NaPRO, Next Generation Nanopharma Process Development Platform

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NaPRO is a unique state-of-the-art testbed with new 'smart' process systems, which will allow to de-risk the scalability and manufacture of nano(bio)pharmaceuticals and facilitate the adaptation of these technologies to existing industrial facilities. NaPRO will enable the development of robust and scalable compliant methods of production of nanomedicines that enable progression from a small production scale (in the mg range) to a commercially relevant scale (in the kg range).

Bringing the processes, process equipments and comprehensive characterization tools under one roof in NaPRO alloww for the development of next generation processes and manufacturing technologies to academic collaborators and pharma/biopharma industry, nationally and internationally, including drug developers.

Associate Professor Luis Padrela and Prof Vivek Renade's NaPRO project was approved for funding from Science Foundation Ireland under the Research Infrastructure programme (Total €1,286M; SFI funding of €808). The goal of NaPRO (Next Generation Nanopharma Process Development Platform) is to provide cutting-edge pharmaceutical nanotechnologies coupled with real-time advanced characterization tools.

Why NaPRO

The testbed will underpin the next generation manufacturing of (nano)medicines and will catapult Ireland into a leadership position in this area.

The range of technologies offered by NaPRO will allow the best manufacturing approach to be selected and scaled-up for a particular nanomaterial.

The system comprises of the following components:

Nanomanufacturing equipment:

- MVS-HP: Multi-vessel High-pressure Screening Setup
- NS: Nano-Spray Dryer B-90
- SASD: ScCO2-assisted Nano-Atomizer
- MF: Microfluidics

PAT Multiphase Characterization Tools:

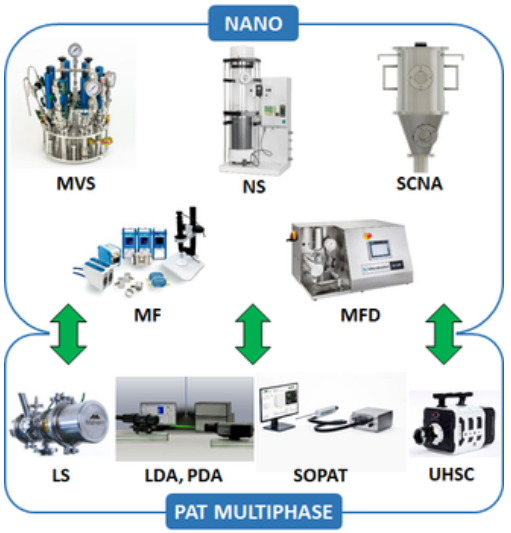
- LS: On-line Laser Diffraction
- LDA: Laser Doppler Anemometer
- SOPAT: Endoscopic probes for particle size measurements
- HSC: High-speed camera
- PAT: Process Analytical Technology
- QbD: Quality by Design

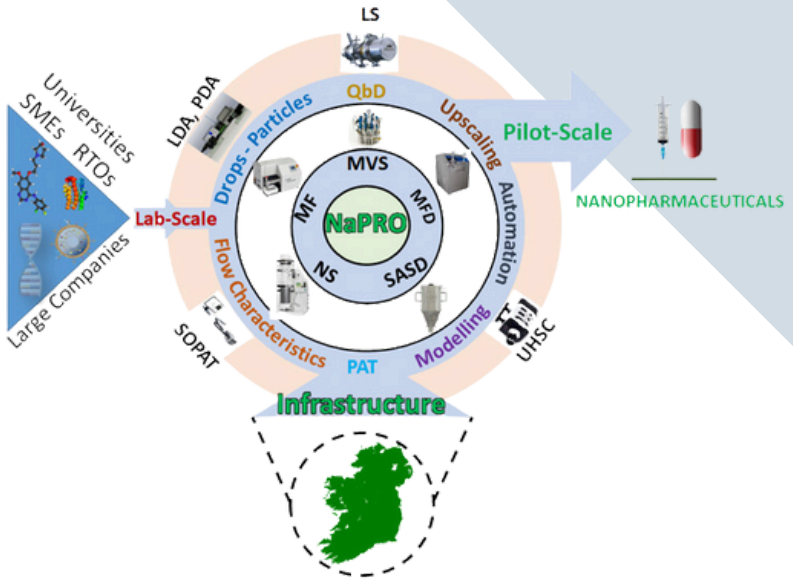
This suite includes a multi-vessel high-pressure reactor screening setup, which will screen processing conditions for the precipitation of micro- to nanoparticles using high-pressure CO2 (as a solvent or anti-solvent). It will inform particle processing conditions using a nano-spray dryer and a (pilot-scale) high-pressure assisted nano-spray dryer. The high-pressure assisted nano-spray dryer restricts high-pressure to small volume mixing coaxial nozzles (ensuring process safety) where the desired polymorphic form is templated/nucleated.

The microfluidizer is the industry state-of-the-art method to produce drug nanoparticles by generating abrupt pressure gradients, high turbulence, cavitation, as well as strong shear. Microfluidics is used in a processing device in which chemical reactions take place in micro-channels and is used to generate nanoparticles, offering several advantages over conventional scale reactors including vast improvements in energy efficiency, reaction speed and yield, safety, and a much finer degree of process control.

A Laser diffraction particle size analyser will allow for on-line continuous sampling and analysis of spray dried nanoparticles. A Laser Doppler anemometer (LDA) with traversing system and Phase Doppler anemometer (PDA) will be established. The LDA/PDA will provide crucial data of particle size and local flow field for solid-liquid flows and gas-liquid flows encountered in spray dryers, microfluidizer and microfluidic devices. SOPAT endoscopic probes will provide essential data on local particle shape and size distributions, as well as local volume fractions of dense multiphase flows like emulsions and sprays.

A high-speed visualization facility (camera and associate lighting) will be established to reveal ultra-fast dynamics of relevant multiphase systems (quantification of drop/bubble breakage in turbulent flows or growth) and guide the development of new multiphase flow models. Together with bottom-up and top-down nanotechnologies, the NaPRO's flow characterization equipments will provide a complete toolkit to investigate the dynamics of multiphase flows and will be able to provide data for the development and validation of computational models.





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