Phoenix SEP

SERVICE PORTFOLIO

STATUS 2025

PHOENIX Open Innovation Test Bed for Enabling Nano-pharmaceutical Innovative Products

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ABBREVATIONS

API	Active Pharma Ingredient
CQAs	Critical Quality Attributes
GMP	Good Manufacturing Process
IMPD	Investigational Medicinal Product Dossier
IPR	Intellectual Property Rights
QbD	Quality-by-Design
R&D&I	Research, Development & Innovation
SbD	Safety-by-Design
SEP	Single Entry Point
SOP	Standard Operating Procedure
SSbD	Safe-and-Sustainable-by-Design

Introduction

Nanopharmaceuticals represent a rapidly advancing frontier in modern medicine, offering novel therapeutic solutions by leveraging the unique behaviors of materials at the nanoscale. Unlike conventional drugs, nanoformulations harness the distinct physical, chemical, and biological properties that emerge when particle sizes are reduced to the nanometer range. These differences—especially in terms of pharmacokinetics, biodistribution, and efficacy—require an equally specialized approach for development, characterization, and manufacturing.

However, translating these promising innovations from the research bench to clinical and commercial application remains a significant challenge for biotech and pharmaceutical companies, especially start-ups and SMEs. Scaling up nanoformulations, ensuring consistent quality, navigating GMP production, and meeting regulatory expectations demand not only scientific excellence but also access to the right infrastructure and expertise.

PHOENIX-OITB (Open Innovation Test Bed) was established to bridge this gap—offering an integrated, end-to-end ecosystem that accelerates the development and industrialization of nanopharmaceuticals. Through its Single Entry Point (SEP), PHOENIX enables seamless access to a consolidated network of facilities, technologies, and expert services. From early-stage R&D to GMP manufacturing and innovation and regulatory support, PHOENIX is designed to streamline every stage of the product journey—saving time, reducing risk, and ensuring quality.

A searchable digital version of this portfolio is available through the PHOENIX SEP website, ensuring transparency and continued accessibility for innovators, researchers, and commercial partners.

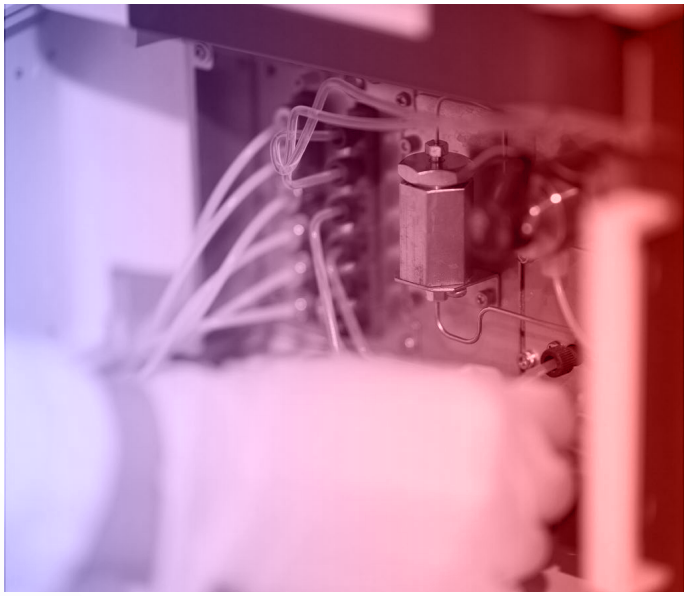
Whether you are scaling a prototype or preparing for market entry, PHOENIX-OITB stands ready to support your nanopharmaceutical innovation with expert-driven, high-quality, and coordinated services.

The PHOENIX-OITB and SEP

PHOENIX-OITB is a unified body and an operational structure to sustainably coordinate and streamline the full value chain for nanopharmaceutical development—bringing together all essential services under one coordinated framework for end users. The structure of PHOENIX-OITB is legally represented by Phoenix gGmbH, which acts as the SEP to the services of the OITB. This central body—PHOENIX SEP—ensures the long-term sustainability, professional coordination, and quality-driven execution of customer projects well beyond the project's conclusion.

The Vision of PHOENIX-OITB is to enable the seamless, timely and cost-friendly transfer of nanopharmaceuticals from lab bench to clinical trials by providing the necessary advanced, affordable and easily accessible services.

Given the broad diversity in nanopharmaceutical technologies—ranging in materials, formulations, manufacturing routes, and delivery methods—a single "one-size-fits-all" platform would be impractical. Instead, PHOENIX-OITB focused on addressing common challenges shared across the sector: scalability, sustainability, regulatory alignment, and GMP compliance. These cornerstones informed the design of a portfolio that helps reduce technical risk and accelerates the path from laboratory to market.



Service & Capabilities Portfolio of PHOENIX-OITB

PHOENIX-OITB is an integrated structure of complementary service providers across Europe who collaborate and cooperate under the roof of PHOENIX-OITB through a coordinated SEP and is legally represented by Phoenix gGmbH. PHOENIX-OITB provides an effective, coherent, adaptable and scalable approach to deliver a high standard of services to its customers. Considering the vast number of nanopharmaceutical preparation methods and the variety of nanopharmaceutical materials, it is almost impossible to offer a "one-size-fits-all" testing, upscaling and manufacturing platform. However, since the challenges of scalability, sustainability and GMP compliance confront all nanopharmaceuticals and their preparation methods, a similar strategy can be employed for reducing the risk and overcoming the barrier to market penetration.

PHOENIX-OITB's concept and implementation strategy are designed to cover a wide range of nanopharmaceutical manufacturing methods, formulations and administration routes so that the most important methods and services are available to the end-user.

PHOENIX-OITB provides an effective, coherent, adaptable and scalable approach

The set of identified services in the service portfolio provides the basis for the compilation and categorisation of the services that PHOENIX-OITB offers through its network of facilities and infrastructures. These include:

- The different quality attributes that can be analysed
- The different techniques available to analyse each attribute
- The quality level of the tests or assays (i.e. R&D level, ISO, GLP-like level, GLP level and GMP level)
- Other complementary services available (e.g. regulatory advice, innovation support, training)

THE PHOENIX-OITB SERVICE PORTFOLIO AND ITS CATEGORIES

The PHOENIX-OITB service portfolio is divided into 6 categories. Each category includes a list of services, which together cover the different topics needed for the development of nanopharmaceuticals from early stage to entry into clinical trials (Figure 1):

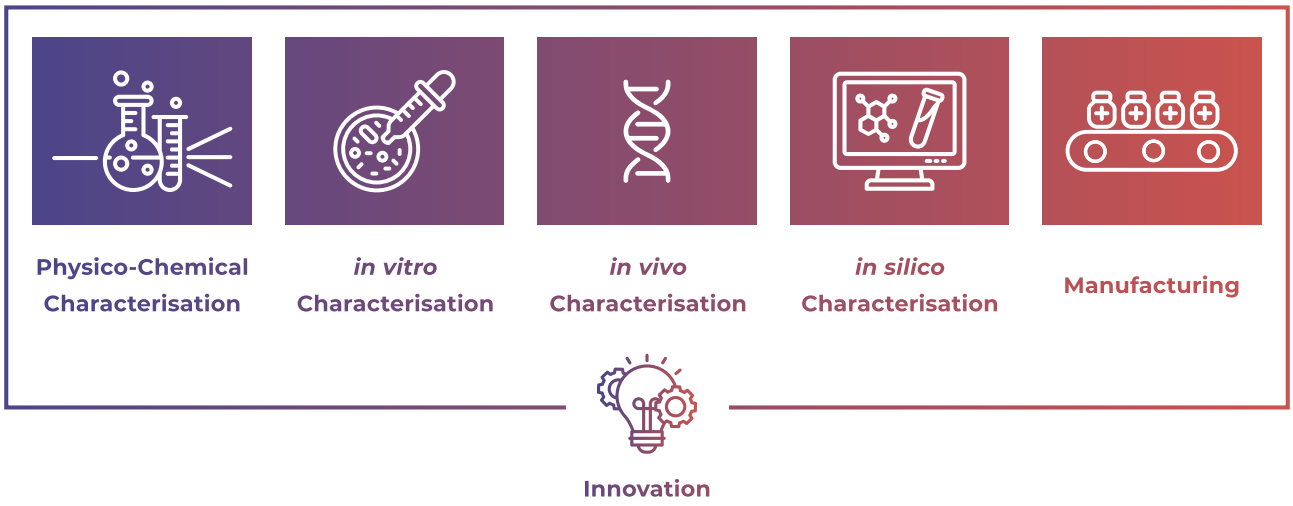


Figure 1: Categories of the PHOENIX-OITB service portfolio.

- The first category includes the services needed to perform an accurate **physico-chemical characterisation**, including techniques to characterise not only nanoparticles but also small and large molecules (synthetic or biological ones) as well as the characterisation of the conjugates (i.e., nanoparticles loaded with drug or active pharma ingredient (API)). A detailed list of the services can be found in **Table 1**.
- The second category includes a broad spectrum of services (**Table 2**) that permits an extensive ***in vitro* characterisation** of the nanomedicine under development, allowing specific and critical questions to be answered related to its toxicity, like cytotoxicity, cell viability, sensitization & irritation, etc. This category confers the data needed to enter into the next category: the *in vivo* experiments in animals.
- The third category includes services that allow to cover part of the pre-clinical ***in vivo* characterisation** of the nanomedicine under study and evaluate its safety (**Table 3**). Most of the assays that are available follow OECD/ICH test guidelines.

- The fourth category includes a series of services allowing the ***in silico* characterisation** of nanopharmaceuticals, leveraging the use of tailored computational tools to enhance the understanding of pharmaceutical manufacturing processes and products (**Table 4**).
- The fifth category includes a series of CMC (Chemistry, Manufacturing and Control) services needed for the scale-up until the **industrial manufacturing** of a nanopharmaceutical (**Table 5**).
- The sixth and last category **'Innovation'** includes different and transversal services that help the client reach its goals. These services are complementary to the ones mentioned above and are equally necessary when developing novel nanopharmaceuticals, such as training in different techniques/ assays, regulatory support & guidance, IPR & business support, Quality-by-Design (QbD), Safety-by-Design (SbD) and Safe-and-Sustainable-by-Design (SSbD) (**Table 6**).

The services within each category are available across various quality and certification levels—ranging from R&D and ISO standards to GLP-like, GLP, and GMP compliance. In several instances, multiple Service Providers are capable of delivering the same service, which enhances the PHOENIX-OITB's overall capacity to meet client demand and ensures flexibility in addressing diverse project needs. This redundancy also serves to mitigate potential conflicts of interest by offering alternative providers for the same service. To further support this, Service Providers submitted prioritisation preferences for their offerings, facilitating transparent service allocation and conflict-of-interest avoidance within the network.

BRIEF DESCRIPTION OF FEATURED SERVICES

The development of a nanopharmaceutical is characterised by a group of challenges to be addressed in order to ensure that the new nanomedicine candidate product can reach the clinics and the market. The different categories of services available from PHOENIX-OITB via the PHOENIX SEP allow its clients to approach these challenges, finding the support needed for each of the steps. They are described as follows:

- **Category 1 – Physico-chemical characterisation of nanoparticles, small and large (bio)molecules and nano-formulations.** This step is essential to understand the behaviour of a nanomedicine and provides guidance for the process of design, development, control and safety assessment. In the case of nanomedicines, an adequate and complete characterisation is inherently complex because of the heterogeneity and structural complexity which in most cases cannot be measured and/or analysed with traditional analytical techniques. PHOENIX-OITB brings together a wide palette of analytical techniques that cover all the physico-chemical parameters that need to be determined. Moreover, the knowledge of physico-chemical characterisation that the service providers have acquired allows them to potentially develop new analytical methods, if needed, tailored to the specific nanomedicine/nanomaterial to be analysed. Finally, PHOENIX-OITB has SOPs for most of the techniques and assays they provide, and offers some specific techniques to determine parameters that cannot be found easily (e.g. distinction between free from encapsulated API).

- **Category 2 & 3 – *In vitro* & *in vivo* characterisation of nanoparticles and nano-formulations.** Pre-clinical pharmacology and nanotoxicology compiles a set of crucial parameters to be determined in order to successfully translate innovative nanomedicines into clinics. The absence of specific regulatory frameworks for nanomedicines and the lack of specific bioanalysis protocols for the *in vitro* and *in vivo* characterisation of nanomedicines hinders the progress of translation into clinics. PHOENIX-OITB offers a large number of tests within these two categories, from which the most appropriate ones can be chosen to perform an accurate and tailored study for each nanopharmaceutical under development; this permits a better understanding of the biological effects and interactions with the cellular/biological compartments and the body, allowing optimisation of the nanomedicine properties in order

to avoid undesired side effects and toxicity. Besides the large number of tests included for an exhaustive *in vitro* analysis, (most of) the tests provided for the *in vivo* characterisation are performed following OECD/ICH guidelines.

- **Category 4 – *In silico* modelling:** Computer-based modelling and simulation approaches are applied to nanopharmaceutical design, testing and manufacturing optimisation to enhance the mechanistic understanding of pharmaceutical manufacturing processes and products. Theoretical and experimental approaches are integrated with simulation tools and computer-assisted methods to decrease development time and costs.

- **Category 5 – Scale-up & Manufacturing:** One of the most challenging steps in (nano)pharmaceutical development is the scale-up and reproducibility of the production process of nanomedicines. To be able to achieve the industrial manufacturing stage of a nanomedicine some hurdles need to be overcome: i) lack of batch-to-batch reproducibility during the process of manufacturing (i.e., passing from low-volumes needed at R&D level, to pilot scale and/or to industrial level), ii) long-term stability of the products, iii) complexity of the manufacturing process and iv) sterile conditions maintenance through the whole manufacturing process. PHOENIX-OITB offers its clients GMP and non-GMP manufacturing and quality control for the development and manufacturing of nanoparticle formulations.

- **Category 6 – Innovation:** This category includes several transversal and complementary services that help throughout the whole process of developing a novel nanomedicine from bench to clinics and into the market.

- **Quality-by-Design (QbD):** In a (nano) pharmaceutical QbD approach it is necessary to identify the characteristics that are critical to quality from the patient's perspective, to translate them into the product Critical Quality Attributes (CQAs) and establish a relationship between variables of manufacturing and these CQAs. This step is crucial in the development of a novel (nano)pharmaceutical product due to changes of the physico-chemical characteristics the product might undergo during the manufacturing process; this needs to be under control and detected (i.e., using the most suitable process analytical technology (PAT) for it) in order to guarantee the quality of a given nanomedicine. PHOENIX-OITB provides support to clients that are not used to the concept of QbD. Since it is essential for the scale-up and manufacturing, it is essential to translate the nanomedicine to clinics and into the market. QbD

needs to be included from the very beginning (already at the R&D level) in order to minimise future problems.

- **Safety-by-Design (SbD):** The SbD approach (like its complementary concepts QbD and SSbD) boosts innovation capacity by reducing late development failures. The SbD approach identifies risks and uncertainties concerning humans and the environment at an early phase of the innovation process so as to minimise uncertainties, potential hazards and/or exposure. The concept addresses the safety of the material/product (i.e. the nanomedicine under development) and associated processes through the whole life cycle: from the R&D phase to production, use, recycling and disposal. A timely insight can be acquired by innovators and regulators with the ultimate goal of striving for negligible risks and avoidance of adverse impact on products (e.g., bans). It is an approach that can be used supplementarily and prior to regulation. The concept performs a “safety loop” early in the innovation process starting with an extensive (i) Information Gathering, followed by (ii) Hazard Assessment and (iii) Exposure Assessment, allowing an early (iv) Risk Characterisation and (v) Refined Risk Characterisation including Exposure Monitoring if needed, while the final settings of the innovation process are still under development and can be easily adapted. This allows potential (vi) Risk Mitigation measures to be implemented before the innovation process is finished.

- **Safe-and-Sustainable-by-Design (SSbD):** This concept contains the previous one, SbD, and takes a holistic system approach by integrating safety with climate neutrality, circularity and functionality of the (nano)materials, products and processes throughout their life cycle. This service is a pre-market approach to chemicals (widely used in the (nano)pharmaceutical sector) that focuses on providing a function, while avoiding volumes and chemical properties that may be harmful to human health or the environment (as much as possible), in particular groups of chemicals/materials likely to be (eco)toxic, persistent, bioaccumulative or mobile. It strives to minimise the environmental footprint of chemicals in particular on climate change, resources, ecosystems and biodiversity from a life cycle perspective.

- **Regulatory support:** The lack of agreed regulations for nanomedicines makes it difficult for researchers and SMEs to translate their innovative nanomedicines to clinics and into the market. PHOENIX-OITB provides support and guidance to its clients for the creation

of the Investigational Medicinal Product Dossier (IMPD) of the nanomedicines under development as well as definition of the development pathway to reach clinical stage and obtain marketing authorisation. The informative value of the IMPD significantly contributes to the overall success of drug development programs and, ultimately, licensing procedures. In addition to competent authorities, potential investors, partners and licensees also perform rigorous reviews of regulatory documentation such as the IMPD. Thus, the value added from the clear, accurate and creatively proactive writing of the IMPD is indispensable through all stages of development.

- **Training:** To support the rapid advances in the nanomedicine field, PHOENIX-OITB provides a wide range of trainings that draw on its long-standing expertise in nanopharmaceuticals testing, safety, sustainability and quality control as well as in the latest regulation updates in the nanomedicine field.

LIST OF SERVICES

Table 1: Physico-chemical characterisation services

	Attribute to measure	Technique	Quality Level				
			R&D	ISO	GLP-like	GLP	GMP
Physico-chemical Characterisation	Surface properties	Isothermal titration calorimetry	X	X			
		DLS	X	X			X
		Laser dopplet electrophoresis		X			X
		SDS-PAGE	X				
		UV-Vis spectrophotometry	X				
		Fluorescence spectroscopy	X				
		Quartz Crystal Microbalance (QCM)	X				
		AFM	X	X			
		Multiple -Angle DLS (MADLS)		X			X
		SPR	X				X
	Moisture / Dry Mass	In-Situ Real-Time Spectroscopic Water Content Monitoring	X				
		Karl Fischer titration	X				X
	Size	AFM	X	X			
		Cryo-TEM	X				
		DLS	X	X			X
		NTA	X				
		SEM	X				
		Laser diffraction		X			X
		TEM	X				
		Automated optical microscopy					X
	Size Distribution	NTA	X	X			
		DLS	X	X			X
	Morphology	AFM	X	X			
		Cryo-TEM	X				
		SEM	X				
		TEM	X				
		Automated optical microscopy					X
	Rheological determinations	Viscosity	X				
		Rheometer	X				
	Particle concentration	DLS MADLS		X			X
		NTA		X			
	Impurity and contamination	GC-FID	X				
		UV-HPLC	X				X
		MS-HPLC	X				
		TLC	X				
		ICPMS/ICPAES	X				
	Structure	Isothermal titration calorimetry	X	X			
		Fluorescence spectoscopy	X				

Physico-Chemical Characterisation	Chemical stability	Conductivity	X			
		pH meter		X		X
		Loss on drying				X
		Freezing point osmometer	X			X
		Turbiscan		X		
		FTIR	X			
		UV-Vis Spectroscopy	X			
		UPLC-MS	X			
	Composition	Traces of solvent --> Gas Chromatography	X			X
		HPLC-ELSD	X			X
		UHPLC-MS	X			
		UPLC-MS	X			
		SEC-HPLC	X			X
		Raman Spectroscopy (compact spectrometers)	X			
		Near-Infrared Spectroscopy (t.b.c miniaturized spectrometer)	X			
		Mid-Infrared Spectroscopy (t.b.c compact spectrometers)	X			
		Hyperspectral Imaging/Mapping (microscopic)	X			
		Optical Photothermal Infrared Spectroscopy (microscopic)	X			
		Fluorescence spectroscopy	X			X
		FTIR	X			X
		Headspace GC				X
		ICP-MS		X		
		ICP-AES	X			
		MALDI-TOF	X			
		Time domain-NMR (relaxometry)	X			
		TGA	X			
		cIEF	X			X
		SDS-PAGE+TGX	X			
		SDS-PAGE	X			X
		CE-SDS	X			X
		UV Spectroscopy	X			X
		13C-NMR	X			
		1H-NMR	X			
		EDX	X			
		Electrophoresis	X			
		ELISA	X		X	X
		hcDNA	X			X
		Host Cell Proteins (HCP)	X			X
		Endotoxins	X			X
		Prot. A	X			
		Western Blot	X			
		Peptide mapping	X			
		ATR-FTIR	X			
		GPC-MALS	X			

Physico-Chemical Characterisation	Free API	HPLC/UV	X				X
		HPLC/RI	X				
		GC	X				X
		SDS-PAGE	X				
	Encapsulation efficiency	HPLC/UV	X				
		HPLC/RI	X				
	Drug (API) Release Kinetics	Dyalisis	X				
		Centrifugation-Filtration	X				
		Dissolution tester	X				X
		UV-Vis spectrophotometry	X				
	Advanced structural characterisation	Small and Wide Angle X-Ray Scattering	X				
		Small and Wide Angle X-Ray Scattering + DSC	X				
		Raman Scattering, Scan Stage	X				
		Raman Scattering, Scan Stage + Microscopy	X				
		In-Line Raman Scattering	X				
		In-Line Near-IR Spectroscopy, Diffuse Reflection	X				
		UV/VIS Spectroscopy, Transmission, Absorption	X				X
		DLS	X	X			X

Table 2: *In vitro* characterisation services

			Quality Level				
	Attribute to measure	**Technique**	**R&D**	**ISO**	**GLP-like**	**GLP**	**GMP**
In vitro Characterisation	Composition, uptake and localisation	Dark field enhanced hyperspectral imaging coupled to Raman spectroscopy	X				
	Bioactivity	4-MUG assay	X				
	Immunocompatibility	Macrophage uptake	X				
		Complement activation	X				
	(A)cellular reactivity and cytotoxicity	Flow Cytometry	X				
		Fluorescent Microscopy-TIRF	X				
		Cell culture systems / LUNG / 3D culture: A549, EA.hy926, (d)THP1	X				
		Cell culture systems / SKIN / Reconstructed Human Epidermis	X				
		Cell culture systems / SKIN / KeratinoSense™	X				
		Cell culture systems / SKIN / h-CLAT (THP1)	X				
		Cell culture systems / INTESTINE / 3D tissue model of human small intestine	X				
		Cell culture systems / LIVER / HepRG (differentiated)	X				
		Cell culture systems / IMMUNE SYSTEM	X				
		ELISA / biological fluids from human, rats, and mice	X				
		Flow Cytometry / Surface marker	X				
		Flow Cytometry / Cell cycle	X				
		Flow Cytometry / Apoptosis	X				
		Oxidative Stress	X				
		Cryo-TEM	X				
		Cell culture systems	X				
		Fluorescence microscopy	X				

In vitro Characterisation	Cellular structure, uptake and localisation	Confocal microscopy	X		
		Fluorescence	X		
	Inflammatory response	Flow Cytometry	X		
		ELISA	X		
	Endocytosis/Exocytosis	Flow cytometry	X		
	Sensitisation/Irritation/Inflammation	Lung / ALIsens(r) model	X		
		Skin / Human Cell Line Activation test (h-CLAT)	X		
		Skin / ARE-Nrf2 luciferase KeratinoSens test method	X		
		Skin / Reconstructed Human Epidermis Skin Irritation Test method (EpiSkin)	X		
		Skin / Reconstructed Human Epidermis Skin Corrosion Test method (EpiSkin)	X		
		Intestine / 3D tissue model of human small intestine (EpiIntestinal™)	X		
	Cytotoxicity and Cell viability	Resazurin	X		
		MTT	X	X	
		ATP	X		
		LDH	X	X	
		XTT		X	
		MTS		X	
		NRU		X	
		Apoptosis by flow cytometry	X		
		Cell culture systems	X		
		Flow cytometry	X		
	Mitocondrial toxicity	Resazurin	X		
		ATP	X		
		Seahorse assays		X	
	Genotoxicity	Comet	X		
		Micronucleous assay	X		
		γH2AX staining	X		
		HPRT	X		
	Microbial evaluation	Endotoxin level: LAL assays	X		X
		Bioburden	X		X
		Sterility			X
	Analysis of cytokines and secondary messenger	Luminex	X		
	Direct quantification of mRNA	qRT-PCR	X		
	Transcriptomics	single-cell Transcriptomics	X		
		bulk Transcriptomics	X		
		qRT-PCR	X		
	Proteomics	Targeted and untargeted approaches	X		
		Protein sequencing and identification	X		
		Labelled and unlabelled approaches	X		
		Gel-based or gel-free approaches	X		
	Gene expression	qRT-PCR	X		

In vitro Characterisation	ADME	Stability in Biological Matrices (blood, plasma, GUT fluids etc.)		X
		Membrane permeation (PAMPA intestinal and BBB)		X
		Membrane permeation / transwell systems: gastrointestinal, placenta, BBB		X
		Membrane permeation / uptake and intenalisation by flow cytometry, florescence and electon microscopy		X
		Protein binding mechanism / Blood partitioning	X	
		Protein binding mechanism / Microsomal binding	X	
		Metabolic stability and Identification / Liver		X
		Metabolic stability and Identification / Kidney		X
		Metabolic stability and Identification / Brain		X
		Metabolic stability and Identification / Blood		X
		Metabolic stability and Identification / Heart		X
		CYP Induction / HepG2 and recombinant human CYPs		X
	Haemocompatibility	Haematocompatibility (hemolysis, platelet aggregation, coagulation time, thrombin generation)		X
		Immunocompatibility (cellular reactivity, cytotoxicity, inflammatory response, complement activation)	X	
	Develpmental toxicity	Embryonic stem cell test (EST)		X
	Endocrine disruption	Estrogen and androgen receptors activity		X
		Steroidogenesis		X
	Pharmacology	HTTP-HCI assay / Parkinson like dompaminergic neurons		X
		HTTP-HCI assay / Cancer spheroids for panceratic, liver, breast and neuroblastoma tumors		X
		HTTP-HCI assay / Patient-derived cancer organoids for pancreatic and neuroblastoma tumors		X
		AFM / Parkinson like dompaminergic neurons		X
		AFM / Cancer spheroids for panceratic, liver, breast and neuroblastoma tumors		X
		AFM / Patient-derived cancer organoids for pancreatic and neuroblastoma tumors		X

Table 3: *In vivo* characterisation services

	Attribute to measure	Technique	Quality Level				
			R&D	ISO	GLP-like	GLP	GMP
In vivo Characterisation	Rodent Models / Toxicity by oral, intraperitoneal, intravenous, subcutaneous, dermal and inhalatory exposure	Acute oral toxicity in rodents			X		
		Acute systemic toxicity in rodents			X		
		Sub-acute oral toxicity in rodents			X		
		Sub-acute systemic toxicity in rodents			X		
		Chronic oral toxicity in rodents			X		
		Chronic systemic toxicity in rodents			X		
		Developmental toxicity in rodents	X				
		Reproductive toxicity in rodents	X				
		Pathology			X		
		Toxicokinetics			X		
		Biomarker analysis for metabolic syndromes, immune response, cancer and neuroscience			X		
	Pharmacology models	Parkinson rat model			X		
		reumatoid arthritis rat model			X		
		pancreatic cancer mice model			X		
		liver cancer mice model	X				
		neuroblastoma cancer mice model	X				

Table 4: *In silico* characterisation services

	Attribute to measure	Technique	Quality Level				
			R&D	ISO	GLP-like	GLP	GMP
In silico Characterisation	Biodistribution	Kinetic modelling to predict PKPD	X				
	Modelling and prediction	Molecular Dynamics (MD)	X				
		Computational Fluid Dynamics (CFD)	X				
		Discrete Element Method (DEM)	X				
		Smoothed Particle Hydrodynamics (SPH)	X				
		Machine Learning (ML)	X				
		Custom Digital Twin Model Development	X				

Table 5: Scale-up & manufacturing services

	Attribute to measure	Technique	Quality Level				
			R&D	ISO	GLP-like	GLP	GMP
Manufacturing	Manufacturing	Sterile production of parenteral formulations	X				X
		Aseptic production of parenteral formualtions with end sterilisation	X				X
		Production of topical formulations	X				X
		Dry granulation	X				X
		Wet granulation	X				X
		Tabletting	X				X
		Hard gelatine capsule fillinf	X				X
		Blistering	X				X
		Liposome formulations	X				X
		Nanovesicle formulations	X				X
		Nanoemulsions, nanosuspensions	X				X
		Lipid-based formulations	X				X
		Nano Spray Drying	X				
		High Pressure Homogenization, Microfluidizer LM 20	X				
		High Pressure Homogenization, APV Lab Homogenizer	X				
		Up-strem Processes	X				X
		Down-Stream Processes	X				X
		mRNA/pDNA	X				X
		Bioconjugation	X				X
	Quality control	Identification	X				X
		Assay	X				X
		Impurity	X				X
		Particle size	X				X
		ZETA potential	X				X
		Redispersibility	X				X
		Water content	X				X
		Packaging integrity	X				X
		Wet chemistry	X				X
		Free API	X				X
		Encapsualted API	X				X
		Osmolarity	X				X
		Residual solvents	X				X
		Hardness	X				X
		Weight	X				X
		Friability	X				X
		Dissolution	X				X
		Disintegration	X				X

Table 6: Innovation services

	Attribute to measure	Technique	Quality Level				
			R&D	ISO	GLP-like	GLP	GMP
Innovation	SSbD consultancy-guidance and implementation	Assessment of critical hotspots		X			
		Risk assessment and mitigation strategies		X			
		Occupational health & safety		X			
		Toxicology and ecotoxicology assessment		X			
		Environmental fate and impact		X			
	Training	Interactive workshop/lessons in SSbD		X			
	Support in business-related aspects	Business case development and creation		X			
		Business model generation		X			
		Business plan generation		X			
	Regulatory services for Pharma	Regulatory and Development Roadmap – Delineate the path towards first in human, phase 2, etc.		X			
		Gap Analysis – Quality, nonclinical, clinical and regulatory perspective		X			
		Regulatory Support		X			
		Early interactions with regulators (EMA-ITF, EU Innovation agencies and US FDA-INTERACT)		X			
		Matured interactions with regulators (Scientific Advice, FDA Pre-IND)		X			
		Orphan Drug Designation (ODD) – EMA and FDA		X			
		Paediatric Investigational Plan (PIP) - EMA		X			
		Due Diligence – Singles asset or portfolio		X			
		Small and Medium Enterprise (SME) – SME application and Legal Representation from non-EU SMEs		X			
		Medical writing - Investigator brochure (IB)		X			
		Medical writing - Investigational Medicinal Product Dossier (IMPD)		X			
		Medical writing - eCTD (Module 1, 2 and 3)		X			
	Regulatory and Development Roadmap - under MDR/IVDR	Gap analysis – under MDR/IVDR		X			
		Feasibility assessments and qualification and classification analyses		X			
		Biocompatibility assessment		X			
		Assistance in the development of combination products		X			
		Notified body selection and interaction		X			
		Regular support – on demand		X			

To access these services, please visit phoenix-sep.com