Your Flexible Partner for Solid Development

Drug Substance Intake	Drug Product Development	Process Development	DS/DP Manufacturing
Compatibility	Oral solid dosage forms	Spray Drying	R&D
Powder characterisation	Amorphous solid dispersions	Granulation	PK/PD
Solid state	Immediate release	Tableting	Toxicology
Solubility	Modified release	Coating	GMP - clinical phase I & II
Supersaturation	Targeted release	Spray Congealing	API
Stability	Nanosuspensions	Hot Melt Extrusion	IMP
	Taste masking	Extrusion/Spheronisation	Biologics
	Encapsulation		
	Inhalation		
	Injectables		
	Long acting injectables		
	Solid lipid nanoparticles		

Accelerate your time to market

How we work

Prior to initial project discussions we always sign a **confidentiality agreement**.

During one or more face-to-face meetings or teleconferences, **we discuss your project in detail**. It is of profound importance that the project is completely understanded by us prior to the start of the collaboration.

A **customized project proposal** is composed. The project plan is divided into several steps, each with **go/no-go decision points** where the customer can decide to proceed, to change direction, or to stop the project.

Typically, we start a project within 4 to 6 weeks after the customer's approval. **Flexibility is one of our key strengths** together with a **direct and transparent communication** to the customer. We regularly update you on the project progress with (a) written report(s) and teleconferences. Upon completion of the project, a **detailed report** is provided.

All our developments (both projects and stand-alone analysis) are always performed on a "fee-for-service" basis with full respect of the customer's IP.

Development

The customer is always welcome to join the test work in our labs during the period of the project. Customers experience this way of working as if XEDEV is an integral part of their team.

We start a project with a feasibility study or pre-formulation work to generate a realistic expectancy. From these first experiments, the product and process development continues, and are further optimised. Realistic process upscaling is always kept in mind during the complete development.

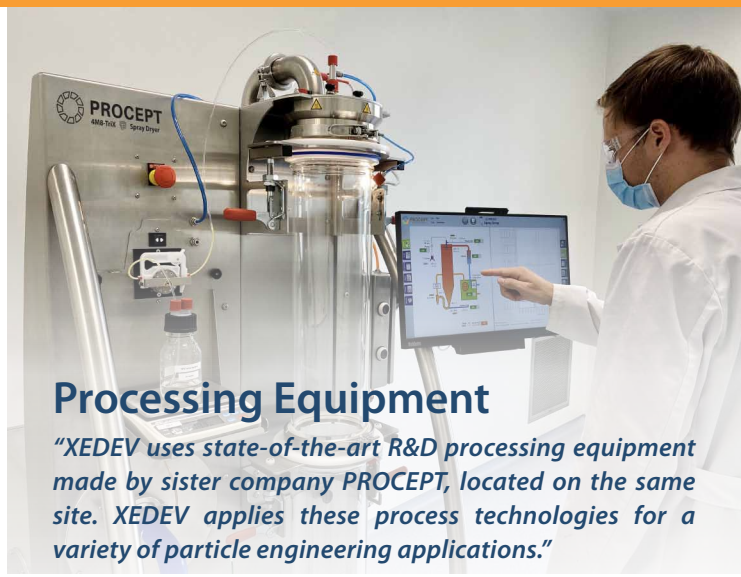
Clinical batches

The critical process parameters are identified together with the main quality attributes of your product. The process window is determined based on a Design-of-Experiments principle (DoE). With a well-defined process window taking the risks into account, your product is ready for GMP production.

"We offer a fast and smooth transition of your project from R&D to GMP production."

Tech transfer & scale-up

We use a stepwise approach to transfer your material to your own facilities or to an external contractor for larger scale manufacturing.



Processing Equipment

"XEDEV uses state-of-the-art R&D processing equipment made by sister company PROCEPT, located on the same site. XEDEV applies these process technologies for a variety of particle engineering applications."

Spray dryer (Procept 4M8-TriX)
- amorphous solid dispersion (ASD)
- inhalation
- physico-chemical stabilisation (e.g. enzymes, RNA)

"With the uprise of spray drying technology in many industries, and the amount of spray drying projects realized by our team, we have become a centre of excellence in spray drying and Spray chilling/congealing."

Spray congealer (Procept 4M8-TriX)
- controlled drug release
- taste masking

Pan coater (Procept 4M8-TriX)
- tablet and capsule coating (wet and melt)

High shear granulator (Procept MiPro)
- granulation: avoid segregation, improve flow
- silica loading

Fluid bed (Procept 4M8-TriX)
- bead coating: taste masking, controlled release
- granulation: avoid segregation, improve flow

Twin screw extruder (Procept Extruder)
- granulation (wet and hot melt)
- extrusion

Tablet press / compaction simulator (Medelpharm Styl'One Evo)

Broad application field

Compounds

- chemicals: e.g. classic API, new chemical entities
- biologicals: e.g. mAb, enzymes, mRNA, bacteria
- alternatives: e.g. pigments, food extracts

Dosing routes

- e.g. oral, inhalation, parenteral

GMP facility


PROCEPT SD3 gmp parallel spray dryer

Our brand new GMP facility is fully compliant with EMA requirements, allowing us to produce clinical batches.

- clean room grade: class D
- investigational medical products (IMP)
- production of API and biologicals

Product characterisation

Physico-chemical characterization

- solid state: e.g. mDSC, XRPD, PLM, FTIR
- others: e.g. SEM, DVS, RWC, GC

Powder characterization

- e.g. PSD, flowability, density

Tablet characterization

- e.g. friability, disintegration, hardness

Formulation characterization

- storage stability: e.g. 40°C/75% RH
- assay/impurities: UPLC/HPLC
- in-vitro dissolution: biorelevant media

Fundamental strategies

- **Continuous in-house innovation**.
- Close collaboration with, and support from **PROCEPT**. This often results in the application of unique engineering solutions in the shortest possible time frame.
- Integrating our **university partners**' state-of-the-art fundamental research and science into our services and solutions.

"Our innovative drive constantly supports our customers through a high level of R&D. In short, innovation is in our DNA and is the fuel of our company. Our strategies are our success formula."

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XEDEV

Particle Engineering Services

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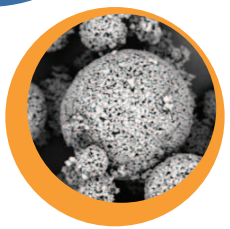
SUPPORTING PHARMA, BIOTECH, CHEMICAL AND FOOD



FAST TRACK FROM SCREENING TO (CLINICAL) PRODUCTION