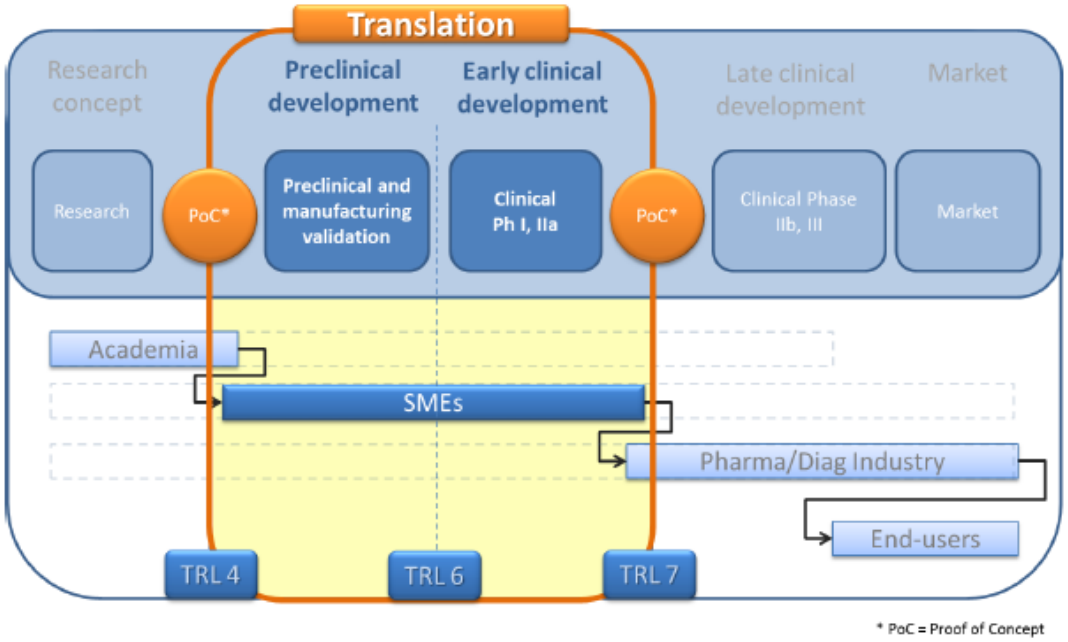
NANOPILOT

A PILOT PLANT FOR THE PRODUCTION OF POLYMER BASED NANOPHARMACEUTICALS IN COMPLIANCE WITH GMP

NanoPilot has received funding from the European Union's Framework Programme for Research and Innovation Horizon 2020, under Grant Agreement no: 646142

Introduction

The traditional business model of 'Big Pharma' has evolved to an **Open Innovation (OI) model**, in-licensing technology from academia or SMEs. **Academia and innovative SMEs** have become **key players** in the first stage of the development and proof of concept studies.



Nanomedicine value chain, stakeholders and interfaces with focus on translation

The European Technology Platform for Nanomedicine has recorded **more than 700 SMEs/Industry working in the field of Nanomedicine**, a number that doubles when including research institutions. Experts in the field have recognized the **high potential of innovation**, however in most cases, **clinical validation is still required**.

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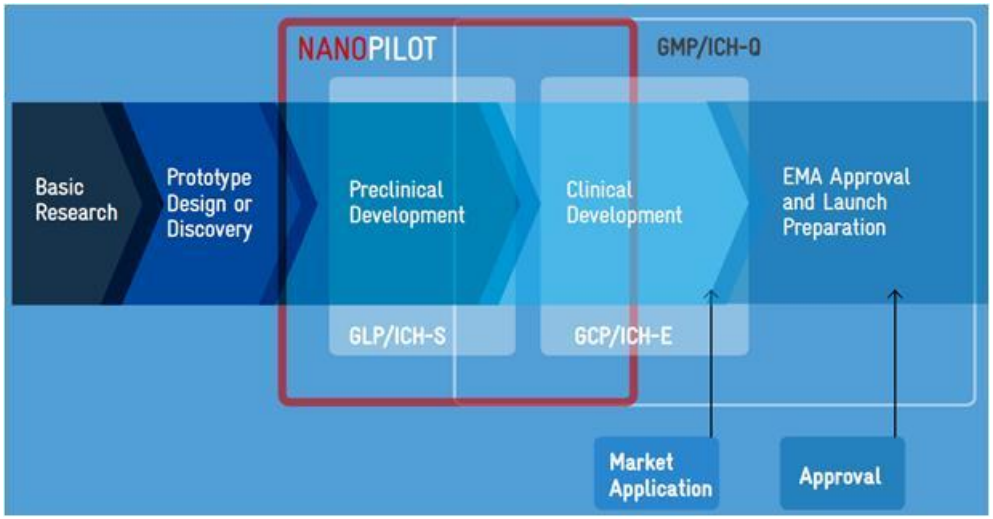

The production of innovative nanopharmaceuticals in quantity and quality (GMP) required **for them to enter clinical trials remains a challenge:**

- Not easy implementation in existing manufacturing plants.
- Lack of resources in small companies to up-scale and implement GMP manufacturing.

This can limit the capacity of these organizations for advancing their research, and as a consequence, **slow-down the development of innovative nanopharmaceuticals** to treat different diseases. In this context, it is urgently **needed to provide** those SMEs with **the tools that can help them with the validation of their technologies.**

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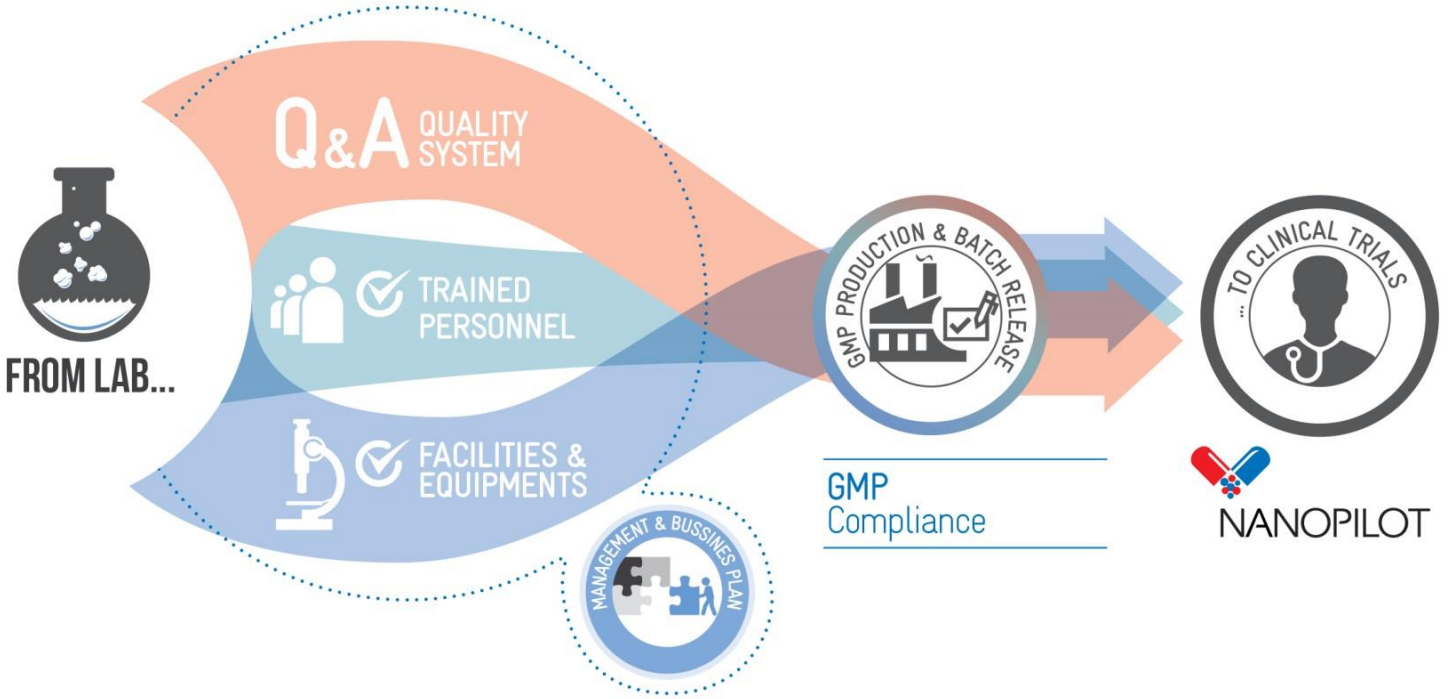
Objectives

NanoPilot will **set-up a flexible and adaptable pilot plant operating under GMP** for the production of **small batches of polymer-based nanopharmaceuticals**, which exhibit significant potential in the field of drug-delivery particularly for the design of second generation nanopharmaceuticals.



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Objectives

OBJECTIVES BASED ON INDUSTRIAL NEEDS

Production of small GMP batches for clinical trials

The pilot plant will provide the small quantities of products that technology developers will require for full preclinical and first clinical validation

Flexibility and Adaptability

A design which will look for a compromise between: specialization, flexibility and economic viability.

Focused on Regulatory compliance

The big pharma will require technology which is robust and translatable, that has completed full toxicological preclinical phase and had been validated in first clinical trials. That technology must fulfil strict regulatory requirements.

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Objectives

SCIENTIFIC OBJECTIVES

Production of three different nanopharmaceuticals

A **short interfering RNA (siRNA)** nanoformulation for the topical treatment of ocular pain associated with dry eye syndrome (DES).

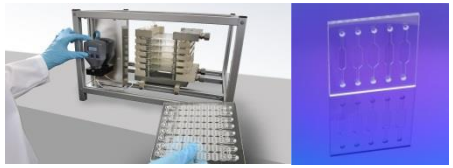
A HIV nanovaccine formulated for intranasal vaccination.

Hyaluronan based particles
A treatment for interstitial cystitis/painful bladder syndrome (IC/PBS).

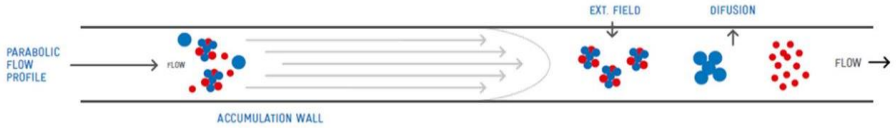
Integration of microfluidics in the plant

Benefits of this technology include:

- Increased process control
- Increased process safety
- Small footprint
- Rapid and robust
- Economical



Implementation of highly advanced characterization techniques



Asymmetrical Flow Field Flow Fractionation (A4F):

- Increasingly used as a separation method to size sort and characterize nanoparticles in native conditions.
- Possibility to analyze a wide variety of macromolecules and particles ranging from the nm to the μm with high resolution.

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Consortium

9 PARTNERS FROM 6 MEMBER STATES

4 RESEARCH GROUPS:

1. IK4-CIDETEC
2. National University of Ireland, Galway
3. University of Santiago de Compostela
4. ADERA-UT2A

3 SMEs:

5. Micronit
6. Mejoran
7. Spinverse

2 INDUSTRIES:

8. Sylentis
9. Chemtrix

IK4 CIDETEC Research Alliance PROJECT COORDINATION, FACILITIES OWNER.	NUI Galway OÉ Gaillimh HYALURONAN SPHERES SPONSOR.	USC UNIVERSIDADE DE SANTIAGO DE COMPOSTELA HIV VACCINE SPONSOR.
sylentis SHORT INTERFERING -RNA SPONSOR.	micronit microtechnologies MICROFLUIDIC CHIPS DESIGNER AND PROVIDER.	CHEMTRIX Scalable Flow Chemistry MICRO REACTOR DESIGNER AND PROVIDER.
MEJORAN QUALITY SYSTEM, GMP, AND LIMS CONSULTANCY.	SPINVERSE BUSINESS PLAN CREATOR, DISSEMINATION AND EXPLOITATION PLAN DEVELOPER.	UT2A Ultra Traces Analyses Aquitaine NANOMATERIALS CHARACTERIZATION EXPERT.

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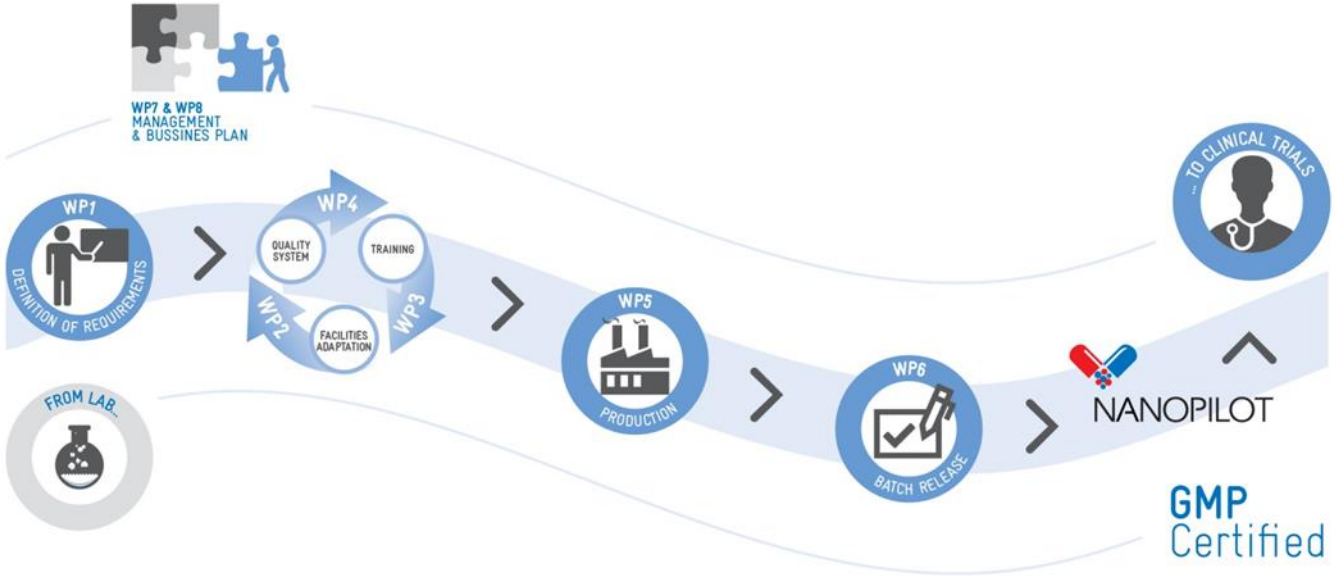
Work Plan



WP1:
Definition of nanopharmaceuticals and design of their GMP production process

WP2:
Adaptation of the facilities to a nanopharmaceuticals production pilot plant working in compliance with GMP

WP3:
Training system implementation

WP4:
Quality system implementation

WP5:
Validation of manufacturing processes and production of nanopharmaceuticals in compliance with GMP

WP6:
Shipping and batch release

WP7:
Development of a business and dissemination plan

WP8:
Management

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Capabilities

Specialized service in technology transfer:

- Customized service
- Definition of specifications
- Reproducibility and technology evaluation
- Definition of critical process parameters
- Characterization
- Optimization of lyophilisation processes
- Scaling-up

NanoPilot will **set-up a flexible and adaptable pilot plant** for the **cost-efficient production** of **small batches** of polymer-based **nanopharmaceuticals, suitable for** pre-clinical and clinical trials. The Pilot plant will be located at IK4-CIDETEC (San Sebastian, Spain) **:**

- Campaign production of:
  - Lyophilizates: Up to 1 500 vials / 2 ml
    - Non-sterile lyophilizates - **June 2017**
    - Sterile lyophilizates - **Dec. 2017**
  - Liquids and aseptic filling
    - Non-sterile liquid formulations
    - Monodoses (500–1000 strips) – **Dec 2018**

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www.nanopilot.eu

Thank you

Time for Questions

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