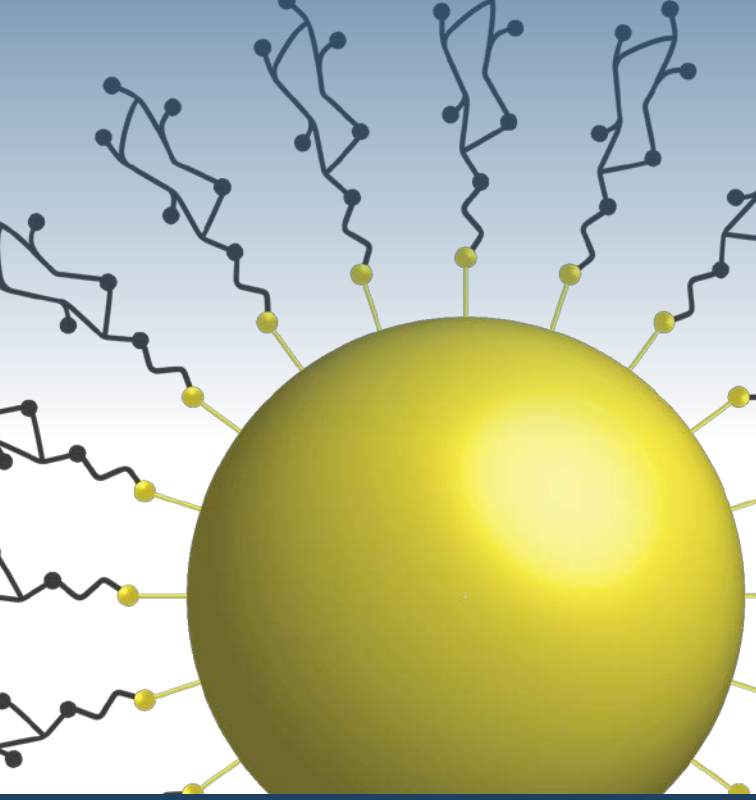


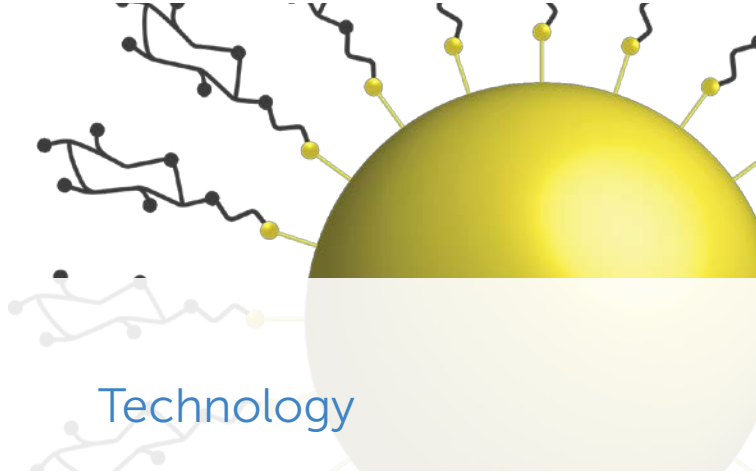
SCALE UP OF ULTRA-SMALL GLYCAN COATED GOLD NANOPARTICLES

nanofacturing

Nanofacturing is a European funded project that brings together a number of expert companies throughout Europe. Together, these partners set out to develop a manufacturing platform to support the extensive pipeline of nanomedicines being developed in Europe.

The project focused on the scale up of glycan coated gold nanoparticles, the latest generation of nanomedicines, and has designed and built pilot manufacturing facilities for the production of nanopharmaceuticals.

It aimed to address the small and medium-scale needs of early phase clinical trials and niche applications, to tackle the bottlenecks in the delivery of these medicines to the market. Furthermore, it supports later stage products with large potential markets, by developing clinically compliant, and sustainable, large-scale manufacturing processes capable of taking these products through to commercial manufacture and supply.



Technology

Nanofacturing's core technology relates to glycan-coated gold nanoparticles.

Gold nanoparticles comprise of a core of gold metal atoms surrounded by a layer of glycans (sugars) to which various ligands can be attached.

The small size of Gold nanoparticles creates several critical qualities for GNP-based drugs:

1. They are able to pass through normal pore sizes in blood vessels and circulate via interstitial flow to normal and diseased organs, therefore allowing delivery to a large number of disease sites

2. GNP's are quickly cleared from the body by excretion in the urine without the need for metabolism thereby increasing the elimination of the product

Tackling the challenges of
nanopharmaceutical manufacture

- There are a wide range of nanopharmaceutical products in development, however very few nanomedicines have been produced due to a lack of success translating ideas developed in the laboratory, through to final commercial product.

- Many innovative SME's do not have the resources to progress to making the volume of materials required and carrying out the testing needed.

- The development, scale up and manufacturing infrastructure and supply chain was not in place, or accessible.

- A greater understanding of how nanomedicines work within the body was required to navigate through a complex regulatory environment.

Project outcomes

The Nanofacturing project has successfully combined experts from a number of European organisations to develop an open-access pilot line, for use by companies throughout Europe, and a commercial batch process that operates under sterile conditions together with specialist analytical capability and custom ligand synthesis.

This provides a route for nanomedicines to be taken through to clinical trials, whilst also de-risking the capital expenditure associated with the installation of the industrial scale process plant, particularly helpful for SMEs. If these clinical trials are successful, this will allow improvements in the treatment of life-changing diseases. There are currently few manufacturing companies in this sector; this therefore provides a significant opportunity for the EU to create additional capacity in this high-value emerging market. Potential applications include:

- Antiviral
- Oncology
- Central Nervous System

Partners

GalChimia

cbni centre for biomedicine and innovation

Applus laboratories

MIDATECH PHARMA

cpi

EPFL

IFOM
ISTITUTO FIRC DI ONCOLOGIA MOLECOLARE

Acknowledgements

Nanofacturing has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 646364.

www.nanofacturing.eu
@nanofacturing