

NANOPILOT:

A Pilot Plant for GMP

Manufacturing of Investigational

Medicinal Products (IMP)

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CIDETEC_Nanomedicine





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INTRODUCTION: The project behind the Pilot





Funded under European Union Framework Programme for Research and Innovation Horizon 2020 under Grant Agreement 646142

Project acronym: NanoPilot Grant Agreement no: 646142 Start Date: January 1st, 2015 End Date: December 31st, 2018 Project Budget: 6.28 M Euro Type: Research and Innovation Action

4 research groups, 3 SMEs and 2 industries, joined forces in NanoPilot.

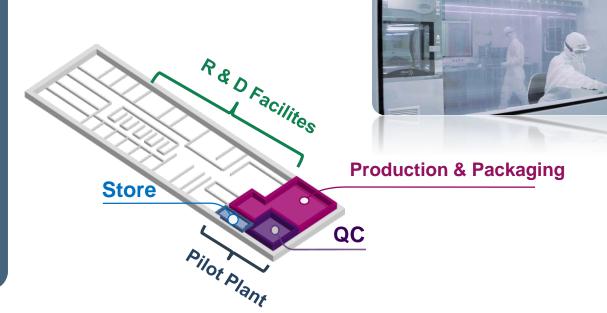
www.nanopilot.eu



NanoPilot is a four-year long project which objective is to set-up a pilot plant operating under Good Manufacturing Practices for the production of polymer-based nanopharmaceuticals.

Pilot Plant is established in San Sebastián in the R&D building of

CIDETEC Nanomedicine.



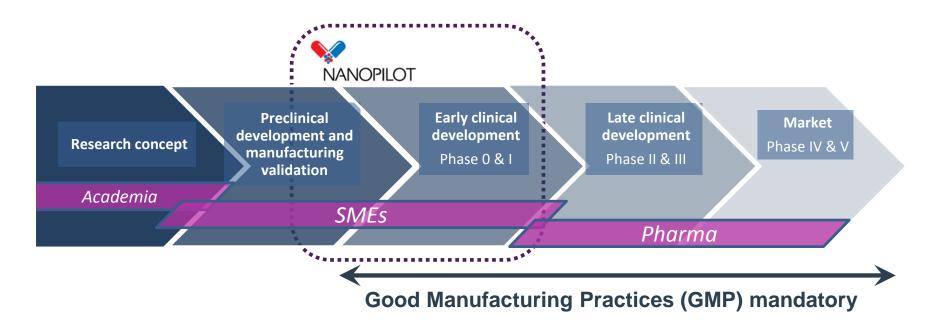


SERVICES & CAPABILITIES: A need to be met



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

- **Medium size companies** with limited R&D facilities, use their existing manufacturing plants, which are too big and too busy for R&D purposes.
- Small companies lack of resources to up-scale and implement GMP manufacturing.





GETTING TO THE END USERS/CLIENTS



A specific deliverable was prepared for dissemination plan

ACTIVITY		Year1							Year 2									Year 3									Year 4									
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Social Media																				10	10															



- International NanoScience Events
- Networking (EPPN, ETPN,...)
- Workshops
- Pharma Sector Events
- Biopartnering
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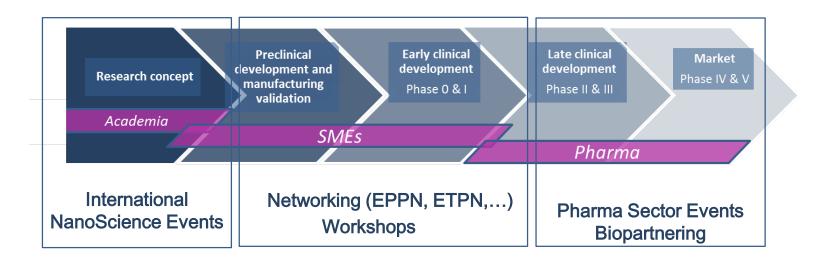


- Academia
- SMEs
- Biotechs
- Pharma
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GETTING TO THE END USERS/CLIENTS





Potential users already showing interest:

Small SMEs at regional level (three projects under negotiation)





BUSSINESS UNIT:



One stop shop / independent service units







Analysis

- Data Collection and Gap analysis.
- Current lab process evaluation.

Launching Stage

Development

- Understand the process DoE (process characterization).
- Development and scaling.
- QC strategy planning.
- QC processes development.
- Verification and validation.
- Sterility Validation.

Execution stage (I)

GMP Manufacturing

- Starting materials/providers evaluation.
- Manufacturing.
- Packaging.
- Quality Control...
- ...

Execution stage (II)-GMP

> FUTURE PLANS



Operate as a CDMO (Contract & Development Manufacturing Organization)
 The Pilot Plant integrated in CIDETEC Nanomedicine.

EU Programmes

- Partner in Test Beds initiatives
- EU Innovative Action (IA) Projects TRL 6-7;....
- Regional funds: Already working in two Programmes of the Basque Government
 - ELKARTEK : Working with R&D groups in QbD implementation.
 - ➤ HAZITEK: Subcontracted by companies taking part in this regional programme.

National funds

- Partner in RETOS programmes
- Subcontracted by companies financed by Spanish Centre for the Development of Industrial Technology (CDTI) programmes...

EXPECTATIONS ON EPPN



- To be a good platform to help us **identify European initiatives or projects** where the pilot plant could be useful.
- RIS3 strategy: EPPN can identify European regions that are or will be specialized in our sector and help us make contacts to find new projects and possible partners. Easy to contact companies in our own region but not so easy around the rest of European regions.
- To operate as a professional **networking to look for synergies** between pilot lines.
- EPPN to be a good showcase for the pilots:
 - ✓ Making it easier for potential users to find the services they need in a single platform.
 - ✓ Sharing information of interesting events where the pilots or the end users will attend.
 - ✓ Sharing examples of successful stories.

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THANKS FOR YOUR ATTENTION



nanomedicine

a greater future today