PHOENIX-OITB – A single entry point to develop and upgrade innovative nanopharmaceuticals

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ABSTRACT

The PHOENIX Open Innovation Test Bed (PHOENIX-OITB) is focused on overcoming the challenges of production of novel and innovative nanopharmaceuticals (NPs) from lab scale to GMP quality and production, maximising bioavailability, stability and manufacturing to allow their implementation in the medicine field.

PHOENIX-OITB is a non-profit, open and self-sustaining legal entity that works as a Single-Entry-Point (SEP) providing its end-users transparent processes and procedures as well as easy access to services and expertise needed to bridge the gap between the bench and the bedside, i.e., providing them with high-quality services, capable of Quality-Efficacy and Safety (QES) evaluation and production of nanopharmaceuticals at large scales, meeting the regulatory and GMP requirements.

METHODS

The PHOENIX-OITB has been structurally conceived, designed and officially registered under the legal non-profit company, PHOENIX gGmbH. To test the operative capacity of PHOENIX-OITB, five demo-cases of different NP types, manufacturing methods and administration routes will be employed. Additionally, two pro bono demo-cases will be launched and granted to external users to test the services at relevant and operational environment.

1 HOW IT WORKS

PHOENIX concept & service strategies

PHOENIX offers solutions to overcome the biggest hurdle in the translation process of most nano-pharmaceuticals – the so-called “innovation valley of death”.

The Single Entry Point of the PHOENIX-OITB provides access to a consolidated network of facilities, technologies, services and expertise for all technology transfer aspects from characterization, testing, verification up to scale up, GMP compliant manufacturing and regulatory guidance. The OITB services include production and characterisation under GMP conditions, safety evaluation, regulatory compliance and commercialisation boost.

2 WORK PLAN

Implementing ideas into action

WP1: Overall Sustainability & Business Development (Exploitation) of the PHOENIX-OITB association

WP2: Quality Management

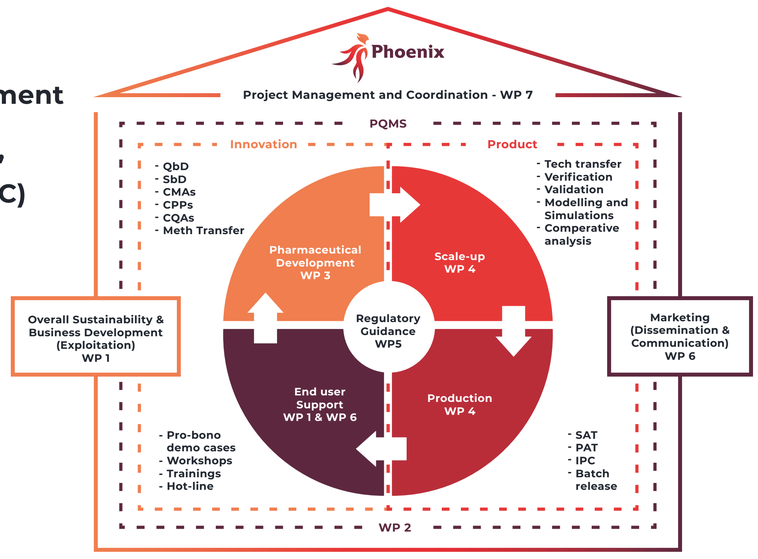
WP3: Research and Development

WP4: Production (Chemistry, Manufacturing, Control – CMC)

WP5: Regulatory Support

WP6: Marketing (Dissemination & Communication)

WP7: Project Management and Coordination



RESULTS

Process transfer and method development for all five demo-cases are ongoing while GMP production area is being constructed. The Pharmaceutical Quality Management System (PQMS) is being established and all exploitation activities are being managed and can be seen through: www.phoenix-oitb.eu. Furthermore, PHOENIX-OITB Open Call for the granting of two pro bono demo-cases to external end-users has been launched and applications are under evaluation.

3 DEMO CASES

Demonstrating scalability from prototype to industrial manufacturing

To establish the operative capacity of PHOENIX-OITB, five demo-cases representative of five different nano-pharmaceutical types, four different manufacturing methods and three different administration routes will be employed to demonstrate and verify the PHOENIX technologies in an industrially relevant environment.

1. **Polymer-based diagnostic agent**
2. **Polymeric particle conjugates loaded with small peptides**
3. **Oral formulation of nanocrystals**
4. **Nanoliposomes loaded with an enzyme for intravenous administration**
5. **Antimicrobial nanovesicles for topical administration**

4 PHOENIX-OITB SERVICE PORTFOLIO

The PHOENIX-OITB service portfolio is divided into 5 different categories. Each category includes a list of services, all of which together cover the different topics needed for the development of nano-pharmaceuticals from early stage to entry into clinical trials.

Physico-Chemical Characterisation

Surface properties, Moisture/Dry, Mass, Size & Distribution, Structure, Morphology, Composition, Chemical stability, Particle concentration, Drug (API) release kinetics, Free/Encapsuled API sterility

***in vitro* Characterisation**

Composition, Bioactivity, Immunocompatibility, Immunoresponse, Extraction of targeted cells, (A)cellular reactivity & cytotoxicity, Cell viability, Cellular structure, Uptake & localisation, Inflammatory response, Endocytosis/Exocytosis, Sensitization & Irritation, Cytotoxicity, Genotoxicity, Nanomechanical prop. of cells & tissues, Dose metrics, Microbial evaluation, Transcriptomics, Metabolomics, Proteomics, Gene expression

***in vivo* Characterisation**

Biodistribution, Hemocompatibility, Pharmacokinetics, Pharmacodynamics, Acute, Sub-acute & Repeated, Dose systemic toxicity, Reproductivity toxicity

Manufacturing

Manufacturing of liquid, semi-solid, solid nanoparticle formulations with a special focus on extended release parenterals; lipid based formulations and nanovesicles, liposomes, solid lipid nanoparticles, crystalline nanoparticles, polymeric nanoparticles, inorganic nanoparticles; On-site lyophilization and fill and finish capabilities.

Innovation

Training, Regulatory Support & Guidance, IPR & Business Support, QbD, SbD & SSbD support

OUR TEAM

The PHOENIX team consists of 12 international partners distributed across 6 countries. The partners are from the following countries: Austria, Croatia, Germany, Luxembourg, Netherlands and Spain. All partners contribute actively to the project to establish the service portfolio of PHOENIX to cover the whole supply chain leading to GMP manufacturing of nanopharmaceuticals.

GET IN TOUCH

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To learn more visit:
www.phoenix-oitb.eu

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