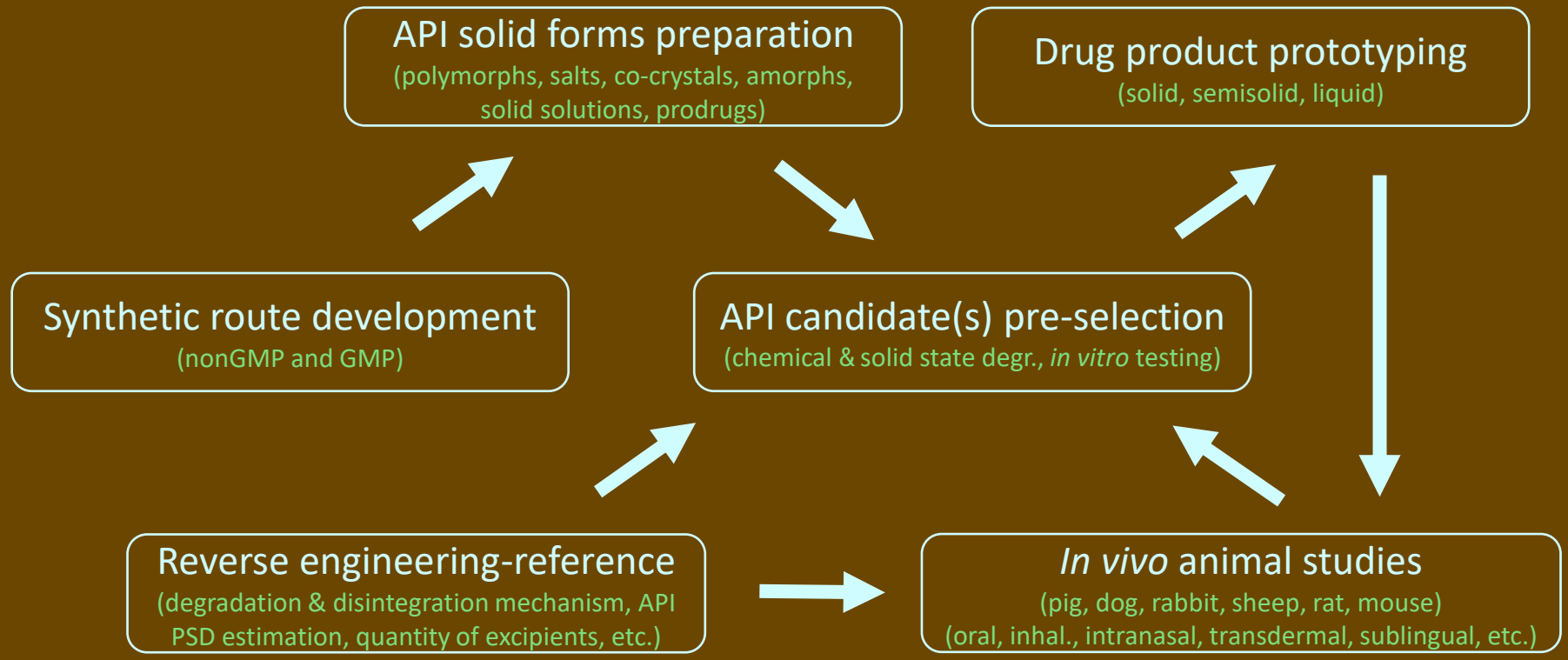
From Molecule to Human Data

Complete Pharmaceutical Development Under One Roof

Comprehensive API and Drug Product Development Support



Verified API form in DP prototype

- ✓ **Synthetic route**
- ✓ **nonGMP or GMP solid form**
- ✓ **Chemical stability in DP**
- ✓ **Solid state stability in DP**
- ✓ **Similar *in vitro* API release**
- ✓ ***In vivo* similarity - animals**
- ✓ **DP process proposal**
- ✓ **Methods proposal**
- ✓ **Ready to transfer**

Project management, IP & clinical & toxicological evaluation, method development

Fastest way how to significantly reduce technical and clinical risks

Comprehensive API and Drug Product Development Support

We offer the complete development process or selected parts of it, tailored to the customer's specific needs.

Project start

In the initial phase, we assist in identifying a suitable molecule, preparing the business case, performing an FTO (freedom-to-operate) patent analysis, and providing a first estimate of technical feasibility based on an extensive literature review.

Synthetic route development & API solid form preparation

We can develop the synthetic route and select the optimal crystallization conditions for preparing a solid form of the API for further testing. If required, we can supply the final selected form(s) in GMP quality for clinical studies. Our portfolio covers a broad range of solid form development capabilities, including the preparation of polymorphs, salts, cocrystals, amorphous systems, and their stabilization using polymers or amino acids. For innovative projects, we also support prodrug design and synthesis, along with relevant preclinical, clinical, and toxicological evaluations, IP checks, and patent drafting (in cooperation with the client's patent attorneys).

Reverse engineering of reference DP

In parallel with solid form screening, we perform extensive reverse engineering of the reference product. We apply unique in-house analytical methodologies to estimate API particle size within the dosage form, determine the quantitative composition of excipients, assess chemical and solid-state degradation pathways, and identify the mechanism of disintegration and critical attributes controlling API release under various conditions.

API solid form candidate pre-selection

All these insights are essential for solid form pre-selection, which involves comparing the reference API form with newly designed forms in terms of chemical stability, solid-state stability, and advanced *in vitro* performance based on reverse-engineering data.

DP prototyping

Pre-selected solid forms are subsequently formulated into prototype drug products. These small-scale formulations are designed to minimize the impact of different physicochemical properties of the new form on the overall drug product performance.

In vivo animal studies

The developed formulations are then tested in *in vivo* comparative studies using the most appropriate animal model. During this stage, a complete clinical program is designed, an LC-MS analytical endpoint is developed, and the optimal administration route is selected according to the dosage form type. The process typically follows an iterative development cycle: API form design - DP preparation - *in vivo* testing - optimization - DP refinement - confirmatory study - until comparable pharmacokinetic or pharmacodynamic profiles (depending on project objectives) are achieved.

DP scale up and transfer

Once similarity to the reference is demonstrated, we proceed with scale-up of the drug product manufacturing process to a non-GMP industrial scale. The final deliverable includes the synthetic route, solid form selection, and drug product that demonstrate *in vivo* similarity to the reference, along with comprehensive process documentation and analytical transfer packages for both process and method technology transfer.

GMP clinical batch manufacturing and pilot human studies

We are currently finalizing our system for pilot studies, which will be initiated in Q2 2026. In 2027, we plan to complete the construction of a GMP pilot plant for the manufacture of clinical batches, enabling us to offer a fully integrated development pathway from early-stage research and solid form design up to clinical data in humans.

Karel Zelenka

15+ yrs experience

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Project management
IPMA certification
API and DP development
Small molecule selection
IP landscape evaluation
Business case support
Organic chemistry
Risk analyses

Kapaji

Radim Horák

12+ yrs experience

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API chemical development
API analytical development
API process development
Process scale up
Polymorph screening
Salts and cocrystals
Amorphous forms
Solid solutions/dispersions

Scale Up Laboratory

Pavel Calta

22+ yrs experience

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Advanced API characterization
API form selection
Reverse engineering
Advanced DP characterization
Advanced in vitro testing
Method development
Stress and stability testing

Kapaji

Josef Mašek

15+ yrs experience

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Animal study design
Human-relevant preclinical models development
Large animal PK/PD models
Pharmacokinetics
Pharmacodynamics
BE preclinical studies
LC-MS dev & analyses
Biodistribution & preclinical imaging

VRI

Martin Bezecný

7+ yrs experience

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Advanced DP development & optimization
Expertise in QbD: Design of Experiments, Risk assessment, Design space
Manufacturing scale-up & technology transfer
cGMP expertise

Kapaji