

Pilot production lines for the health, transport and industry-EPPN workshop

Venue: Parque Científico y Tecnológico de Gipuzkoa, Paseo Mikeletegi 53

San Sebastian, SPAIN

Date: November 5th 2019

Successful pilot production, from lab scale to small production, is an important success factor for the innovation potential and management of every manufacturing company.

EPPN: EPPN is the **European Network for Pilot Production Facilities and Innovation Hubs**. Pilot facilities respond rapidly to scaling-up needs, which are essential for SMEs and start-ups. They are tools to train next generation, upgrade European industry to stay competitive, generate business and potentially help create new business, jobs and growth across Europe by offering a dedicated infrastructure and service ecosystem.

This EPPN Workshop, in collaboration with SPRI, Business Development Agency of the Basque Government, dependent on the Department of Economic Development and Infrastructures and its Science, Technology and Innovation Network, address and gives the opportunity for exchange between pilot facilities and Open innovation test beds and for establishing further relations with industry.

AGENDA

9:30-10.00 Registration

10:00-11:15 Welcome. EU, national and regional perspectives

- Welcome- SPRI, Cristina Oyón
- Pilots and Innovation test-beds landscape, EC (tbc)
- EIT Innovation Communities – A success to integrate the Knowledge Triangle-
Antoni Pijoan - EIT Manufacturing
- Spanish participation in OITBs-Nieves Gonzalez, CDTI
- Basque Industry 4.0 -A regional example of an innovation hub –Cristina Oyón,
SPRI & Rikardo Bueno, BRTA

11:15-11:45 Coffee break

11:45-13:00 Initiatives supporting pilots & OITBs

- EPPN – Opportunities for SMEs, & marketplace
- ACEnano- Analytical innovation for complex nanomaterial characterisation-
Andy Chetwynd, University of Birmingham
- NanoCommons - How it can help you?- Beatriz Alfaro, BioNanoNet

13:00-14:30: Networking Lunch + Transfer to Test Bed Facilities

14:30-17:30 SECTORIAL PARALLEL SESSIONS AND PILOTS VISITS

Parallel session 1: Pilot lines and OITBs for INDUSTRY AND TRANSPORT SECTORS	
Venue: TECNALIA. Parque Científico y Tecnológico de Gipuzkoa Pº Mikeletegi, 1-3	
14:30-14:50	IZADI-NANO2INDUSTRY: Nanotechnology reaches industry Maider García de Cortazar, TECNALIA
14:50-15:10	Intelligent Open Test Bed for Materials Tribological Characterisation Services Alberto Alberdi, TEKNIKER
15:10-15:30	Battery Manufacturing Pilot Line as a tool for technology transference to the energy storage Industry Oscar Miguel, CIDETEC Energy Storage
15:30-15:50	Pilot for the fabrication of nanostructures across large and non-planar surfaces Isabel Obieta, TECNALIA
15:50-16:10	FormPlanet – Sheet metal forming testing hub
16:10	VISIT TO TECNALIA FACILITIES: buckypapers & composites manufacturing automatization
17:00	VISIT TO CIDETEC Surface Engineering facilities: <i>Anaphoretic electrocoating pilot line and other electrochemical surface treatment and complementary pilot lines</i>

Parallel session 2: Pilot Lines and OITBs for the HEALTH SECTOR	
Venue: CIDETEC. Parque Científico y Tecnológico de Gipuzkoa Pº Miramón, 196	
14:30-14:50	TB-MED An Open Innovation test bed for the development of high-risk medical devices Iraida Loinaz, CIDETEC Nanomedicine
14:50-15:10	Boosting the adoption of nano-enabled medical technologies: SAFE-N-MEDTECH Open Innovation Test Bed Ángel del Pozo, BOKERALTY Research Institute
15:10-15:30	MDOT – a platform for simplified conformity assessment of medical devices Ulrich Froriep, Fraunhofer Institute for Toxicology and Experimental Medicine
15:30-15:50	INNPAPER-Configurable and recyclable electronic platform based on paper CEA (tbc)
15:50-16:10	French open innovation platform for chemistry & environment (tbc)
16:10-17.15	VISIT TO CIDETEC Nanomedicine Facilities- <i>Pilot Plant for GMP Manufacturing of Investigational Medicinal Products</i>

SUMMARY OF PRESENTATIONS

Initiatives supporting pilots & OITBs

Acenano –Analytical innovation for complex nanomaterial characterisation

Andy Chetwynd, University of Birmingham



NanoCommons - How it can help you?

Beatriz Alfaro, BioNanoNet



The NanoCommons Transnational Access (TA) is an opportunity for nanosafety researchers from industry, academia and regulatory bodies to access the state-of-the-art expertise free of charge and take advantage of the NanoCommons services, facilities and knowledge to advance their work, solve problems and take their research to the next level.

NanoCommons is designed to provide innovative solutions for data mining, harmonisation, utilisation and re-utilisation, including incorporation of a range of modelling and decision support tools that require organised high-quality datasets on which to run, provided via an Open Access, federated Knowledge Commons platform. Access to the platform and the supporting tools will be provided to the nanosafety community and its broad set of stakeholders (enterprise, regulators, insurance and society broadly) via funded calls for Transnational access, as well as development of demonstration user case studies targeting the key stakeholders (academia, industry, regulators).

Benefits available to the pilot lines and industries community:

- Funded access to nanoinformatics tools
- EU funded access to expertise in data management and nanoinformatics tools
- Facilitate open access data to help reduce duplication of tests, regulation, animal-testing, bureaucracy...
- Assistance with capture and databasing of your data to comply with EU open data initiatives and achieve FAIR data principles (<https://www.openaire.eu/how-to-make-your-data-fair>).

Parallel session 1: “Pilot lines and OITBs for INDUSTRY AND TRANSPORT SECTORS”

IZADI-NANO2INDUSTRY: Nanotechnology reaches industry

Maidar García de Cortazar, TECNALIA



IZADI-NANO2INDUSTRY project aims at fulfilling market potential of nanotechnology through the production and validation of nano enabled products in pilots installed in industrial plants. Real solutions for the casting, injection moulding and thermal spray technology.

It proposes different solutions based on KETs such as nanotechnology, advanced materials and advanced manufacturing. The project aims to implement the master-batches, the master-pellets and the nanostructured powders in three innovative PILOTS, developed and installed at three existing production plants that will effectively manufacture real components (B-pillar, Swash plate and Valve plate) integrating safe-

by-design approaches into the developments stages. The project follows to develop inherently safer production methods.

IZADI-NANO2INDUSTRY is an industry driven project with up to 44% of the budget devoted to SMEs. It proposes solutions that will generate new market opportunities for European Automotive, Construction and Agricultural Machinery sectors offering to OEMs new added-value products. It is supported by the government of the regions where the PILOTS will be installed. The project addresses an innovation action that is in line with the Basque Country, Lombardy and Emilia-Romagna region's RIS-3 Smart Specialization Strategy.

Intelligent Open Test Bed for Materials Tribological Characterisation Services

Alberto Alberdi, TEKNIKER



Wherever moving bodies are in contact with each other, the respective materials undergo certain friction and wear that define their tribological performance. To support industrial innovation among European industry, the incorporation of new advanced materials is required that demands an extensive tribological characterisation.

i-TRIBOMAT aims at establishing the world first open test bed for tribological characterisation of materials to support industrial innovations by upscaling new advanced materials to the mechanical component level. i-TRIBOMAT services combine conventional laboratory level tribotests with Artificial Intelligence tools, i.e. federated data analytics, database searches and finite element modelling, which allow up-scaling laboratory test results and online monitoring data to infer friction and wear behaviour of real components.

To do so, an intelligent tribological infrastructure is set up. GRANTA and ATOS as artificial intelligence experts develop the platform and 4 of the most competent European tribology centres, AC2T, BAM, VTT and Tekniker, provide their expertise and share their tribological characterization equipment, among which are more than 100 tribometers.

Battery Manufacturing Pilot Line as a tool for technology transference to the energy storage Industry

Oscar Miguel, CIDETEC Energy Storage

This Battery Manufacturing Pilot Line was initially set up at the premises of a local customer company, a consumer battery manufacturer, in the context of a joint R+D cooperation to position the Company in the Li ion manufacturing market.

Today, this pilot line is fully owned by CIDETEC Energy Storage, located in its main building. This pilot line is being intensely used in EU funded projects, where CIDETEC gains knowledge about new battery materials, offering its extensive expertise in processing them into industry-standard electrodes and battery cells. Some of them are: [SPIDER](#), [SI-DRIVE](#), [IMAGE](#), [GreenLion](#) and [MARS-EV](#).



Moreover, our Battery Manufacturing Pilot Line has become a benchmark for our activities in technology transference towards the industry, with customers ranging from start-ups and SMES, to large automotive OEMs doing their research in battery materials and components.

As a highlight, CIDETEC Energy Storage is involved in the core consortium of a brand new initiative under the auspices of the European Battery Alliance, targeted to establish an European Lithium Ion Pilot Line Network. The initiative, tentatively named LiPLANET, is currently under Grant Agreement preparation together with the EU Commission.

The pilot plant was funded with regional and internal resources. Nevertheless, it is an Open Pilot Line, and in this moment, as mentioned, CIDETEC Energy Storage is doing research and innovation with different clients, both large enterprises and SMEs.

Pilot for the fabrication of nanostructures across large and non-Planar surfaces

Isabel Obieta, TECNALIA

The aim of SUN-PILOT is to develop a novel and cost-effective platform for up-scaling the fabrication of sub-wavelength nanostructures across large and non-planar surfaces. This is to be achieved using state-of-the-art block copolymer chemistry and highly scalable etching and injection moulding methods.



SUN-PILOT is an EU-funded collaboration that aims to prototype an industrial and cost-effective process for creating nanostructures similar to the moth eye on a variety of materials.

Using advanced polymer chemistry, plasma etching and injection moulding techniques, the surface properties of target materials will be transformed. Some will become antireflective and hydrophobic, whilst others will become more tactile and softer to touch. With SUN-PILOT, biomimicry will come to life.



VISIT: TECNALIA Facilities

1.-BUCKYPAPERS_ Carbon nanotubes in thin sheet.

Buckypapers enable nanotechnology to be efficiently and safely introduced into materials compounds providing multifunctionality. Carbon nanotubes available in manageable and easy-to-integrate format.



Introducing high carbon nanotube contents into composite structures is Complicated. In processes such as roll to roll and automatic layup and prepreg manual, for example safety aspects associated with the use of nanomaterials in the form of dust or

Masterbatch. In liquid process processes, the well-known filter effect is added: bottleneck introducing nanotechnology into composite manufacturing processes.

Advantages: Allows transition from nano to macro. Transferring the properties of nanomaterials to macroscale composite materials getting together functionalities in a single product.

2.-LOW FLIP- Automation of composite manufacturing.

This is an automated composite component-manufacturing cell. This cell is the industrial



evolution of Tecnalia Tecnacomp's asset, and allows cure the resin to get the final piece. The cell is based on a robotic material handling gripper, which in the demo typically captures and deposits pre-impregnated and/or dry fabrics and a foam core into the mold. On the other hand, the cell has a conveyor belt that moves the mold through the different manufacturing stations, a preformed first with a high-

extension membrane and a second where a self-heated 3D membrane allows the resin to be cured to make the final piece.

VISIT: CIDETEC Surface Engineering Facilities

3.- Anaphoretic electrocoating pilot line and other electrochemical surface treatment and complementary pilot lines

The pilot line of CIDETEC (EPPN registration) can develop anaphoretic electro-coatings (e-coating) on light metals (such as Al, Mg and Ti alloys) and it is a versatile pilot line in which Al alloy parts can be anodized and metal parts electropolished.

Anaphoretic e-coating consists of applying an organic coating anodically by immersion using electric current. It has the advantage of enabling painting without the need of preliminary priming. CIDETEC has a complete pre-treatment line including degreasing (175 L), pickling (150 L), anodizing (230 L) and several rinsing stages (120-150 L) for an excellent surface preparation before applying the anaphoretic e-coating. The e-coating system itself has a capacity of 400 L of anaphoretic bath divided in two tanks, one of them for the bath recirculation and maintenance. Versatile titanium jigs are used for validation panel's preparation. They are adjustable jig carrier systems to coat several panels of different dimensions at the same time and in some cases for specific prototypes geometries is useful.

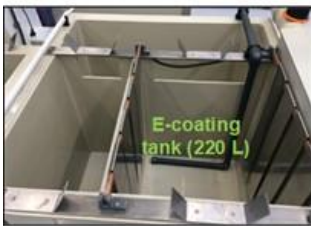


ECOLAND is the most singular project in which CIDETEC is using this pilot line. The project is a Clean Sky2 Project focused on the development of an alternative treatment to Cr(VI) anodising that is based on an anaphoretic electrocoating or "E-coat" process that meets REACH standards. More information in the next links:

More information can be found in the next links:

<https://www.cidetec.es/en/projects/surface-engineering-6/ecoland-4>

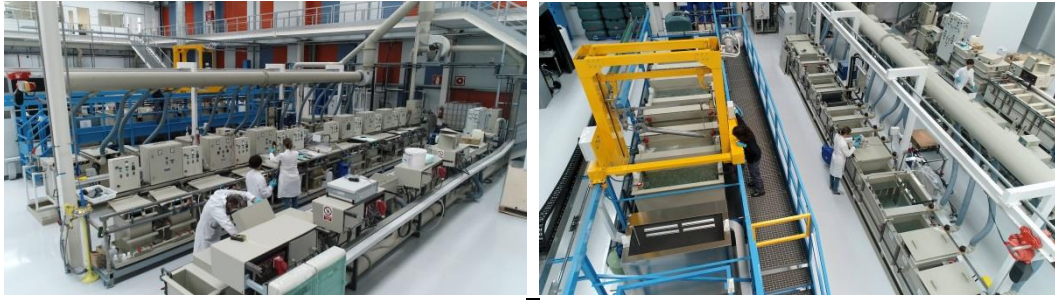
https://www.cidetec.es/qestor/recursos/uploads/archivos/ECOLAND_TRIPTICO.pdf



Facilities

- Pre-treatment line with degreasing (220 L), pickling (150-180 L) and several rinsing stages (150-180 L)
- Anaphoretic electrocoating system (400 l, divided in two tanks)
- Ultrafiltration unit (140 l)
- Complementary facilities (for prototype testing):
 1. Corrosion testing laboratory
 2. Chemical analysis laboratoryNot available at CIDETEC – Fatigue testing

CIDETEC has also a second pilot line for other electrochemical surface treatments to deposit metal or metal matrix composite coatings, such as, electroless nickel plating and electroplating (direct current or pulsed current).



Parallel session 2: “HEALTH SECTOR” (Pilot/ OITBs PRESENTATIONS WITH CASE STUDIES)

TB-MED-An Open Innovation test bed for the development of high-risk medical devices

Iraida Loinaz, CIDETEC Nanomedicine



Due to long reimbursement processes, patient access to innovative high-risk medical devices (\geq Class IIb) in Europe can take four times longer than in the U.S. In addition to this, the new regulations will stricter ex-ante controls for this type of devices. This scenario represents a big challenge for European high-tech SMEs (representing 95% of the MedTech sector in Europe) to maintain their competitiveness and innovation capacity. TBMED will provide an integral service to accelerate the development of medical devices reducing time to market, covering technology development from TRL4-7 based on Quality-by-Design (QbD) concept and business management services. QbD concept enhances product and process understanding together with process control, based on robust scientific knowledge and quality risk management.

TBMED aims to establish an open innovation testing bed (OITB) specialized in the development of high-risk medical devices. Once operating (in 2022), the OITB will integrate:

- 1) A SME office that will provide business advice and IP management;
- 2) Services on regulation, early health technology assessment advice and QbD;
- 3) Biomaterial synthesis lab;
- 4) Characterization facilities;
- 5) Testing lab for in vivo and in vitro efficacy testing;
- 6) Safety assessment; and
- 7) Clinical testing.

Three case studies will be used to validate the concept and will help to establish the OITB: 1) An osteoinductive hydrogel; 2) Keratoprosthesis; and 3) Magnetic NPs for hyperthermia.

For more information see: <https://www.tbmed.eu/>.

Boosting the adoption of nano-enabled medical technologies: SAFE-N-MEDTECH Open Innovation Test Bed

Ángel del Pozo Pérez, BIOKERALTY Research Institute



SAFE-N-MEDTECH aims to bring a strong and competitive cooperation throughout its Open Innovation test Bed (OITB). This OITB will offer a multidisciplinary and market-oriented innovation approach to academics, SMEs, Healthcare providers and Industries for the translation to the market of nano-enabled MTs,

based on a deep understanding and knowledge of the material nano-properties, their use and applications in MTs and all the aspects involved in MT safety (biocompatibility, toxicology, electromagnetic properties, etc).

SAFE-N-MEDTECH will build an innovative open access platform to offer companies and reference laboratories, the capabilities, knowhow, networks and services required for the development, testing, assessment, upscaling and market exploitation of nanotechnology-based Medical and Diagnosis Devices. This across the whole Life Cycle of nano-enabled MTs.

MDOT – A platform for simplified conformity assessment of medical devices

Ulrich Froriep, Fraunhofer

The Medical Device Regulation has introduced a new level of patient safety, product reliability, and clinical performance criteria within the conformity assessment process. This, however, places a heavy burden on medical device innovation in Europe, since the clinical and the reporting and surveillance requirements have significantly increased. Small and medium-sized enterprises (SMEs) are particularly affected by the extensive documentation and reporting obligations and the new clinical testing requirements of the MDR. To support SMEs and simultaneously enhance quality and regulatory compliance, MDOT will establish a platform enabling automated conformity assessment processes and access to technical and clinical data across Europe. Through the MDOT platform, manufacturers can get information about the requirements they have to meet for their conformity assessment, compile the required documentation, and they receive access to state-of-the-art test beds when additional data is required. The feasibility of this process will be demonstrated using three technological developments in the fields of inhalers, neural and hip implants.

INNAPER - Configurable and recyclable printed electronic point of care bioplatfrom based on paper

CEA and CORIS Bioconcept (tbc)



The detection of DNA is of central importance for the diagnosis of genetic diseases and infectious agents. Traditional technologies for DNA detection, such as Polymerase Chain Reaction (PCR), have been widely used in well-equipped laboratories. However, truly portable PoC DNA tests are still missing. Specific challenges associated with

the development of PoC DNA tests include the integration of the sample pretreatment and amplification steps in the PoC device. Several disposable paper-based lateral-flow assays for DNA detection exist and are commercially available, but all of them require trained personnel to perform the sample pre-treatment and amplification steps out of the PoC device.

INNAPER main progress in this field will be providing truly portable paper-based PoC devices for DNA detection, integrating the sample pretreatment, DNA amplification and detection steps in one system, enabling users to obtain accurate results directly on the display integrated on the strip and to manage the data from their Smartphones.

Within INNAPER the bioplatfrom prototypes are being developed by CEA-LETI and CEA-LITEN, in close collaboration with CORIS Bioconcept, a Belgian SME specialized in developing, manufacturing and marketing rapid diagnostic tests. The protoypes will be manufactured at the CEA printing platform called "PICTIC". The PICTIC platform is opened to industrial partners, especially SMEs and start-ups to foster TOLAE products to enter the market. It is designed to

scale up printed devices from laboratory level (TRL 3-4) to TRL 7. It includes a complete set of industrial coating, printing equipment and characterization tools.

CORIS Bioconcept will test and validate the resulting paper-based PoC genetic assays by comparing the results obtained with the developed devices and the ones obtained with an official method (such as the quantitative-PCR).

For more information see: <https://innpaper.eu/> or [project video](#).

VISIT: CIDETEC Nanomedicine Facilities

1.-Pilot Plant for GMP Manufacturing of Investigational Medicinal Products

Related project: NANOPILOT



NANOPILOT

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

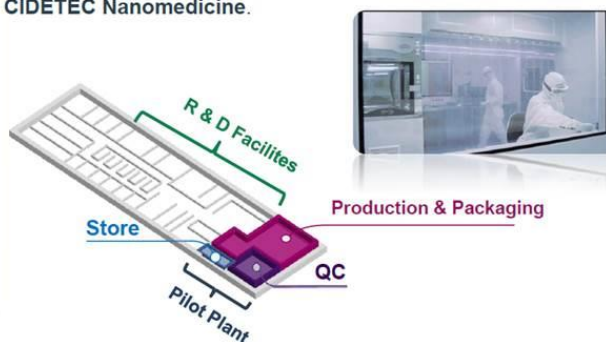
4 research groups, 3 SMEs and 2 industries, joined forces in NanoPilot.

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.



More Info: <http://www.nanopilot.eu/homepage> and <https://www.cidetec.es/en/projects/nanomedicine-9/nanopilot-2>