

# Process Development & GMP Manufacturing of APIs

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

Technical Expertise	Hundreds of process development and tech transfer projects with nearly 100% success rate		
Trusted Partners	With direct access to our scientific & regulatory experts, our team will help navigate challenges and mitigate risk		
Efficient, Timely Delivery			



#### **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

#### Comprehensive **Analytical Suite**

- 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.

Karl-Fischer,

Sulfated ash

#### **Product Development Process**



### Custom Synthesis & GMP Manufacturing of APIs

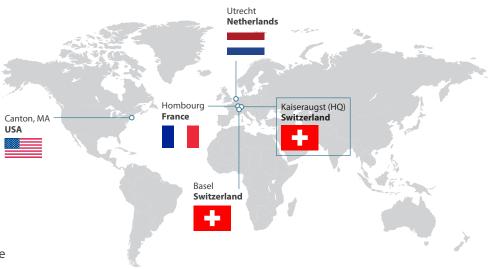
API synthesis is highly complex field requiring interdisciplinary expertise in organic chemistry, process design, analytical chemistry and regulatory compliance. Solvias' experts will reduce your rick and deliver a successful anorra

chemistry an	lu legulatory	compliance. Solvias experts will reduce	e your risk and denver a successful pro	grann.				
	API S	ynthesis						
Route Scout	ting		Route Scouting					
Process R&D	)							
		Screening & Development						
Crystallizatio	on servering a	Development	Pre-Validation Lab Work					
			Pre-Validation Lab Work					
Salt & Co-Cry	ystal Screening	Screening & Selection						
Early-Phase I	y-Phase Polymorphism Late-Phase Polymorphism							
Catalysis Ser	Catalysis Services & Troubleshooting							
Ligand Supp	ply							
		Synthesis of Reference Marker & Cold-Labele	ed Compounds					
		Synthesis of Registered Starting Materials (n	on-GMP)					
		Method Development & Validation				- Method Transfer		
		Stability & Degradation Studies						
		Extractables & Leachables						
			Accov Validation		Mothod Transfor		- 00	
		Analytical Assay Development	Assay Validation		Method Transfer		— QC	

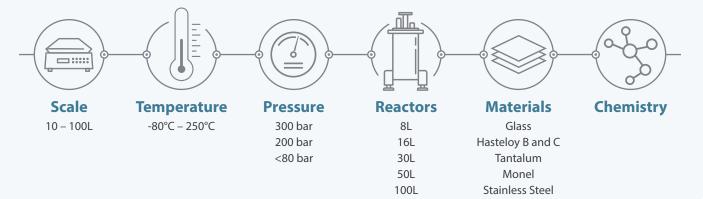
• Spectroscopy (IR, Raman, NMR)	Solubility
X-Ray powder diffraction	• pK <sub>a</sub>
Thermal methods	• logP/LogD
Hygroscopicity (by DVS)	Stability of API and API
HPLC, GC, GC headspace	excipient mixtures: physical, chemical, mechanical
• Karl-Fischer,	ICP-OES

# 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 O2 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

PFA

• Separation units 50–150L

160L

- High throughput catalysis screening
- Key analytical capabilities

#### Contact us to speak with an expert

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#### solvias.com

