National Innovation Hubs – Best Practices

BIO NANONET

Falk, A.[1], Resch, S.[1], Schimpel, C.[1], Jagersbacher, S.[1], Ladenhauf, N.[1], Halbedl-Herrich, A.[1], Köstler, S.[2], Klein, T.[3], Khinast, J.[3], Smolka, M.[4], Katz, G.[1,4]

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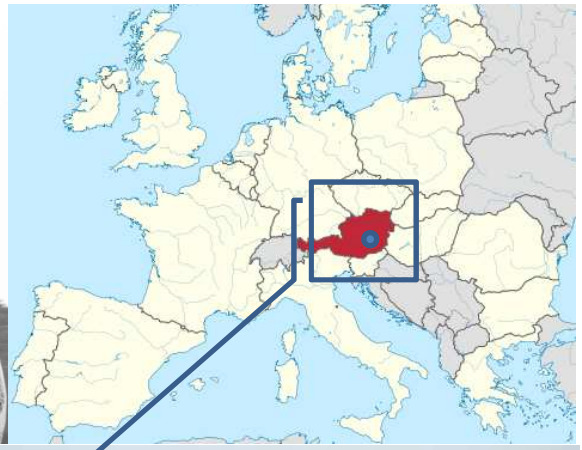
Building Innovation Hubs 4.0
18th September 2017| Porto| Portugal

Agenda

- Hub concept / strategy for establishment of the hub
- Hub services and thematic areas
- Structure of **Austrian Innovation Hub** BioNanoNet
- What does our innovation hub offer
- Best practices / Pilot facilities
- Take home messages

Who we are: BioNanoNet Forschungs-gesellschaft (BNN)



located in Graz, Austria

BioNanoNet association - Members (18th of Sept. 2017)

Industrial Liaison Department

supported by

Hub services and thematic areas

- Our partners offer **scientific expertise:**
  - Molecular Imaging, Drug delivery, Molecular targeting, Nanotoxicology, Biobanking, Biosensors, Process analytical technologies (PAC)…
- …and BioNanoNet adds know-how in…
  - NanoSafety, Safe-by-design, regulatory aspects
  - Coordination, management, communication and dissemination activities

BIONANONET NANO TOXICOLOGY

BIONANONET HEALTH SAFETY MEDICINE

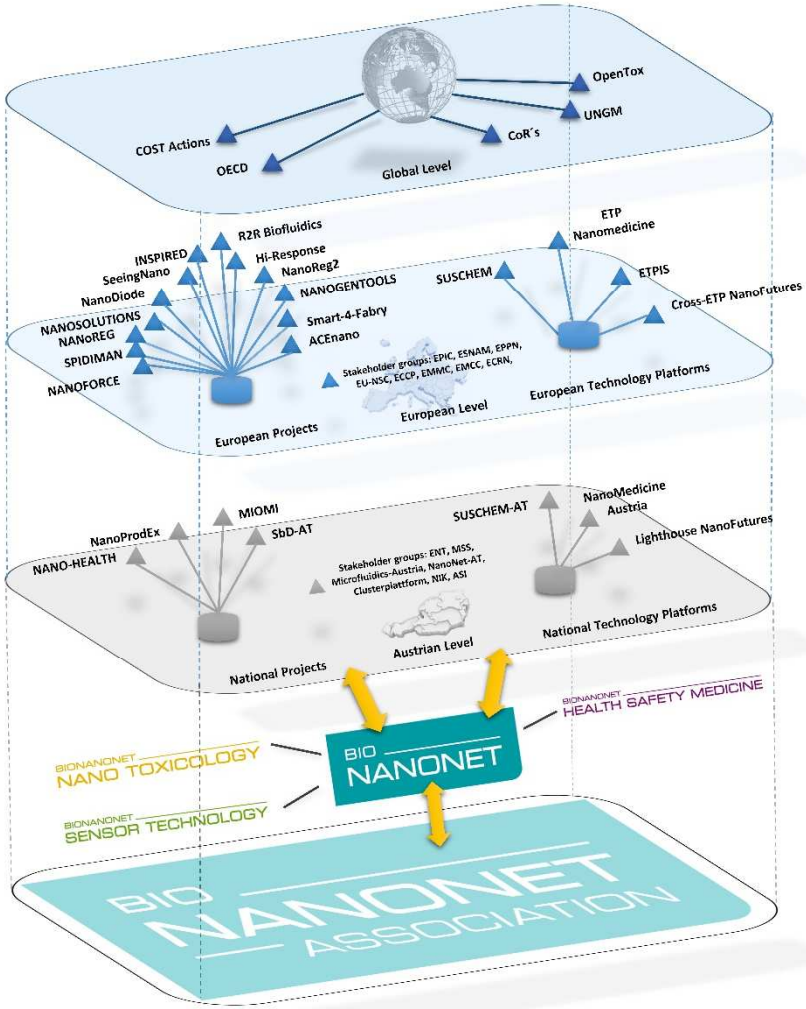
BIONANONET SENSOR TECHNOLOGY

Structure of Austrian Innovation Hub

BioNanoNet network

…enabling:
* stability
* continuity
* sustainability
* value added

by collaboration



Innovation hub → Pilots → Industrial innovation liaison (i2L)

SUSCHEM AT

NANO MEDICINE AUSTRIA

BioNanoNet - hub concept (1/2)

- Supporting the **technical development** from the very early stages in the production cycle to market;
- Developing safety assessment strategies tailored to special requirements **in different domains**
- Providing access to design (incl. SbD), testing (e.g. (pre-)clinical), safety assessment, and upscaling **facilities for different domains**; **Upscaling** specialisation e.g. in (nano)pharma, (nano)medicines, printing, medical parts
- Bridging nanosafety with production/application **along the entire value chain** (incl NSC / EPPN, etc.)
- Connecting regional strengths to international needs

BioNanoNet - hub concept (2/2)

Thematic areas:

- Medical technologies (in-vitro Diagnostics, Point-of-care, …)
- Smart Sensor & Actuator Systems (IoT, Automotive, etc.)
- Printed Electronics
- Sensors (e.g. wearable sensors, medical sensors, biosensors)
- Process control for Chemistry and Biotechnology, process analytical technologies
- Environmental Monitoring
- Nanomedicine (Nanopharmaceutics/Therapy, Diagnostics, Regenerative Medicine)
- NanoSafety along the entire value chain

Best practices & Pilots

Facilities (examples!):

- Research Center Pharmaceutical Engineering GmbH
- PAYER Medical GmbH
- JOANNEUM RESEARCH GmbH

Projects:

- R2R Biofluidics → → roll-to-roll-printing
- INSPIRED → → large scale synt. f. printed electr.
- Hi-Response → → high resolution printing
- Smart-4-Fabry → → nanopharmaceutics
- ACEnano → → characterisation (*no pilot*)

BIO NANONET

research center pharmaceutical engineering

We make tomorrow's drugs possible.

RCPE GmbH
Quality – Knowledge – Experience
New Pilot Plant Building

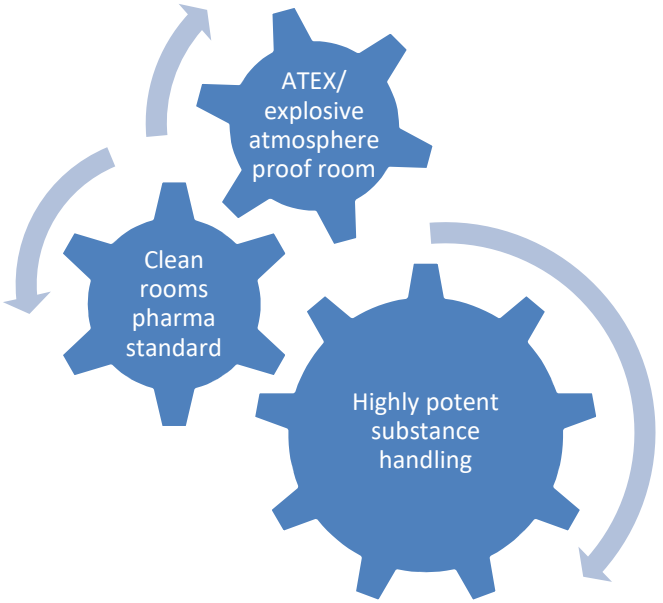
September 2017

K1 Competence Center - Initiated by the Federal Ministry of Transport, Innovation and Technology (BMVIT) and the Federal Ministry of Science, Research and Economy (BMWFW).
Funded by the Austrian Research Promotion Agency (FFG), Land Steiermark and the Styrian Business Promotion Agency (SFG).

RCPE – State-of-the-Art New Pilot Plant

Open and upgraded facilities at the EU level for the design, development, testing, safety assessment and upscaling:

- New building with **400 m²** of state-of-the-art facilities
- Pharma standard clean rooms **(ISO 7)**
  - Occupational Exposure Banding **(OEB) Level 4**
  - Handling of highly potent substances **(~ 100 m²)**
  - Negative pressure and decontamination air locks
- One dedicated VEXAT room
- **Certified ISO 9001** Quality Management
- **Certified ISO 14001** Environmental Management



RCPE – New pilot plant with Cutting Edge Technology

Highly promising applications in industrial productivity, reliability, environ-mental performance,durability,reduction of life-cycle & energy consumption

Facilities and equipment:

- Six new process rooms
- Continuous manufacturing focus, e.g.:
  - ConsiGma25 (GEA) – 25 kg/h
    1. Granulator unit
    2. Dryer unit
    3. Discharger unit
  - Courtoy tablet press (GEA)

- Extensive selection of equipment (different scales)
- RCPE Modelling and Simulation at call
- RCPE analytical laboratory on site

Hot melt extrusion

Co-extrusion

Injection molding

Continuous processing

Tablet press

Capsule filling

Others…

ConsiGma 25 (GEA) + Courtoy tablet press for continuous processing – exemplary layout
Source: GEA, www.gea.com

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PAYER

Perfect. From Experience /

PRINTED SENSORS PILOT MANUFACTURING LINE

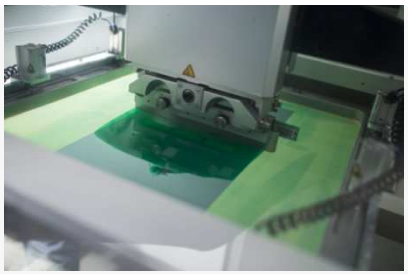
PAYER MEDICAL GMBH

SENSOR TECHNOLOGY
ADVANCED CONSUMABLES
SYSTEM INTEGRATION

Falk A., Porto, September 18th, 2017

PRINTED SENSORS PILOT MANUFACTURING LINE

- **Manufacturing of printed sensors** & **biomedical consumables** in a **flexible and modular set-up**.

Printed Sensors Pilot Manufacturing Line			
Functional Materials Printing	**Functional Materials Deposition & Curing**	**Polymer Moulding & Tooling**	**Assembly, Bonding & Packaging**
			

- technical, personal, and logistic capabilities for
  - **Materials & process development and optimization**
  - **Gradual ramp-up to pilot production**
  - **Transfer to full scale industrial production**

- ISO 7 & ISO 8 cleanroom production facilities.
- EN ISO 13485 certified and FDA registered for **development and manufacturing of medical products**

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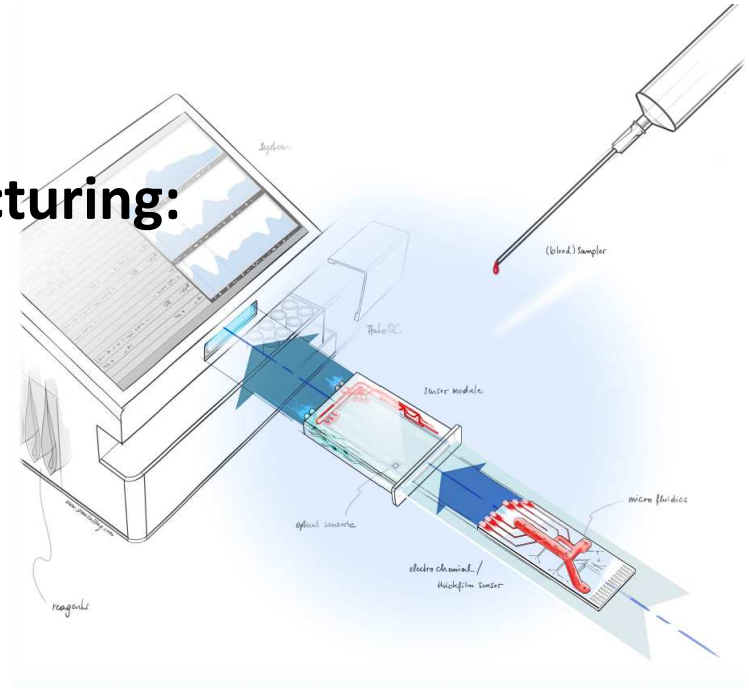
PRINTED SENSORS
CASE STUDIES / EXAMPLES

Conception, Development & Pilot Manufacturing:

Example: Blood Electrolyte Sensor Modules

- Module for integration with clinical analysers or point-of-care instruments
- Screen printed sensors and electrodes, injection moulded microfluidics, fluidic & electronic connections, reagents, etc.

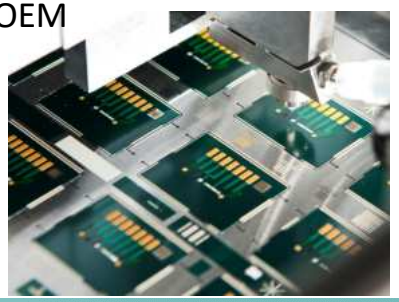


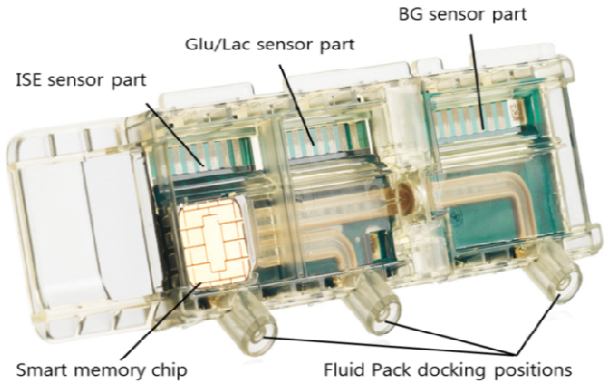
Upscaling & Industrial Series Production:

Example: Blood Gas, Electrolyte & Metabolite Biosensor-cartridges

- 10 parameters from 125 µL of whole blood
- >30.000/year produced for large diagnostics OEM (incl. assembly, QC, packaging)

pO_2	pCO_2	Na^+	K^+	Glucose
pH	Hct	Ca^{++}	Cl^-	Lactate





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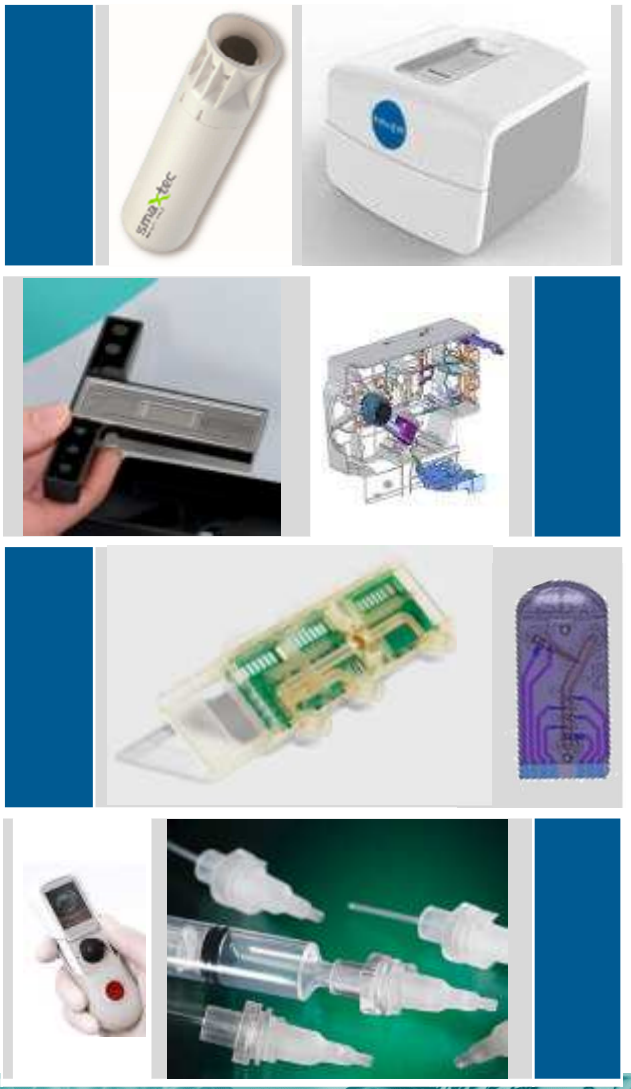
FURTHER POSSIBLE EXAMPLES AND APPLICATION AREAS

- Product and Process Examples:
  - Electrochemical and Optical Chemo- and Biosensor Systems
  - Biomedical Consumables and Cartridges
  - Flexible Electrodes
  - Capacitive, piezoelectric or impidimetric sensor and actuator structures
  - Materials Deposition & Functionalization of PCB or microchip based platforms
  - etc.

- Potential Application Areas:
  - **Medical Technology (in-vitro Diagnostics, Point-of-care, …)**
  - **Smart Sensor & Actuator Systems (IoT, Automotive, etc.)**
  - **Printed Electronics**
  - **Wearable Sensors**
  - **Process control for Chemistry and Biotechnology**
  - **Environmental Monitoring**
  - **etc.**



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OPEN INNOVATION HUB
TECHNOLOGY OFFER

- Development of **printable formulations and inks** from functional materials
  - **Advanced materials, nanomaterials, composite materials, biomaterials, etc.**
- Development of **processing techniques** for functional materials formulations
  - **Screen or stencil printing process development**
  - **Dispensing and materials deposition process development**
  - **Drying and curing process development for printed materials**
- **Upscaling** of these processes and **transfer to industrial production scale**
  - extensive **in-process control** (IPC) for process optimization, QC and traceability
- **Prototyping** and **pilot series manufacturing** of **injection moulded polymer parts**
  - Commodity polymers, medical & optical grade polymers (COP/COC,…), high performance polymers (PEEK, …), composite materials, …
  - Two-component injection moulding
  - Moulding tools (from prototyping to series tools)
- **Systems integration**, Module assembly, etc.

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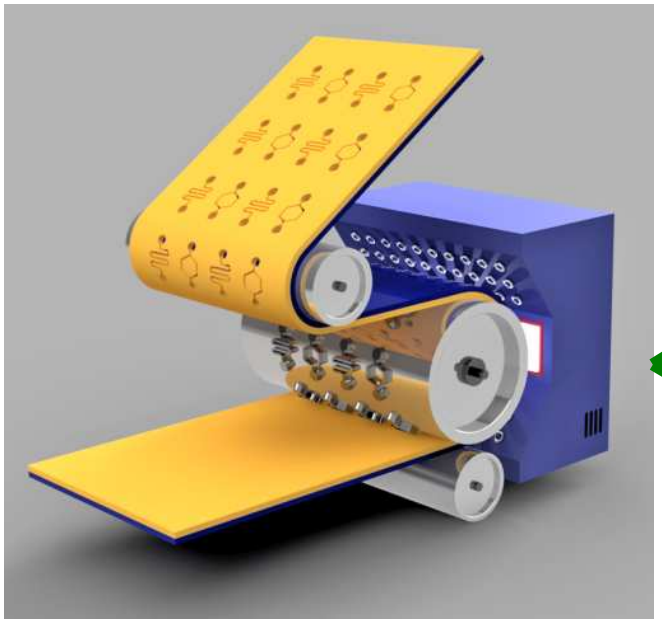
Roll-to-Roll production of Microfluidic Devices

Cost effective manufacturing of Microfluidic Systems

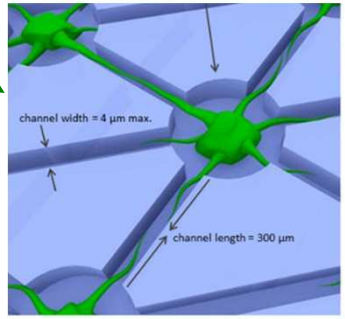


Microfluidic biosensors

FFG

MoMiFlu@FOil

Smart cell culture substrates



R2R BIOFLUIDICS

Pilot facility under development – open to become part of proposal

Take home messages

BioNanoNet offers **technical development** part in/for your innovation hub e.g. in the field of medical technologies and safety, nano-enabled surfaces and multifunctional materials, nano-pharmaceutical production.

Together with our network we provide:

- **access to** design (incl. Safety-by-design support), development, testing, safety assessment, and upscaling **facilities for different domains**
- quality control processes
- pilot facilities / demonstrators / upscaling

Thank you very much for your attention

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Nikolaus Ladenhauf

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