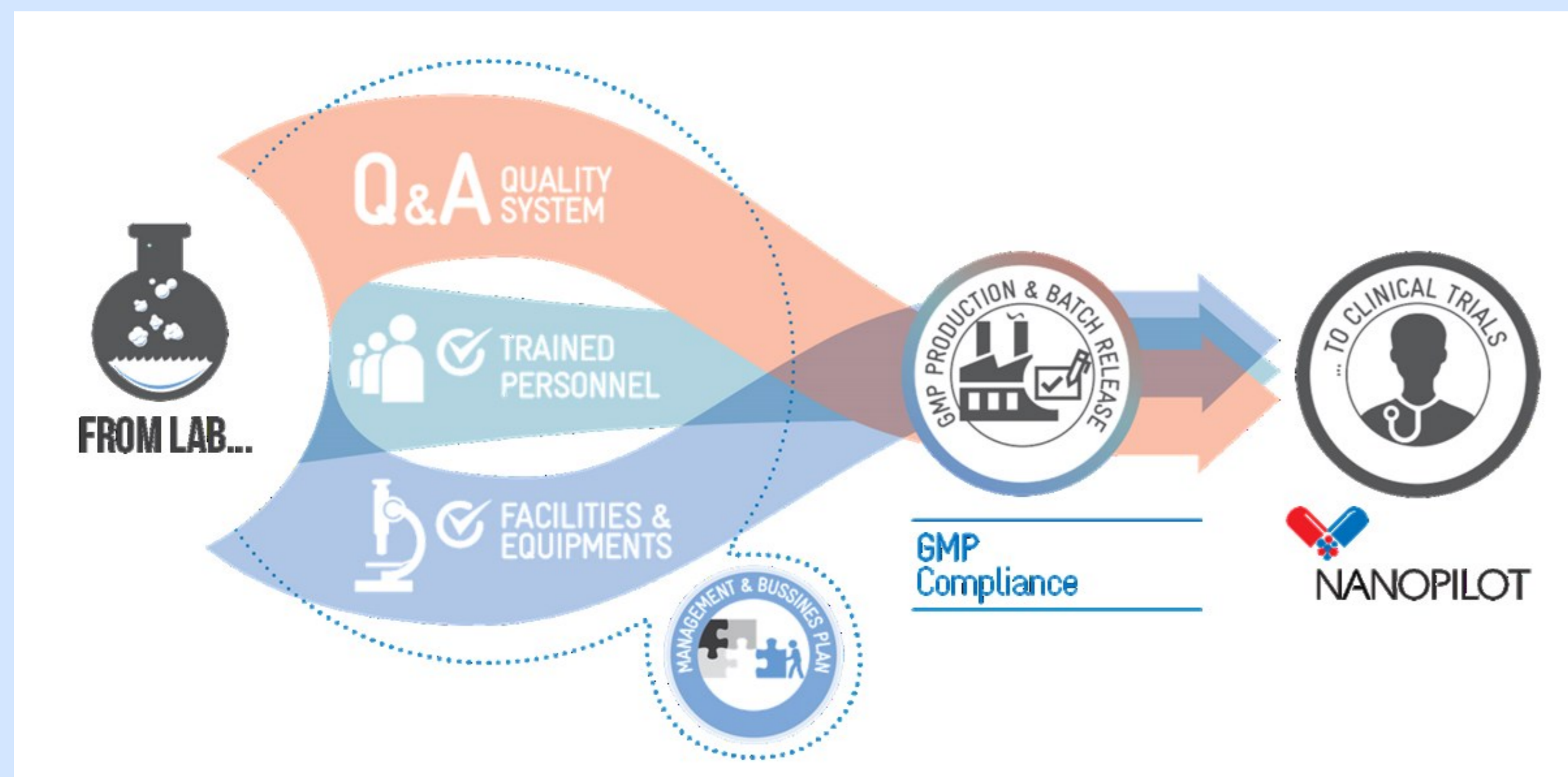


# A Pilot Plant for the Production of Polymer-based Nanopharmaceuticals in Compliance with GMP

## INTRODUCTION

### What is NanoPilot?

**NanoPilot** is an EU funded (H2020) research project that brings together the expertise of 9 partners to **set-up a pilot plant operating under GMP for the production of nanopharmaceuticals**.



NanoPilot aims to accelerate the development of nanomedicine, currently in its infancy within the pharmaceutical sector, **bringing into operation a flexible and adaptable pilot plant for the production of small GMP batches suitable for clinical trials**.

## OBJECTIVES

### What to expect from NanoPilot?

Three different nanopharmaceuticals will be produced during the project. The plant will integrate cutting-edge characterization techniques and microfluidics to control the production processes.

At the end of the project the pilot plant will be fully operating under GMP conditions, addressing some critical industrial needs:

- Production of small GMP batches for clinical trials.
- Flexibility and adaptability to prepare wide variety of nanopharmaceuticals.
- Specialization that guarantees the high quality of the products.

### THREE DIFFERENT NANOPHARMACEUTICALS PRODUCTION



*A RNAi-based nanoformulation for ocular pain treatment*

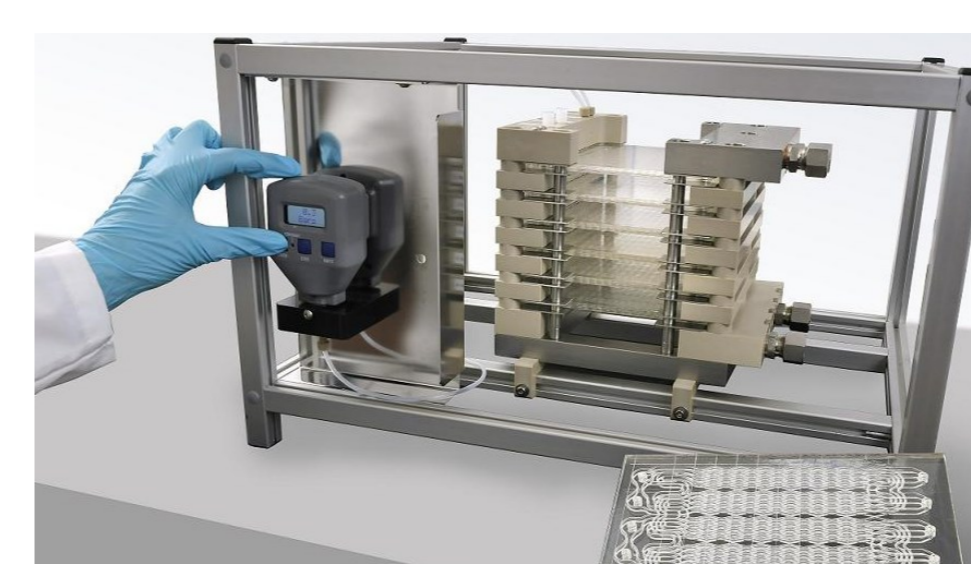


*A nanovaccine for HIV treatment*

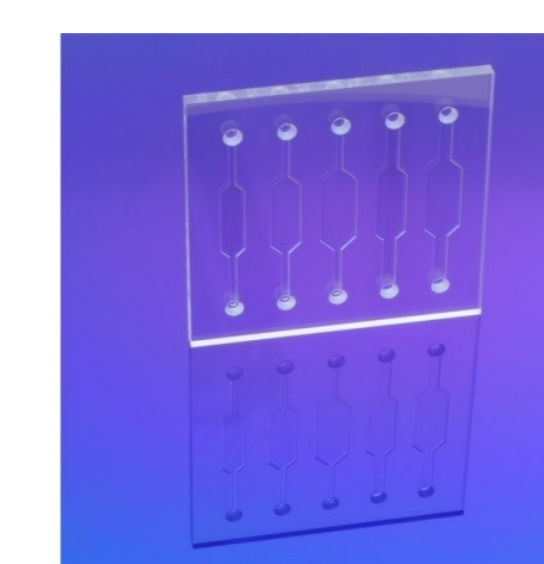


*Hyaluronan particles for interstitial cystitis/painful bladder syndrome*

### CUTTING-EDGE CHARACTERIZATION TECHNIQUES AND MICROFLUIDICS INTEGRATION



*Microreactors*



*Microfluidics chip*

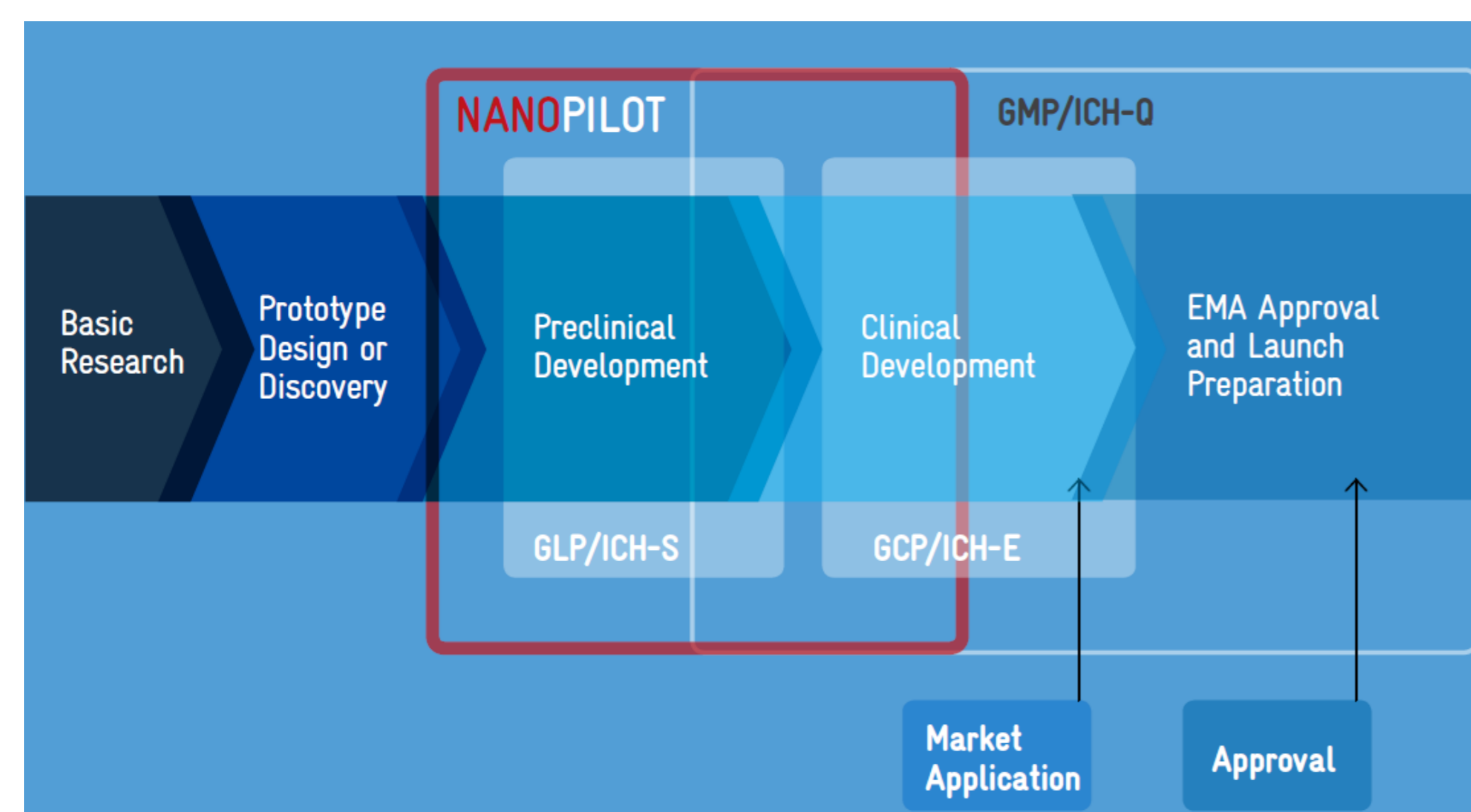


*Particle size fractionation in A4F*

## AN INDUSTRIAL NEED TO COVER

### Why NanoPilot?

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.



There is a **high potential of innovation** in SMEs/Industries working in nanomedicine. However, in most cases **clinical validation is still required** and production in quantity and quality (**GMP**) needed **remains a challenge**. In this context, it is **urgently needed** to provide those SMEs with the **tools that can help them** to validate their technologies.

## THE CONSORTIUM

**9 partners have joined forces to guarantee the successful outcome of the proposed project.**

### 2 INDUSTRIES

8. Sylentis
9. Chemtrix

### 3 SMEs

5. Micronit
6. Mejoran
7. Spinverse

### 4 RESEARCH GROUPS

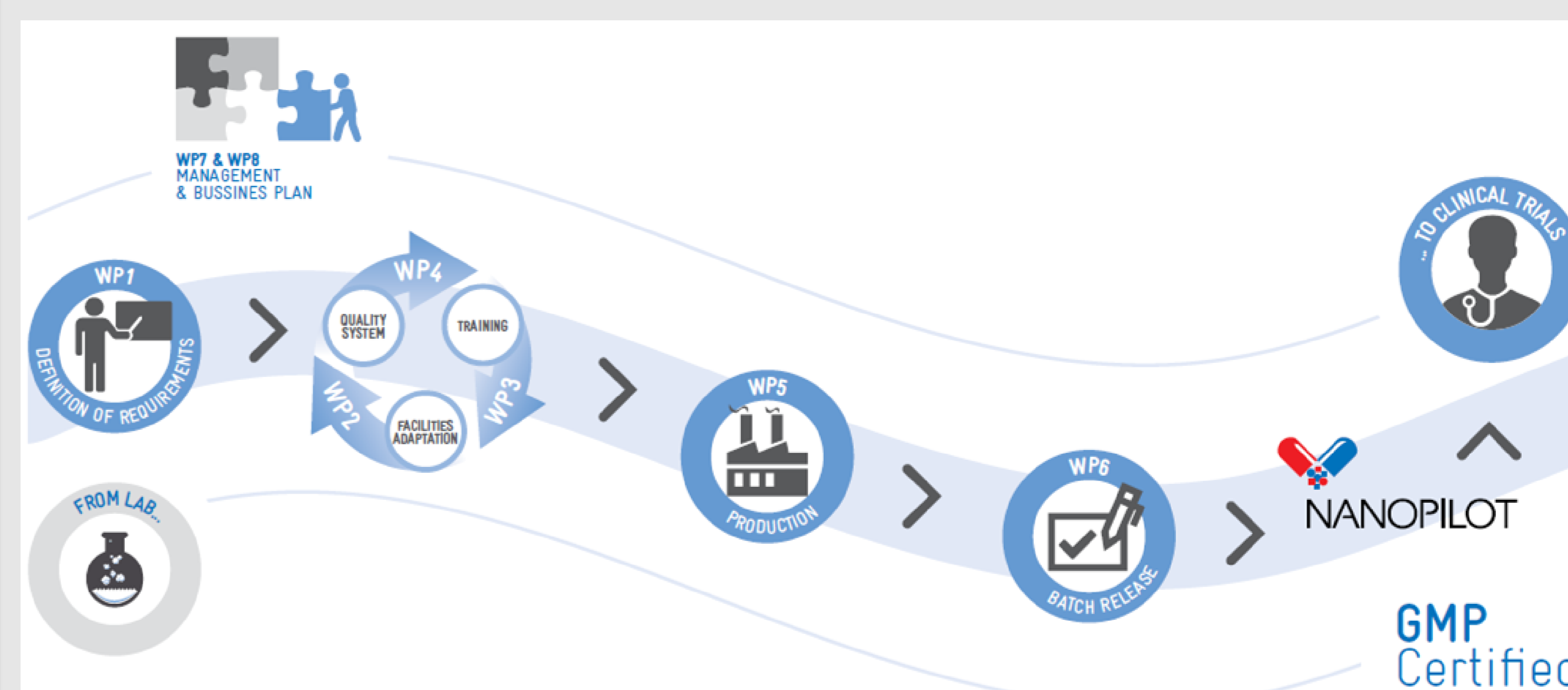
1. IK4-CIDETEC
2. National University of Ireland, Galway
3. University of Santiago de Compostela
4. ADERA-UT2A

## THE NANOPILOT CONSORTIUM



## WORK PACKAGES

### Project step by step



**WP1:** Definition of nanopharmaceuticals/design GMP production processes.

**WP2:** Adaptation of the facilities to a pilot plant working in compliance with GMP.

**WP3:** Training system implementation.

**WP4:** Quality system implementation.

**WP5:** Validation of GMP manufacturing processes and production.

**WP6:** Shipping and batch release.

**WP7:** Business and dissemination plan.

**WP8:** Management.

