

Drug Substance

Small Molecules & Highly Potent

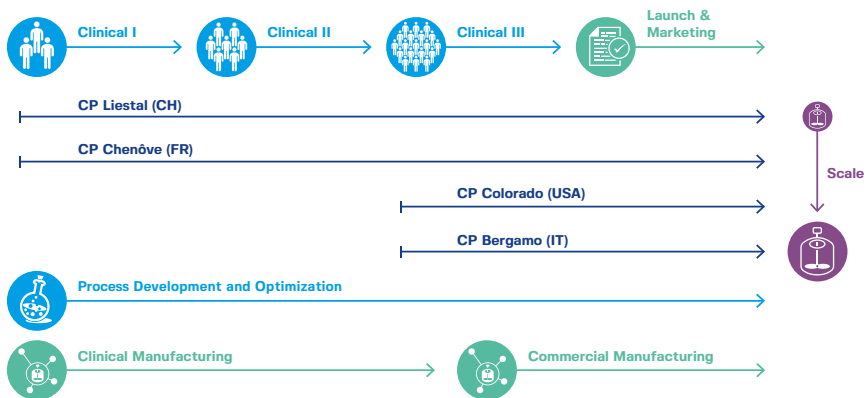


Your Expert Partner

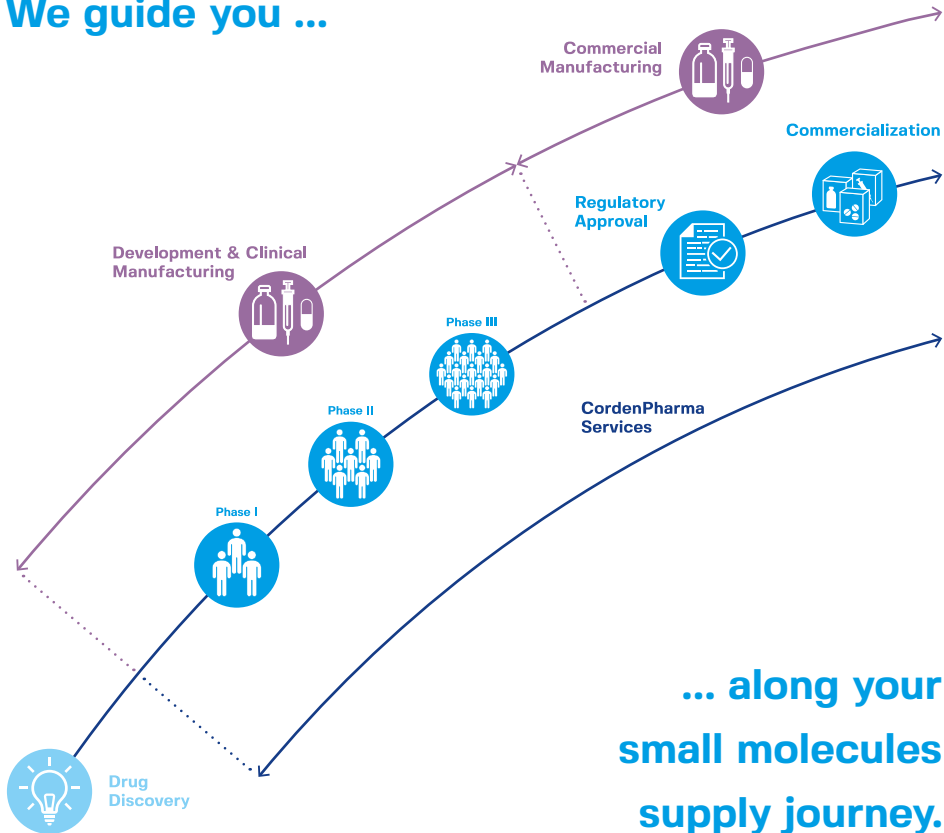
for Active Pharmaceutical Ingredients Supply

With **deep technical experience** and a **proven track record** in small molecule API manufacturing, we offer **flexible production** from gram to multi-ton scale across all clinical phases through to commercialization, including highly potent and oncological compounds.

Our **R&D team ensures on-time GMP manufacturing** of APIs and drug products, supporting your clinical timelines and paving the way for future development.



We guide you ...



... along your
small molecules
supply journey.

Your One Partner Benefits



Proven Track Record & Scientific Excellence

Leverage deep technical expertise and a strong track record to develop robust, phase-appropriate processes and methods tailored to your specific challenges.



Broad Development & Manufacturing Capabilities

Benefit from versatile capabilities for a wide range of molecule classes, from early development to commercial scale, including highly potent and oncology compounds.



Integrated Supply

Access fully-integrated solutions, from API development to finished drug product, within a global facility network.



Regulatory Support & More

Gain end-to-end guidance across regulatory strategy, industrial scale-up, GMP readiness, and filing support - so you can confidently advance through every stage of development.



Trusted Quality & Compliance

Rely on our commitment to seek the highest standards of quality & compliance as the foundation of all our activities and projects.



End-to-End Partnership Made Easy

Benefit from a single point of contact throughout your project for both APIs and drug products, streamlined process collaboration and aligned project management across our network.

Process Development

Our development team brings **extensive experience across a wide range of molecular targets** and is equipped to support the successful scale-up of your process in a phase-appropriate manner. With a strong understanding of both your project goals and future regulatory expectations, we go beyond scalable route design to **develop robust, end-to-end control strategies grounded in the principles of Quality by Design (QbD)**.

Process development at CordenPharma.

Selection of services:

- Route scouting & selection
- Process development & optimization
- Industrialization strategies
- Impurity isolation / identification
- Fate / purge studies
- Crystallization development
- Analytical method development & validation
- Forced degradation studies
- QbD & DoE
- Safety / hazard screening
- CMC support
- Stability studies
- Reference standard qualification



HIPO Range Potency

We specialize in the **development and cGMP manufacturing of highly potent APIs**, with proven expertise in handling compounds requiring containment for OEL values $\leq 0.05 \mu\text{g}/\text{m}^3$. Our capabilities include **process development and clinical-to-commercial manufacturing** of small molecule entities (including linker-payloads for ADCs), across a **broad range of scales, technologies, and purification methods**.



Highly potent manufacturing at CordenPharma.

Your Solution - No Matter the Potency

	Regular Potency			Potent	Highly Potent		
Criteria	OEB1	OEB2	OEB3	OEB4	OEB5	OEB6a	OEB6b
	Low Hazard	Moderately Hazardous	Hazardous	Highly Hazardous	Very Highly Hazardous	Extremely Hazardous	
OEL Range	$> 1000 - 10 \mu\text{g}/\text{m}^3$			$< 10 - 1 \mu\text{g}/\text{m}^3$	From 1 to $< 0.05 \mu\text{g}/\text{m}^3$		

Flow Chem & Solid State

Centres Of Excellence

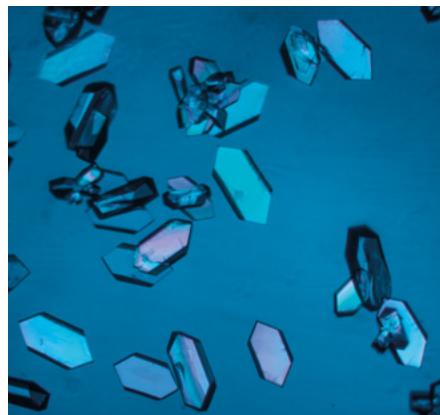
At our Centre of Excellence in flow chemistry, a dedicated team operating a well-equipped R&D laboratory is able to design and optimize tailored flow processes to solve complex chemistry challenges. Our pilot manufacturing facility enables us to demonstrate our designed flow process solutions at small production scale (10s of kgs) under full GMP environment.

At our solid state Centre of Excellence, a dedicated team operating state of the art technologies, offers tailored and phase appropriate services such as:

- design and development of crystallization process for API and intermediates
- polymorph screening and investigations
- salt and co-crystal screening and characterization
- racemate separation via resolution (available bank of chiral amines / acids for fast screening)

Micrograph of a crystalline API developed at our solid state CoE.

Flow Chemistry
at CordenPharma.



Purification & Micronization

Purification equipment
at CordenPharma.

Our purification services span **from grams to multi-100 kg scale and support all phases** (from Phase 1 to commercial manufacturing). With an extensive range of solutions, including crystallization, reverse and normal phase preparative chromatography, Supercritical Fluid Chromatography (SFC), and Tangential Flow Filtration (TFF), we tailor each purification program to your specific goals at every stage of development.

Our drug substance manufacturing in Europe offers **comprehensive micronization capabilities**, with a range of Jet Mills suited for **mid- to large-scale API production**. This in-house capacity enhances supply chain efficiency by eliminating the need to transfer materials for final processing. Leveraging the expertise of our Centres of Excellence in bioavailability and solid state, we can design and integrate the micronization process as early as the clinical development phase.





The project
management
team from
CordenPharma.

Technology Transfer

Technology transfers are critical to ensure reliable product manufacturing. We follow a **risk-based approach aligned with Quality by Design (QbD) principles**.

Prior to executing a full-scale engineering batch, small-scale and Design of Experiments (DoE) trials may be performed. The transfer process is guided by a comprehensive technology transfer protocol and report, and any necessary changes are managed through a structured change control process. Both giving and receiving project teams are regularly trained and used common procedure and tools.

Fully-Integrated Services

for All Your Product Needs

Products	Services	Manufacturing Sites
RSM & GMP intermediates	→ Technology transfer	CP Bergamo, IT
	→ Commercial manufacture	CP Chenove, FR
APIs	→ Development	CP Bergamo, IT
	→ Clinical manufacture	CP Chenove, FR
	→ Technology transfer	CP Colorado, US
	→ Commercial manufacture	CP Liestal, CH
	→ CoE solid state	
	→ CoE flow chemistry	
	→ Purification services	
Drug products	→ Formulation development	CP Ettingen, CH
	→ Technology transfer	CP Fribourg, CH
	→ Bioavailability enhancement	CP Lisbon, PT
	→ Commercial manufacture	CP Plankstadt, DE

* **Our cGMP facilities** are fully compliant with current regulatory requirements and applicable standards, while undergoing frequent regulatory inspections and customer audits.





Peptides



Oligonucleotides



Lipids & LNPs



Injectables



Highly Potent
& Oncology



Small Molecules

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Get in touch
with our experts