



# Process Development & GMP Manufacturing of APIs

Solvias offers a complete package of seamlessly integrated early phase API process & analytical development, catalysis & solid-state services

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**Technical Expertise**

Hundreds of process development and tech transfer projects with nearly 100% success rate

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**Trusted Partners**

With direct access to our scientific & regulatory experts, our team will help navigate challenges and mitigate risk

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**Efficient, Timely Delivery**

High-quality material and processes, rapidly developed and delivered on time

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## Reaction Optimization & Process Development

- Implementation of PR&D concepts in lead structure synthesis
- Scalability considered in route scouting for future scale up
- Efficient and practical route design
- Optimization of reactions and processes for scale up
- Workflow and isolation procedure streamlining
- Expertise in asymmetric synthesis, hazardous chemistry, complex heterocycles & catalysis

## Scale-Up & Process Transfer

- Seamless transition from mg to kg scale
- Phase appropriate development and scale-up with future scalability in mind
- GMP & Non-GMP manufacturing
- Comprehensive process and method transfer
- Reference substance supply

## Catalysis & Ligands

- More than 50 years industrial experience in applied catalysis
- Rapid discovery of catalytic systems using expert HTE design and extensive ligand library. Meaningful results in just 1 week.
- Most diverse library of commercially available ligands and catalysts

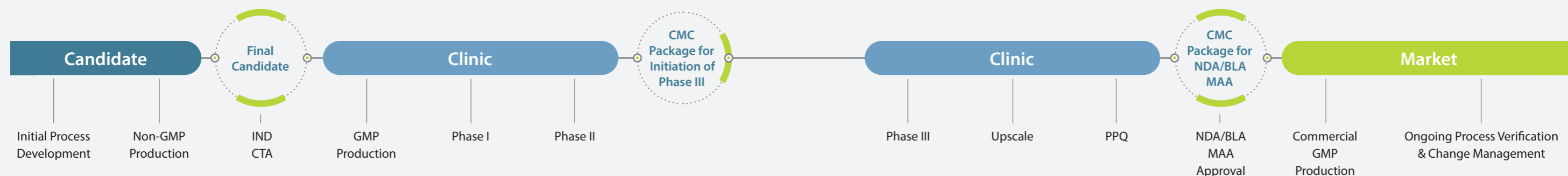
## Crystallization & Solid State

- Salt, co-crystal and polymorphism screening for improved bioavailability, solubility, shelf life, yield and IP protection
- Intelligent solid form evaluation of drug substances using predictive expertise
- Crystallization development integrated into custom synthesis. A robust process is essential for consistent manufacturing.

## Comprehensive Analytical Suite

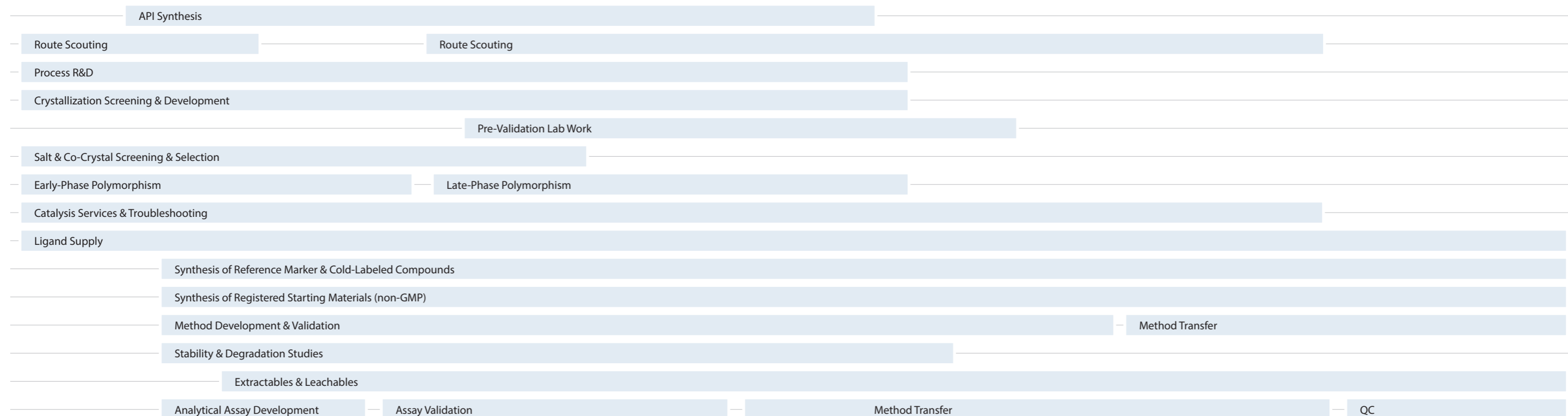
- Spectroscopy (IR, Raman, NMR)
- X-Ray powder diffraction
- Thermal methods
- Hygroscopicity (by DVS)
- HPLC, GC, GC headspace
- Karl-Fischer,
- Sulfated ash
- Solubility
- $pK_a$
- logP/LogD
- Stability of API and API excipient mixtures: physical, chemical, mechanical
- ICP-OES

## Product Development Process



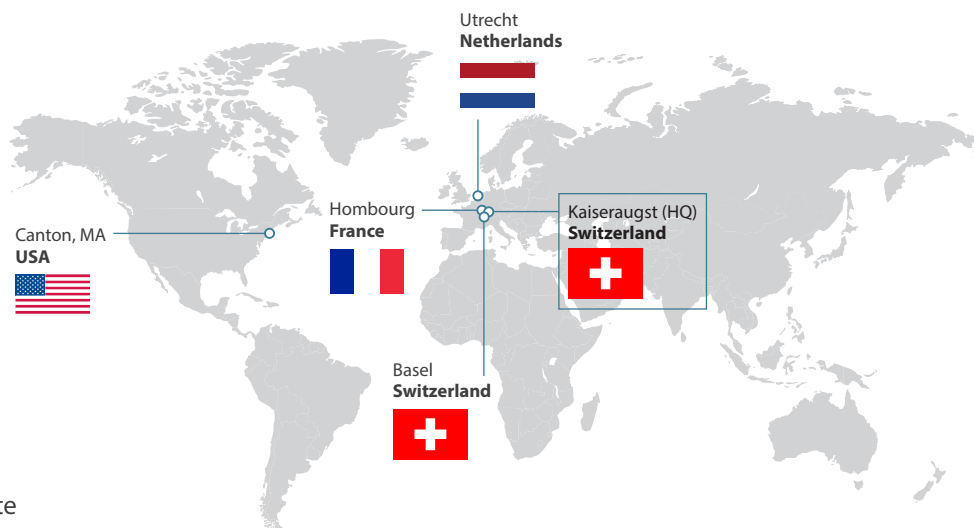
## Custom Synthesis & GMP Manufacturing of APIs

API synthesis is highly complex field requiring interdisciplinary expertise in organic chemistry, process design, analytical chemistry and regulatory compliance. **Solvias' experts will reduce your risk and deliver a successful program.**

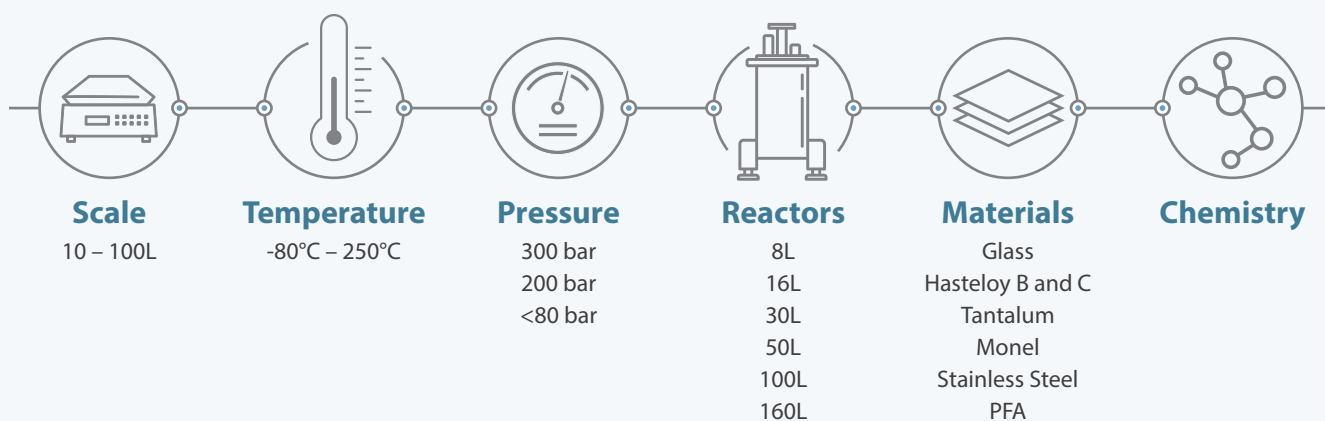


## Solvias Group

- CRO/CDMO
- Founded in 1999
- 800+ employees
- 5 Locations worldwide
- Custom synthesis and GMP manufacturing of APIs in Kaiseraugst, Basel & Canton
- Coming soon 160L volume reactor to Canton, MA, US site



## Global Footprint & State of the Art Facilities



## Kilo Lab GMP – Covering a wide range of conditions

- 4 fully equipped reactor trains including filters & dryers
- 8 safety boxes for mobile pressure reactors
- 2 containment laboratories including external O<sub>2</sub> compressor
- Chromatography up to 20kg stationary phase
- Total reactor volume ~850L
- HEPA filtered air, laminar flow cabinets
- Multipurpose reactors 30–160L
- Temperature range -85°C to 160°C for GMP vessels
- Separation units 50–150L
- High throughput catalysis screening
- Key analytical capabilities

### Contact us to speak with an expert

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