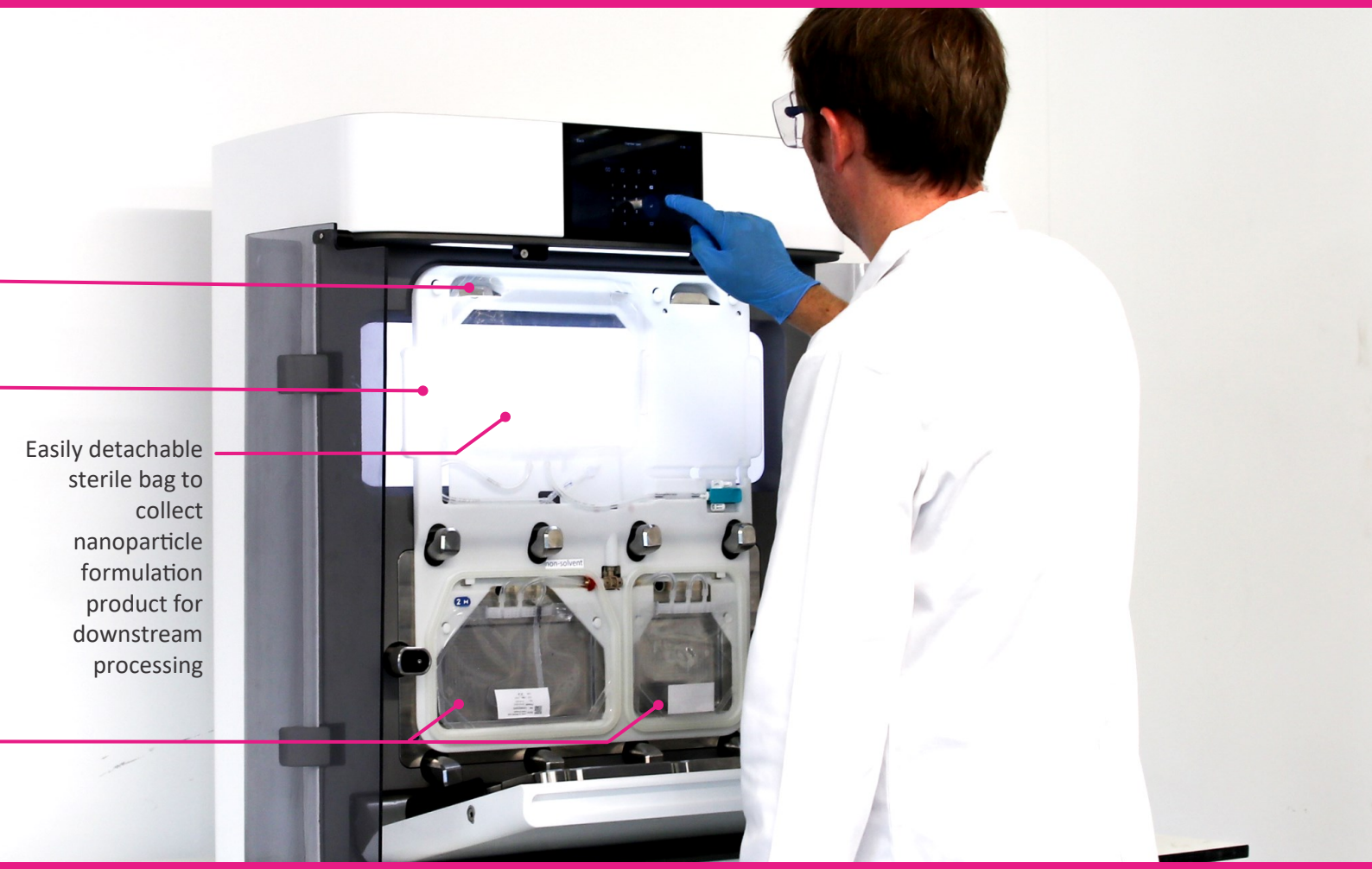
Sterile bags for aseptically filled starting solutions

HOW IT WORKS

SIMPLE PLUG & PLAY APPROACH FOR BACK-TO-BACK GMP NANOFORMULATION MANUFACTURE

1. Place the filled NANOme® disposable kit into the NANOme® apparatus.
2. Input process parameters and run the process (typical run time 10-20 minutes).
3. Remove the filled product bag for downstream processing.

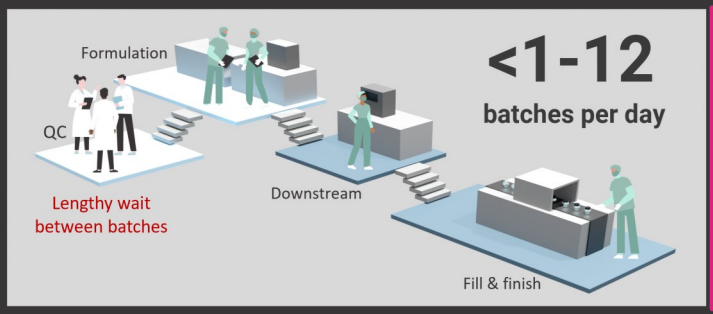
Repeat steps 1-3 for next batch.



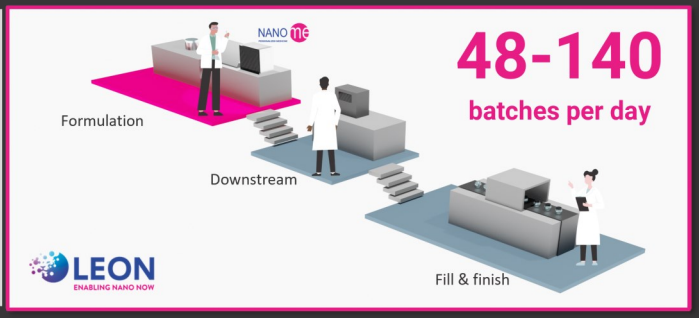
BATCH OR PRODUCT CHANGEOVER IN AS LITTLE AS 5 MINUTES!

An easy-to-handle disposable kit, which completely eliminates the need for cleaning, sterilization or validation steps in-between batches and saves time significantly.

Conventional 'use and reuse' systems require cleaning and cleaning validation between batches



No cleaning or cleaning validation steps necessary between formulation batches with the NANOme®



Note: Number of batches estimated assuming 24-hour operations.

NANO JS
PROPHYLACTIC VACCINES

EFFORTLESS LARGE-SCALE GMP STERILE BATCHES

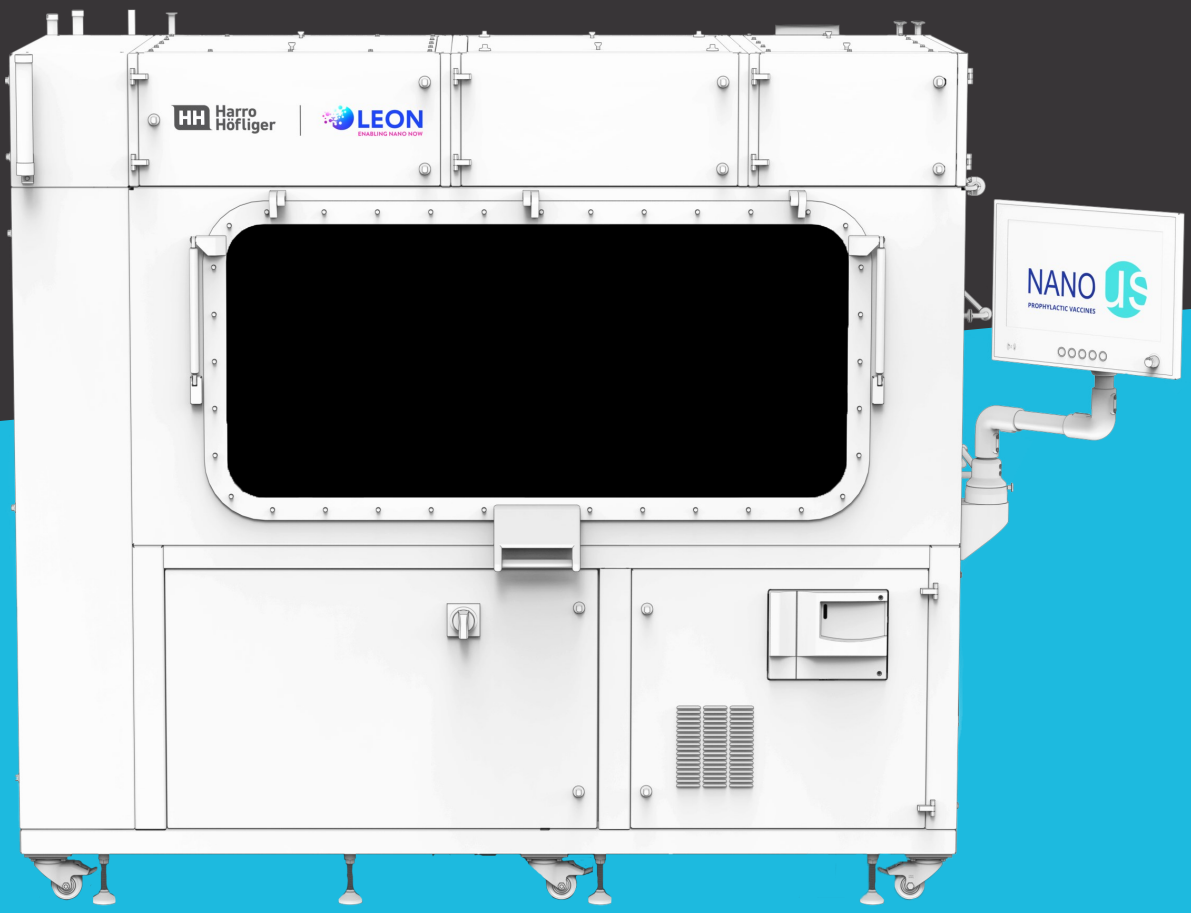
Our fully-automated large scale NANOus® aseptic system for continuous manufacturing offers flexible volume outputs.

FULLY CLOSED AUTOMATED SYSTEM FOR LARGE BATCHES

Integrated in-process controls and in-built aseptic process conditions enable time savings and ensures high product quality even at multiliter volumes (throughput up to 1200 mL/min).

CUSTOMIZABLE TO YOUR MANUFACTURING NEEDS

The NANOus® system features such as CIP/SIP, PAT, temperature control can be fully customized to serve your manufacturing process requirements.



HAVE QUESTIONS? TALK TO OUR EXPERTS.

MARTIN ERHARD

Lead Scientist, Product Development & Application

- NANOme® system
- Process transfer
- GMP workflow

m.erhard@leon-nanodrugs.com

BLERINA SHKODRA, PhD

Senior Lead Scientist, Process Development & Lab Manager

- FR-JET technology
- Lipid-based nanoformulations
- Characterization methods

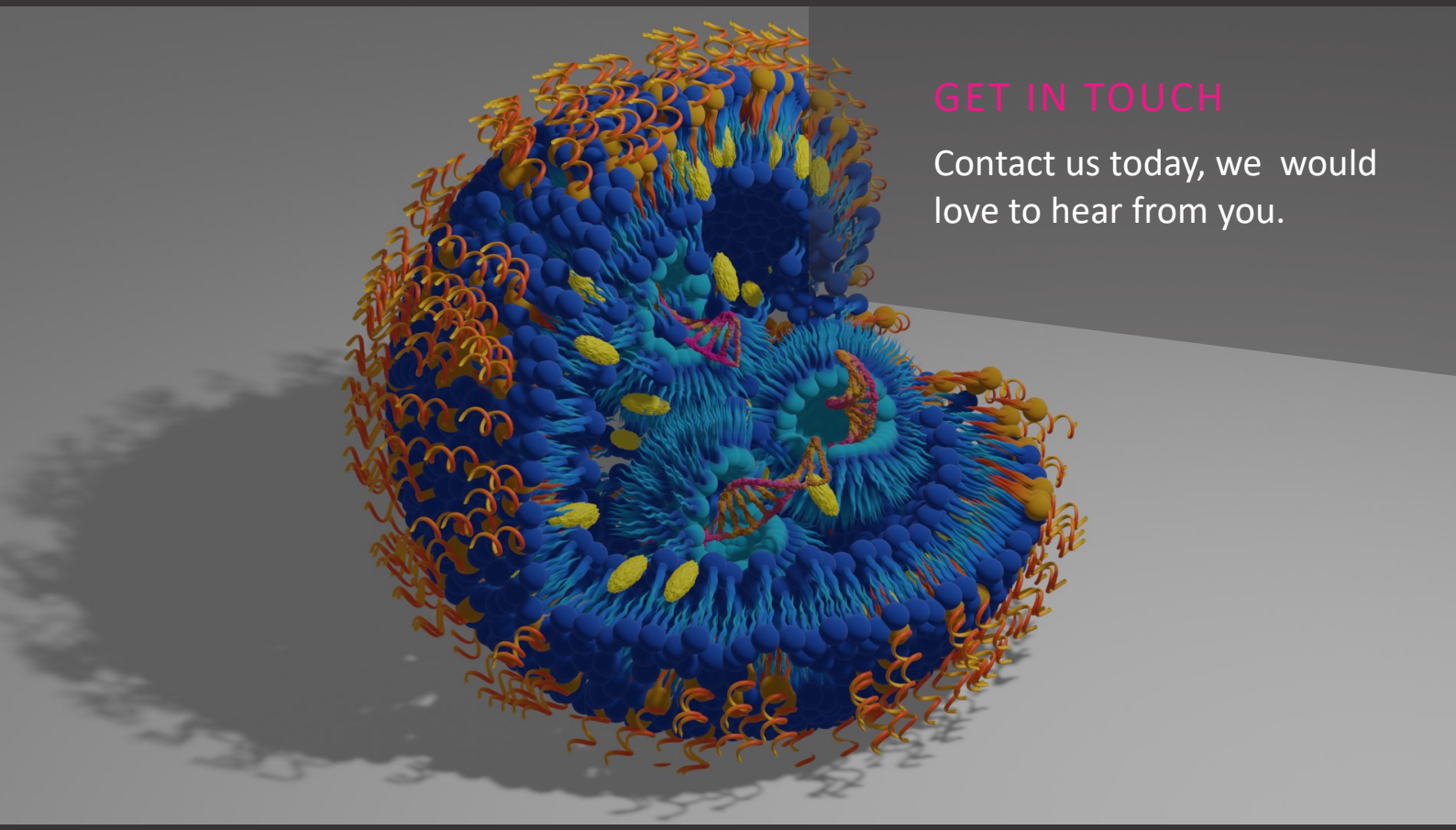
b.shkodra@leon-nanodrugs.com

MATTHIAS SCHUMACHER, PhD

Senior Lead Scientist, Product Development & Application

- Non-lipid based nanoformulations
- NANOlab® & NANOus® systems
- Process scale up

m.schumacher@leon-nanodrugs.com



GET IN TOUCH

Contact us today, we would love to hear from you.

CONTACT US

The complete solution to high-quality GMP nanocarrier formulation manufacturing

OFFICE ADDRESS

leon-nanodrugs GmbH

Kopernikusstraße 9

D-81679 Munich

Germany

LABORATORY ADDRESS

leon-nanodrugs GmbH (IZB)

Am Klopferspitz 19

D-82152 Munich

Germany

FOR GENERAL ENQUIRIES

info@leon-nanodrugs.com

VISIT OUR WEBSITE

www.leon-nanodrugs.com

FOR COLLABORATION OPPORTUNITIES

We are **inviting industry partners** to explore our devices prior to market launch. If you are Interested or would like a demo, please contact:

Dr. Setu Kasera, Chief Scientific Officer

s.kasera@leon-nanodrugs.com

LEON

ENABLING NANO NOW