

# Small Molecules

Technology Platform





Expect excellent process knowledge from early phase to commercial?

Aiming for fully-transparent process development & documentation?

Want one partner for a full range of clinical to commercial scale-up services from kg to MT?

Seeking phase-appropriate process & analytical development?

Need access to innovative technologies such as Continuous Flow Manufacturing?

Looking for rapid scale-up services?

Searching for assistance with backward integration of complex regulatory starting materials?



**The right partner is one partner.** Working and coordinating with several providers can be demanding and time consuming when outsourcing a project. No matter where your project starts, Cordenpharma is the partner you need for a fully-integrated solution spanning the complete product life cycle at all stages, from preclinical to commercial, supported by dedicated regulatory and project management

services. A straightforward communication with one supplier alleviates the need for excess resources required to manage multiple providers. Through our network of integrated cGMP facilities across Europe and the US organized under six Technology Platforms, we have fostered an efficient exchange between API & Drug Product teams to decrease your development time to market.

# Your Benefits – Our Strengths

## Foster Entrepreneurial Spirit

**Flexibility & Transparency**  
Benefit from our collaborative commitment to react with flexibility & transparency to your changing needs.

## Development Experience

We know what you need before you realize you need it. Your project will benefit from our extensive expertise and capabilities in process development, scale-up and manufacturing.

## Guidance Throughout the Entire Drug Life-cycle

## Our Experience is Your Foundation

Over 200 years of combined Small Molecule manufacturing experience with over 100 years of cooperation with the FDA & EMA. Approximately 1.2 million litres of volumetric reactor capacity and 100s of millions of tablet and capsule manufacturing capacity to focus on your asset via an integrated product offering.

## Proven Production Capabilities

## Seamless & Effortless Management of Your Program

## Aligned Project Management & Synergy of Teamwork

Overseeing the entire journey will be our robust Global Project Management Team. Coordinating activities at the sites & acting as your main conduit into the organization, the experienced team will also offer insight & assistance on your journey.

## Focus on Patient Safety

## Our Motto is Quality

Rely on the integrity of our robust quality & regulatory compliance standards at the foundation of every step your project takes, from initial process development through product delivery and beyond.

## Ingenuity at Work

## Thinking Outside the Box

Grow from our scientific passion and ingenuity in finding new ways to solve complex problems that help you take the most efficient path to reach your project goals.

## Continuous Exchange & Knowledge Sharing

## Transparent Communication

Work closely with our dedicated project management teams to receive regular project updates, gain continual access to your batch records and reach your defined target.

## Streamlined Fully-Integrated Supply

Speed up your program with our one partner – one source philosophy to enable faster times to clinical trial & market with reduced costs, from Drug Substance to Drug Products & Packaging Services.

## Faster Time to Market with Reduced Cost



**Your Goal is our Goal.** We turn our strengths into your benefits by keeping in mind that your goal is our goal: to produce high quality pharmaceutical medicines through efficient, lean processes with reduced times to market.



# Your Full-Service CDMO for a Global Market

## Secure Your Supply Chain with our Fully-Integrated Solution

CordenPharma is the partner you need for a Fully Integrated Supply solution spanning your complete product life cycle at all stages, from sourcing of raw materials to secure your supply chain, through preclinical & commercial development and manufacturing of GMP starting materials, APIs, finished dosage Drug Products & Packaging > resulting in reduced time & cost. Your project is all the while supported by dedicated regulatory & project management expertise at every step along your outsourcing path.



## The Beating Heart of CordenPharma – The Small Molecules Platform

The heart of CordenPharma's manufacturing history and capacity remains our Small Molecules Platform. Our integrated network of facilities brings a combined 200+ years of manufacturing experience to bear on your project. With over 1,200,000 Liters of volumetric capacity and reactors ranging from 20 L to 28,000 L made of various materials of construction, we can produce your API and manufacture 100s of millions of tablets or capsules with various formulation options. With our commercial track record we develop and advance your small molecule projects through clinical trials to commercial launch. A strong financial background formed from existing commercial projects means you can rely on the stability of our small molecule CDMO partnership to support you through clinical trials to commercial launch.

Our extensive network of facilities in Liestal (CH), Chenôve (FR), Colorado (US), Bergamo (IT), Ettingen (CH), Fribourg (CH) and Lisbon (PT) allows for services that enable your asset to travel smoothly from preclinical supply to a successful commercial launch with phase-appropriate development for effective management of financial budgets.

Beyond the Small Molecules Platform, your benefit expands to the seamless tech transfer of your project within our facility network for the production of Aseptic & Terminal Sterilization Fill & Finish in Pre-Filled Syringes (PFS), ampoules, liquid & lyophilized vials, as well as combination device products, packaging & labeling, and clinical trial kit management within our Injectables Platform.



# Stages of Small Molecule Production

## Just Selected Your Clinical Candidate?

**We have you covered!** We can provide initial route scouting to devise an appropriate, robust, scalable and cost effective approach to the manufacture of your small molecule at scale. This process is tailored to your specific needs, as we understand the budget constraints that often drive decision making at these early milestones. Taking your medicinal chemistry route as the starting point, we then perform a criticality analysis to identify potential stumbling blocks for the scale-up including safety concerns, price drivers, green chemistry options, atom economy & isolation challenges, and then devise a customized development plan to address your exact needs to safely execute the process at scale.

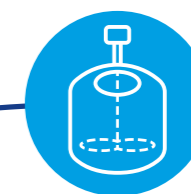
With recently expanded small-scale production facilities comprised of movable and interchangeable equipment, our aim is to create a highly flexible manufacturing space geared towards meeting your wide-ranging requirements and aggressive timelines.

## Already Demonstrated Your Process at Scale? Looking For a New Manufacturing Site?

**We have you covered!** With four API and three Drug Product manufacturing sites in different geographic locations depending upon your preference, requirements or strategies, our network allows for a continuum of scales available from low kilos to metric tonne demands. Whether you may initially only be projecting small annual de-

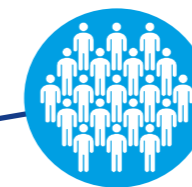
mands of 100s of kilos or hit a home run in the clinic and suddenly have an annual demand growing in orders of magnitude – no issue! Through an internal technology transfer system, our team can seamlessly transfer your process between sites to execute on a scale-up in minimal timeframe to keep your program on track.

## Regulatory Approval



Commercialization

Phase III



Phase II



Clinical Development

GMP Manufacturing



Phase I

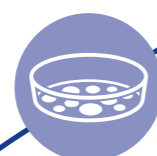


In Vivo



Lead Optimization

In Vitro



Discovery



## Product Approved & Launch Projections Growing Faster Than Supply? Need Commercial Manufacturing & Second Source Selection?

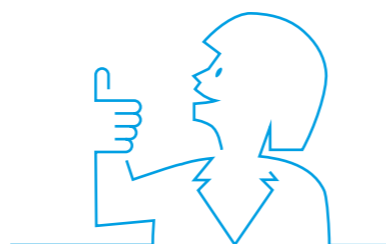
**We have you covered!** At the core of the small molecule platform is our manufacturing capacity with a combined 200+ years of facility experience supplying commercial products to US and European markets, all with excellent regulatory backgrounds.

Having cGMP manufacturing sites across Europe and the US de-risks your projects from a geographic supply point of view, enabling manufacture of APIs within the region of drug product distribution if required. This flexibility also provides dual-site manufacture solutions for «Act of God» planning scenarios.



# Innovative Technologies & Supply Chain

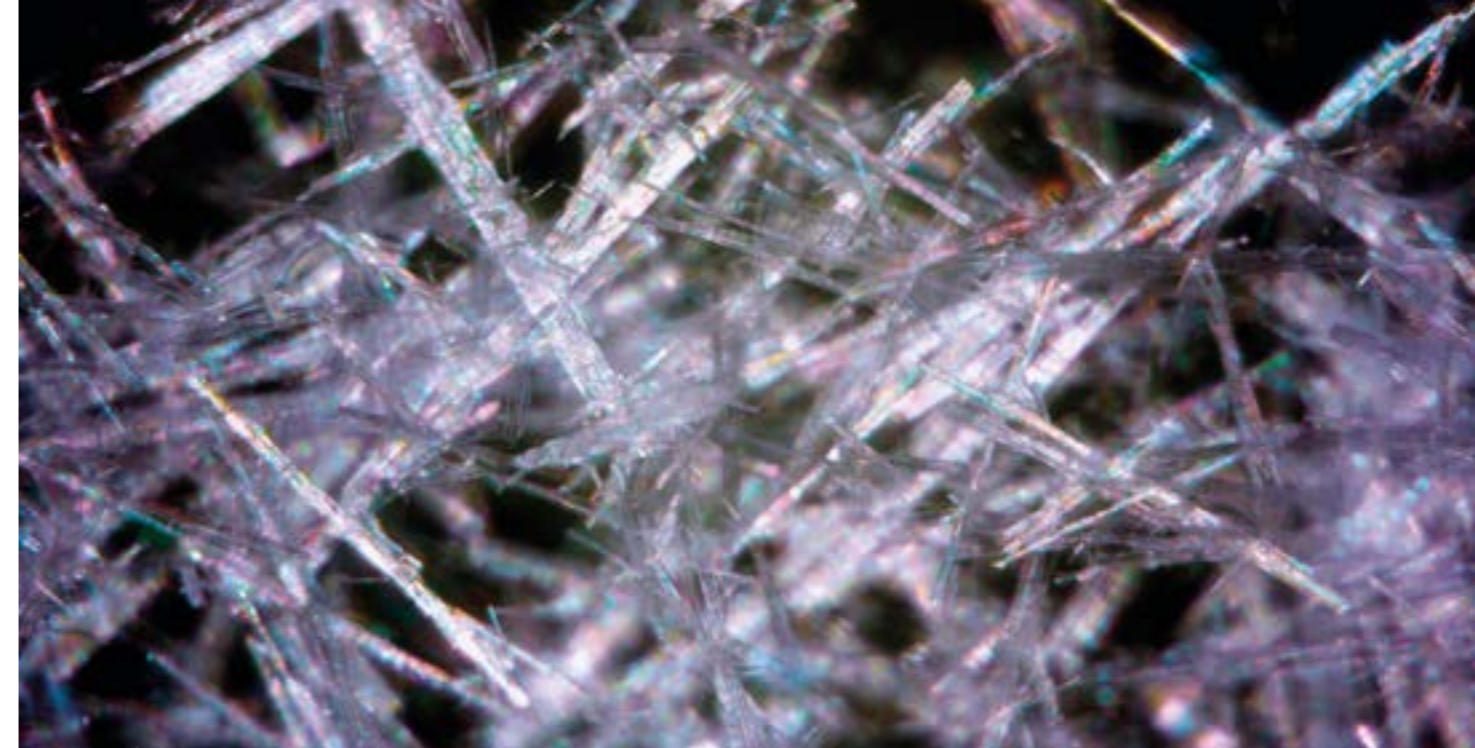
 **Want Maximum Manufacturing Flexibility with Cutting-Edge Technology?**



**We have you covered!** Continuous manufacturing, and in particular flow chemistry, remains a highly attractive technology option. Although slightly more expensive upfront costs are required to set up the methodology, the long-term savings from reduced manufacturing costs and eliminated scale-up / development cycles, as well as greater scale & manufacturing flexibility, will far outweigh these larger starting costs.

Beyond mere costs savings, the de-risking potential of the technology offers you even greater savings or risk mitigation strategies. The potential smaller volumes involved mean more reactive chemistry can be considered, along with an increased overall safety margin of the chemistry. The smaller volumes also allow for less money to be put at risk with each batch, which is a particular concern with an expensive raw material or potential batch failure risk in a long multi-step synthetic approach. Smaller footprint manufacturing skids can be cloned and then located in multiple geographic locations to address potential supply concerns associated with trans-global shipping and distribution channels.

Flow chemistry manufacturing facility at CordenPharma Chenôve (FR)



Crystalline intermediate in polarized light at CordenPharma Liestal / Switzerland (CH).

 **Need Solid-State Development or Looking for a New Novel Polymorph?**

**We have you covered!** Developing the best polymorphic form of your API is a critical step in the development of your asset, as it will have significant impact on the effectiveness of your drug product formulation via the bioavailability of your API.

Our industry leading team of dedicated scientists are ready to support your needs via support services ranging from:

- Crystallization investigations
- Solid state characterization
- Salt screening & salt selection
- Polymorph screening
- Solubility & crystallization screening, including the creation of solubility curves
- Optimization of the crystallization process
- Identification of critical parameters
- Optimziation of solid-liquid separation process during API isolation


Our services are designed as flexible, bespoke offerings to address your current needs, appropriate for your stage of development and manufacturing needs. Our services can be accessed directly, or as part of an integrated drug substance and/or drug product development program within CordenPharma.



Discover The Benefits of our Flow Chemistry Services





 **Need Various Drug Product Dosage Forms?**

**We have you covered!** Our Drug Product manufacturing sites have a broad range of capabilities and specialize in the development and manufacturing of various dosage forms. These facilities provide a complete offering from small scale formulation development prototypes, to clinical scale batches, and commercial scale manufacturing. This continuum allows us to support your needs, regardless of your stage of development.

- Coated & Uncoated Tablets, Minitablets
- Hard Gelatin & HPMC Capsules filled with Powders, Granules, Pellets
- Conventional processing technologies including Roller Compaction, High Shear & Fluid Bed Granulation (aqueous & solvent processes)
- Solutions for APIs with Bioavailability Challenges including Hot Melt Extrusion, Spray Drying, Micronization, and Nanomilling
- Immediate & modified release formulations
- Powder for suspension via sachet dosage forms
- Non-Sterile liquid dosage forms such as Nasal Sprays & Oral Syrups
- Rectal Dosage forms (Enemas & Suppositories)
- Labeling, packaging & distribution services
- Full analytical capabilities
- Supply compliant with all major markets



Our finished dose facilities meet the serialization compliance requirements aimed at combatting global counterfeiting. In addition, a team has been established to standardize processes, logistics and maintain the integrity of the data. All CordenPharma facilities are routinely inspected by major regulatory agencies and regularly supply global regulated markets.

Capsule production at CordenPharma Lisbon (PT).



Discover our Drug Product Services





«This was an exciting project for me because I was able to see how the entire site came together and worked as a team to successfully develop and scale-up our customer's small molecule project within an unbelievable time frame.»

**Beatrice Lucas**, Head of Project Management, CordenPharma Chenôve

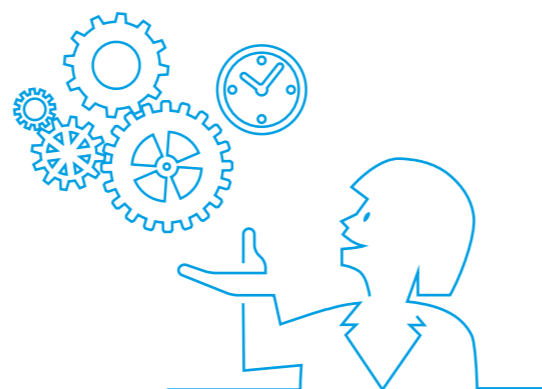
Our team at CordenPharma Chenôve (FR) performed rapid & efficient development, scale-up and manufacturing of a small molecule process from a medicinal chemistry route to a 100 kilogram scale in a short period. The original process the customer brought to us was a classic medicinal chemistry route that had only been performed in the past at small gram scale. We were assigned to manufacture it even though key isolation strategies for each intermediate and final product had not been developed, and the isolations in the procedure we were provided read at each stage «evaporate to dryness».

Based on this limited process, our team took on the challenge, rapidly developing a sound process in the laboratories that was further demonstrated in the kilo lab and followed-up by production at 25 kg scale. Despite raw material supply challenges and last minute particle size requirement changes, we managed to produce the material on time and in full, while also shipping the product to the USA under a compressed timeline.

Subsequently, we received more follow-up campaigns from this customer.



# One Partner Process & Project Management

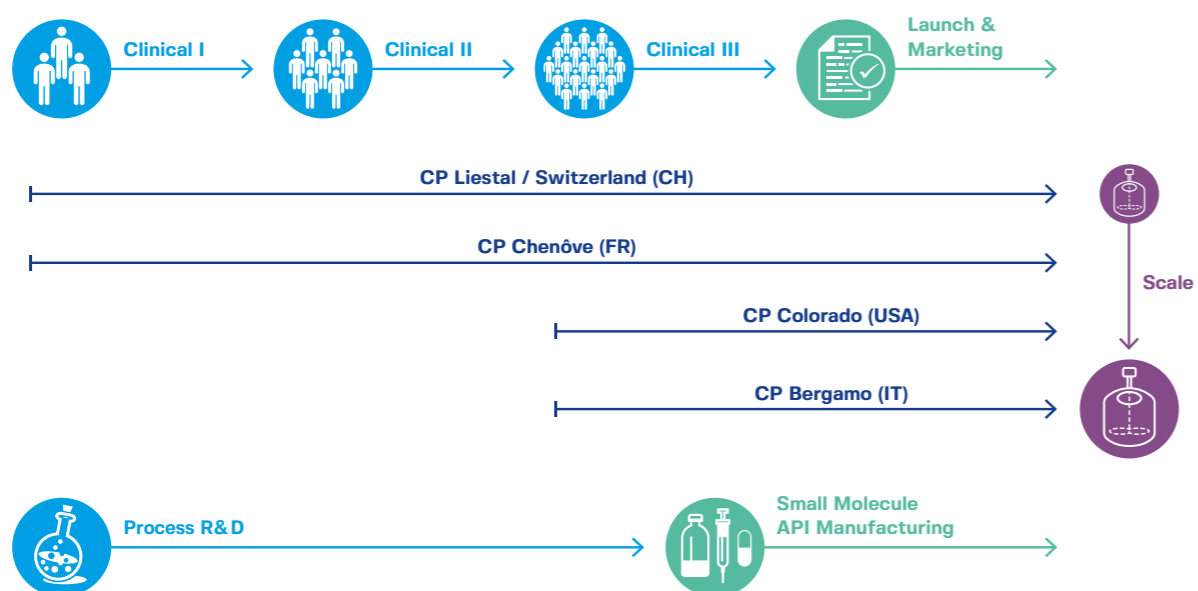


## Process R&D

- Process Development
- Process Optimization
- Analytical Method Development
- Crystallization Optimization
- Polymorphism Studies
- Impurity Identification & Screening
- Fate / Purge Studies
- Regulatory Support
- Stability Studies

## Small Molecule API Manufacturing

- Scalable and Cost Effective Routes
- Process Validation
- Analytical Method Validation (ICH)
- Impurity Profile Characterization
- Stability Studies
- Gram to Multi-ton Manufacturing



CordenPharma Colorado (USA) solvent handling infrastructure to support small molecule manufacturing.

## Streamlined Process Collaboration

Our approach to every project begins with fostering a constant exchange between the applicable API & Drug Product Process Development teams involved. Ongoing alignment with analytical, quality and compliance support guarantees you fast and consistent results, independently of where your project starts.

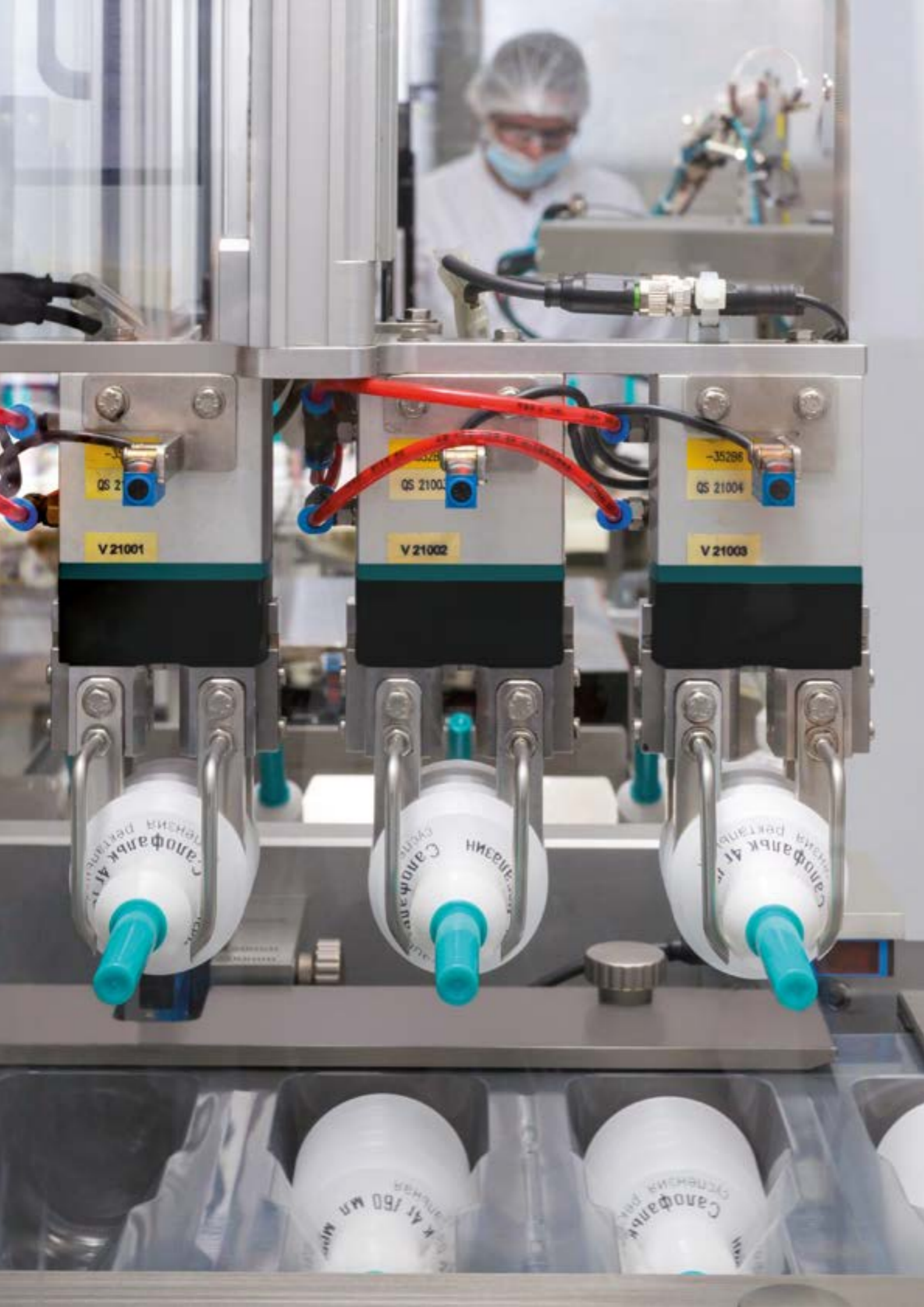
## Aligned Project Management

CordenPharma's Global Project Management Team carefully assigns an appropriate amount of time & resources to each phase of development, while monitoring all tasks to ensure your project progresses in a controlled and timely way. Our project management organization safeguards the alignment of resources with local project managers throughout our network of facilities for your integrated supply projects involving multiple sites and technologies to deliver on our promise – one source, one partner.

## Your One Partner Benefits:

- Single point of contact throughout your project for both APIs & Drug Products
- Global SOPs mean shorter tech transfer time for materials & documentation
- Knowledge transfer guaranteed with consolidation of stability testing, analytical methods & physical property
- One CDA / MSA with single-data entry point ensures ease of sharing data internally & externally and speed of execution
- Improved data integrity guaranteed by controlled single-source data with integrated project planning



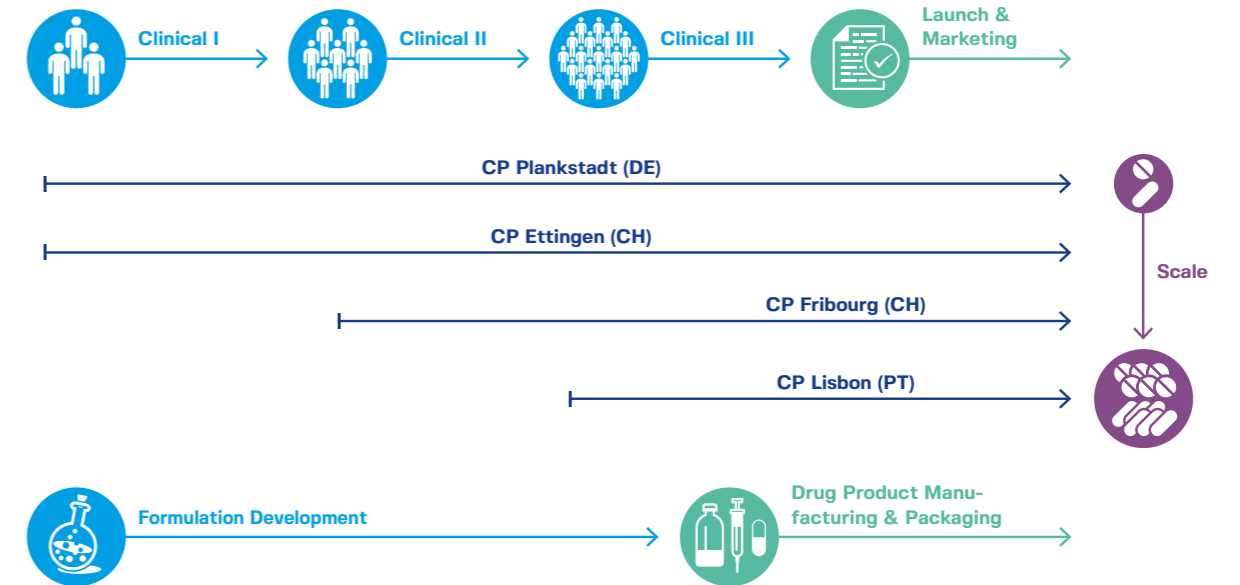


### Formulation Development Services

- Formulation Development
- Prototype Manufacture
- Formulation Optimization
- Bioavailability Enhancement
- Analytical Method Development
- Impurity Identification & Screening
- Clinical Batch Manufacturing
- Regulatory Support
- Stability Studies
- Packaging Development

### Drug Product Manufacturing & Packaging

- Process Validation
- Analytical Method Validation (ICH)
- Stability Studies
- Commercial Manufacturing
- Tablet, Capsules, Sachet, Non-Sterile Liquid & Rectal Dosage Forms
- Primary & Secondary Packaging
- Temperature- Controlled Storage, including Cold Storage capacity



Enema  
production at  
CordenPharma  
Ettingen (CH).





# Quality & Compliance First

Our commitment to seek the highest standards of Quality & Compliance First is the backbone of all our activities and projects. We make no compromises in this area. We have and continue to invest heavily in compliance programs, with the objective to meet and surpass applicable regulatory requirements & legislations. Our focus on quality & compliance will be ongoing, with budgeted investment in improvements such as compliance-enhancing IT solutions.



## CordenPharma Continuous Improvement Program

You will benefit from the ongoing support of CordenPharma's Continuous Improvement Program, based on the consistent completion of corrective and preventive actions arising from self-initiated proactive third party group-wide gap assessments, agency inspections, as well as internal, annual corporate & customer audits. This approach enables us to not only meet, but surpass general requirements needed to see your project through to completion.

## CordenPharma Global Compliance Team

The CordenPharma Global Compliance Team systematically interprets these continuous improvement program audit and assessment results on your behalf to generate corporate policies and global standards enabling employees at all levels to comply with current applicable guidelines and legislations in their daily activities.

Corporate compliance standards & policies are then implemented at all CordenPharma sites globally, with the objective of complete harmonization to foster transparency and straightforward communication, both internally and externally with our customers. The whole organization works together, from the Executive Leadership Team and Facility Managing Directors to the Marketing & Sales team and operators, to make sure all employees effectively comply with implemented policies, Standard Operating Procedures (SOPs), master work instructions, plans & forms to meet all the requirements for your pharmaceutical success.

Market	Agency	Bergamo (IT)	Chenôve (FR)	Colorado (USA)	Liestal (CH)	Ettingen (CH)	Fribourg (CH)	Lisbon (PT)	Plankstadt (DE)
	EMA, EU local	●	●	●	●	●	●	●	●
	FDA	●	●	●	●		●	●	●
	PMDA	●	●	●	●				●
	TGA	●	●	●					●
	Health Canada	●	●	●	●				●
	ANVISA	●		●			●	●	●







## Our Manufacturing Sites

Manufacturing Sites	Products	Phase	Specialities
● CordenPharma Bergamo, IT	→ API	Phase III to Large-Scale Commercial	→ Large-Scale / Competitive Pricing → Hydrogenation → Micronization Capabilities
● CordenPharma Chenôve, FR	→ API	Preclinical to Mid-Scale Commercial	→ Flow Chemistry Expertise → Micronization Capabilities
● CordenPharma Colorado, USA (Sites 1 & 2)	→ API	Phase III to Large-Scale Commercial	→ Cryogenic RXNs → Hydrogenation → Extensive Purification → Micronization Capabilities
● CordenPharma Liestal, CH	→ API	Preclinical to Small-Scale Commercial	→ Small Molecule Development Centre → Hydrogenation & Purification Capabilities
● CordenPharma Etingen, CH	→ Drug Product → Non-Sterile Liquid → Rectal Dosage Forms	Preclinical to Mid-Scale Commercial	→ Formulation Development Centre (Liquid) → Oral Solutions & Syrups, Nasel Spray, Drops → Suppositories & Enemas
● CordenPharma Fribourg, CH	→ Drug Product → Oral Solid Dosage → Non-Sterile Liquid	Preclinical to Large-Scale Commercial	→ Formulation Development Centre (OSD) → Tablets & Capsules
● CordenPharma Lisbon, PT	→ Drug Product → Oral Solid Dosage	Preclinical to Large-Scale Commercial	→ Tablets, Capsules & Sachets → Extensive Packaging Capabilities
● CordenPharma Plankstadt, DE	→ Drug Product → Oral Solid Dosage	Preclinical to Mid-Scale Commercial	→ Bioavailability Enhancement → Formulation Development Centre (OSD) → Tablets & Capsules





# CordenPharma

## International

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Switzerland

[cordenpharma.com](http://cordenpharma.com)



**Peptides**



**Lipids &  
Carbohydrates**



**Highly Potent  
& Oncology**



**Injectables**



**Small Molecules**



**Oligonucleotides**