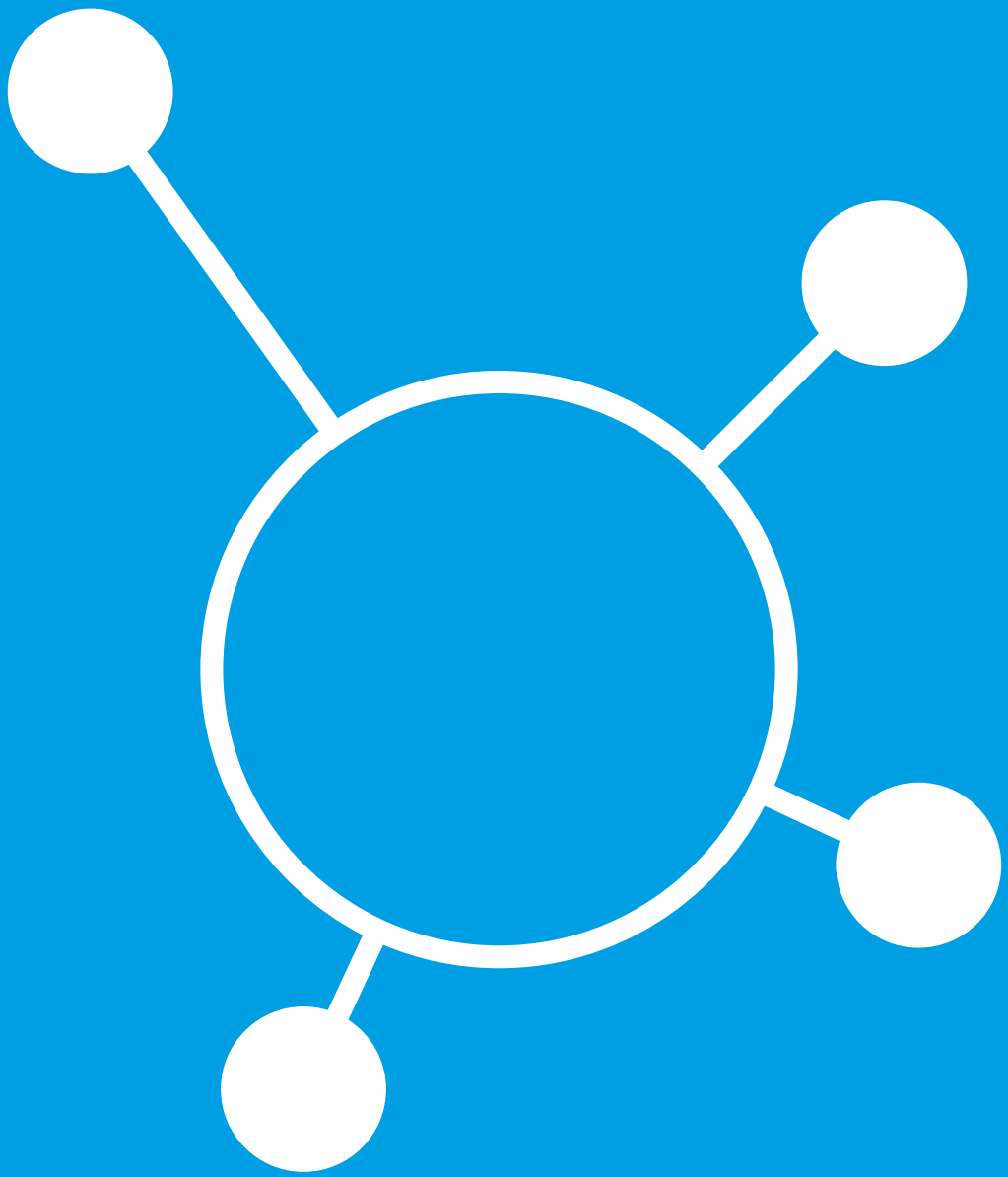
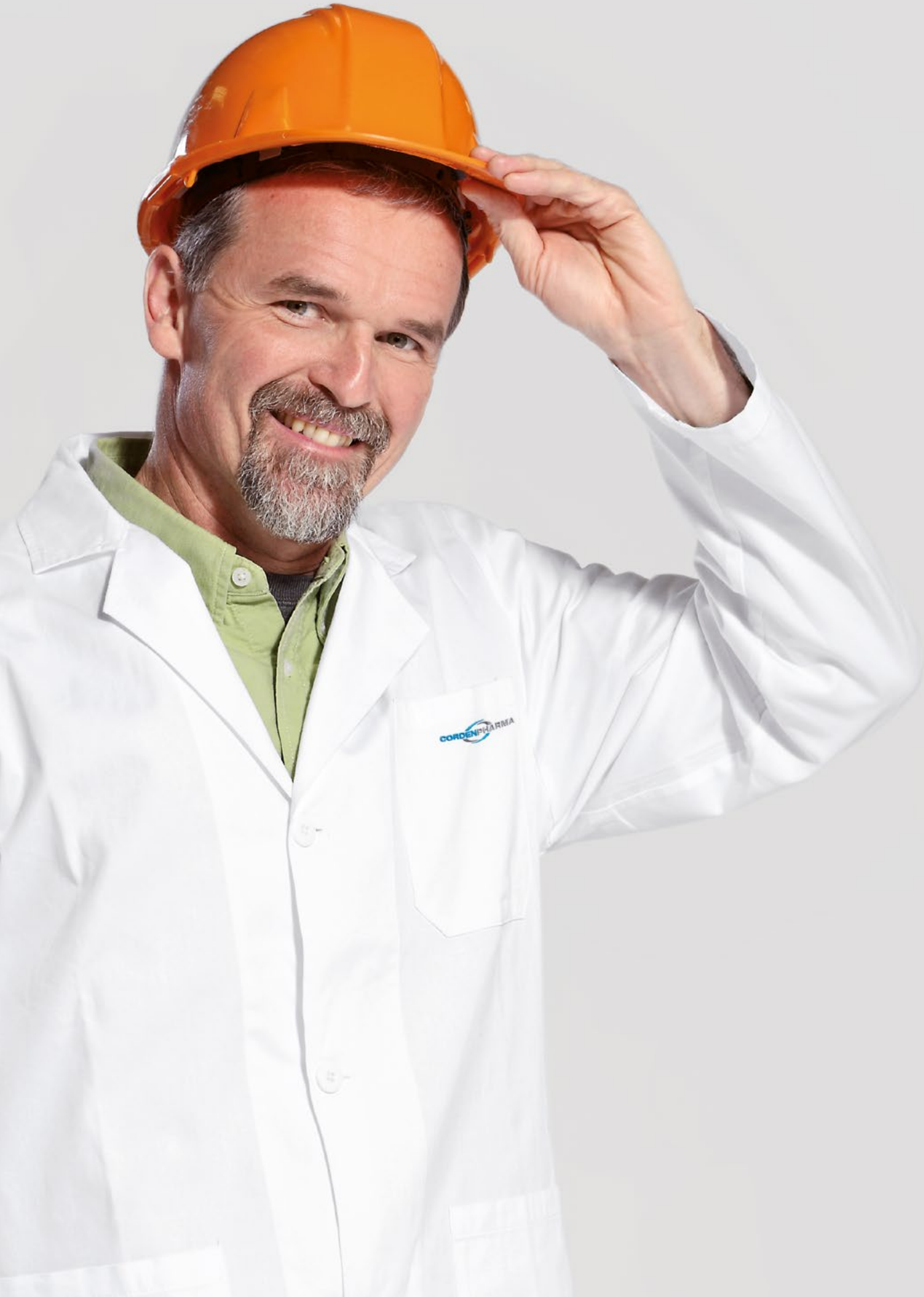
CORDENPHARMA

SMALL MOLECULES
TECHNOLOGY PLATFORM




CORDENPHARMA

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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, we believe in the concept of ONE PARTNER providing you an 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 five Technology Platforms, we have fostered an efficient exchange between API & Drug Product teams to decrease your development time to market. We can also assist in sourcing your complex regulatory starting materials through our sister organization Weylchem Group of Companies, truly providing you with ONE PARTNER.

YOUR BENEFITS – OUR STRENGTHS

Guidance Throughout the Entire Drug Life–cycle

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.

Foster Entre–preneurial Spirit

Flexibility & Transparency
Benefit from our collaborative commitment to react with flex–ibility & transparency to your changing needs.

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.

Faster Time to Market with Reduced Cost

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 back–integration of non–GMP raw materials to Drug Substance, Fill & Finish Drug Products & Packaging Services.

Continuous Exchange & Knowledge Sharing

Transparent Communication
Work closely with our ded–icated project management teams to receive regular project updates, gain continual access to your batch records and reach your defined target.

Proven Production Capabilities

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 to focus on your asset.

Seamless & Effortless Management of Your Program

Aligned Project Management & Synergy of Teamwork
Overseeing the entire jour–ney 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.

Ingenuity at Work

Thinking Outside the Box
Grow from our scientific pas–sion and ingenuity in finding new ways to solve complex problems that help you take the most efficient path to reach your project goals.

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

ONE PARTNER provides you with a Fully–Integrated Supply solution spanning your complete product life cycle at all stages, from manufacturing of back–integrated non–GMP Intermediates 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.

Aseptic Fill & Finish at CordenPharma Caponago (IT).

The Beating Heart of CordenPharma APIs – Small Molecules Platform

The heart of CordenPharma's API 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 ranging from 20 L to 28,000 L reactors of various materials of construction. 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) and Bergamo (IT) 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.

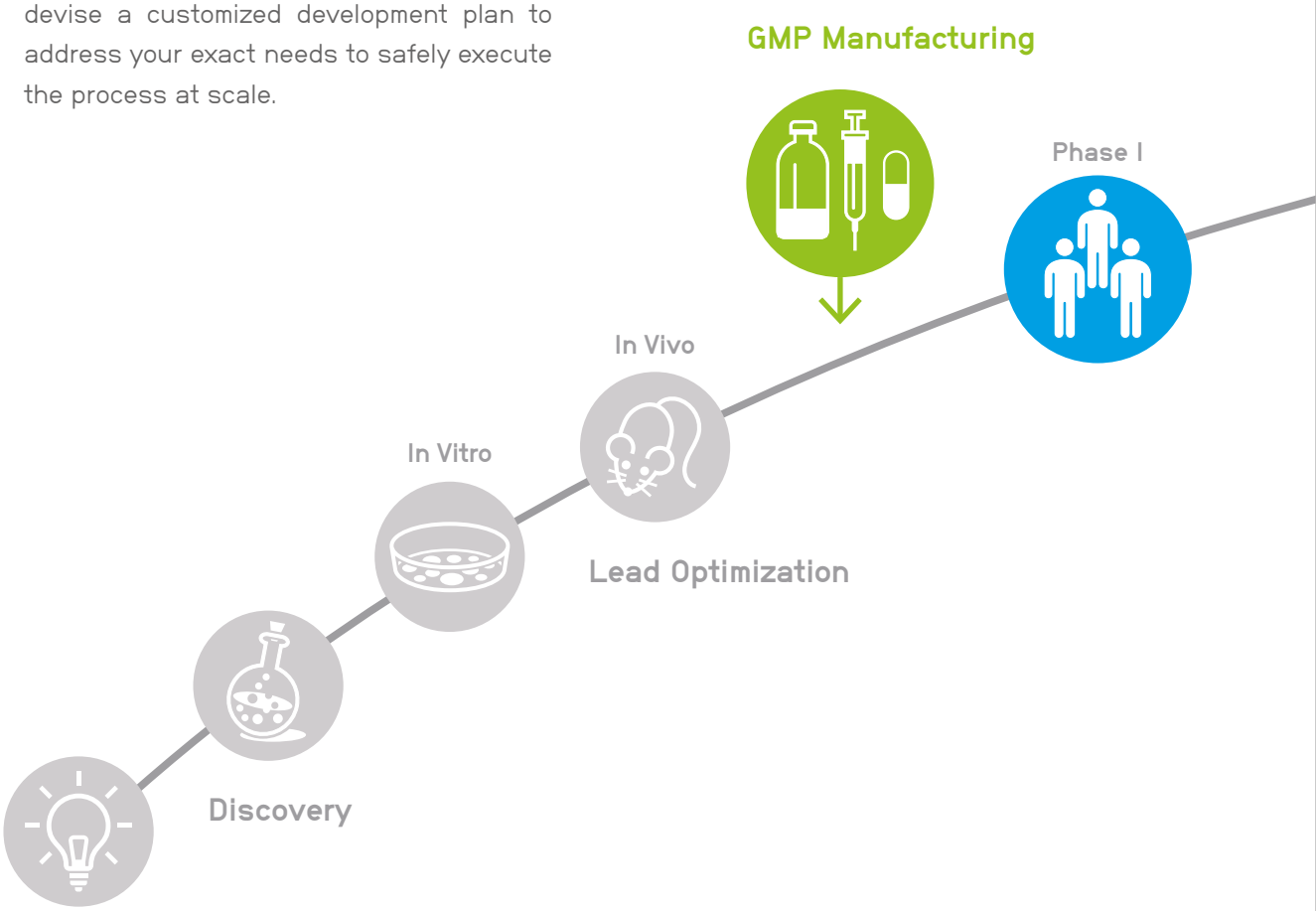
Beyond the Small Molecules Platform, your benefit expands to the seamless tech transfer of your project within our facility network for the production of Drug Products & Packaging Services. The Injectables Platform provides Aseptic & Terminal Sterilization Fill & Finish in Pre-Filled Syringes (PFS),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

STAGES OF SMALL MOLECULE PRODUCTION

Just Selected Your Clinical Candidate?

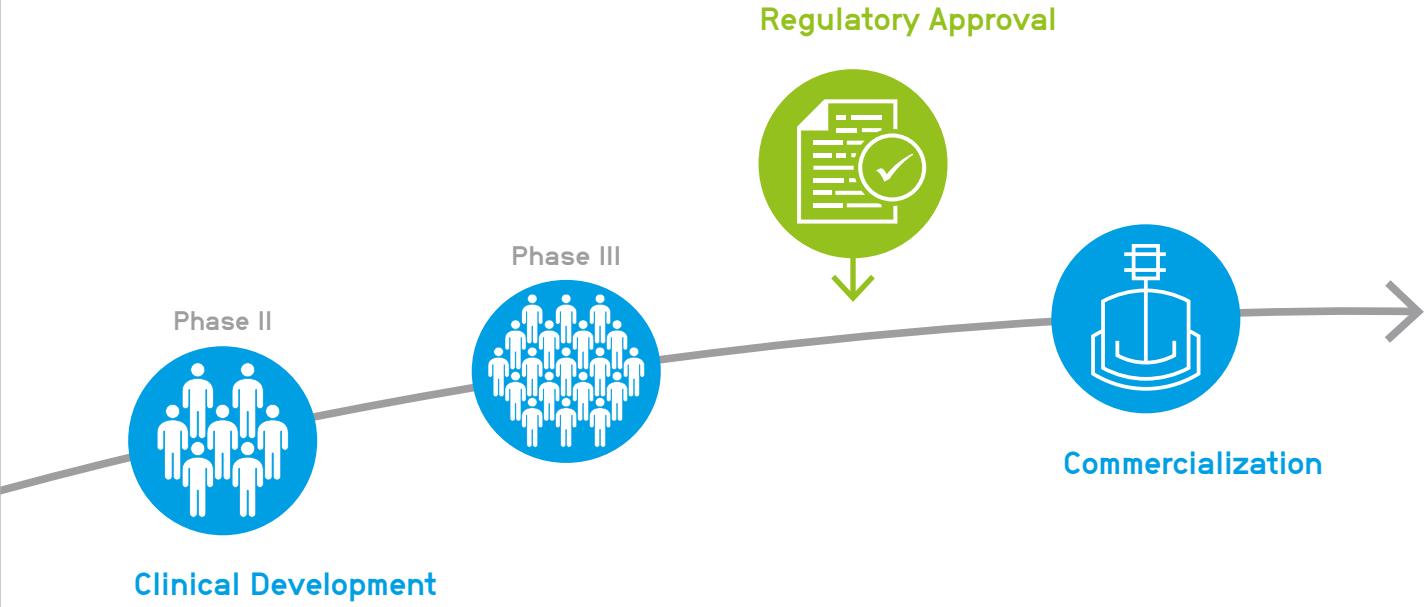
We have you covered! We can provide initial route scouting to devise an appropriate, robust, scalable and cost effective approach to the manufacture of your small molecule at scale. This process is tailored to your specific needs, as we understand the budget constraints that often drive decision making 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 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 demands 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.



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 APIs 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.

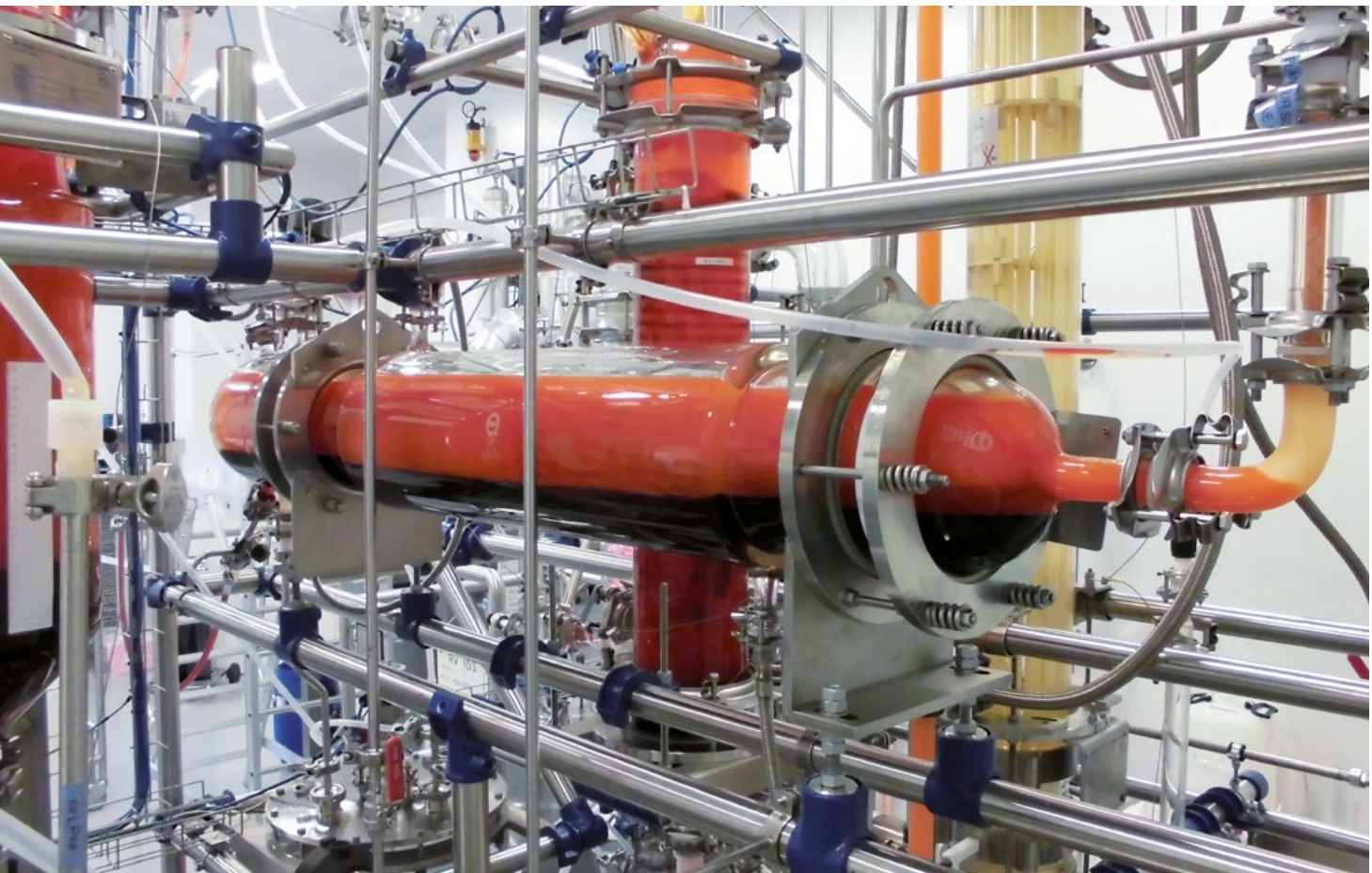
Want Maximum Manufacturing Flexibility with Cutting–Edge Technology?

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.

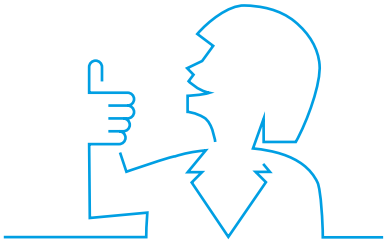
Beyond mere costs savings, the de–risking potential of the technology offers you even greater savings or risk mitigation strategies. The potential smaller volumes involved mean more reactive chemistry can be considered, along with an increased overall safety margin of the chemistry. The smaller volumes 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.

Reference:
Chemical Engineering News,
June 25, 2018, Volume 96, Issue 26

Continuous extraction process in development at CordenPharma Chenôve (FR).

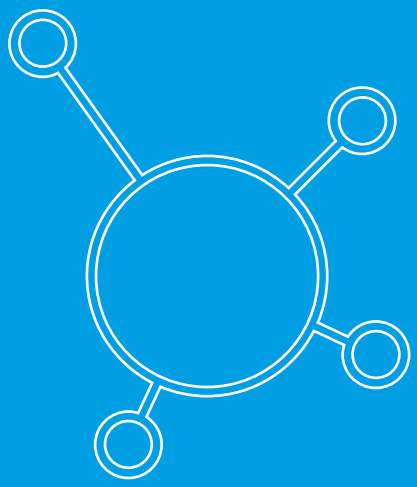


CordenPharma Colorado (USA) solvent handling infrastructure to support small molecule manufacturing.



Have Complex Regulatory Starting Materials or Tired of Your Supply Chain Headaches?

We have you covered! Through our sister organization Weylchem, we have access to non-GMP fine chemical manufacturing assets in Europe and the USA. With a wide range of expertise, experience, chemistry technologies and reactor capacity, we assist with the manufacture of your complex regulatory starting material in an open, transparent and controlled fashion under Western business ethics & standards. Although not as competitive from a price point of view as some other sources, the slightly higher cost brings peace of mind and reliability of supply – delivering the quantity needed, at the quality standards requested, on the date promised. Since Weylchem is a sister company under our parent company ICIG, legal situations are simplified by operating under one CDA, while the development & production is managed within our Global Project Management team, resulting in only one point of contact for you, the customer.



«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.»

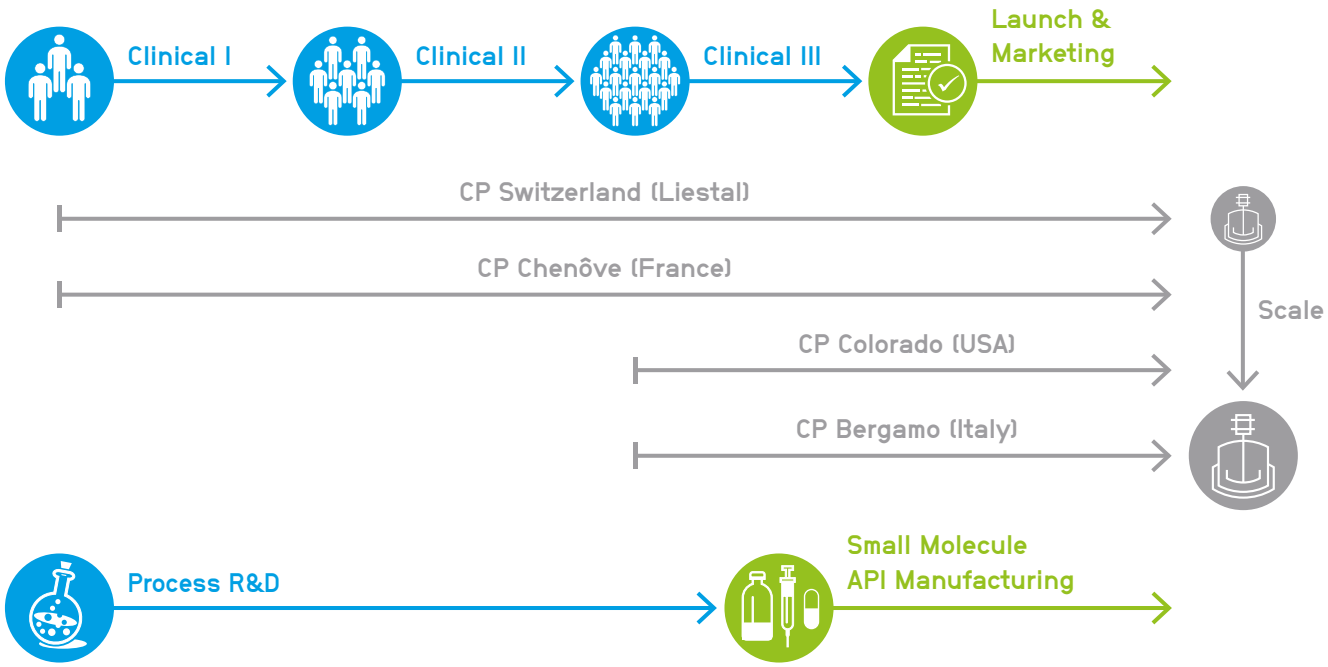
Beatrice Lucas, Head of Project Management, CordenPharma Chenôve

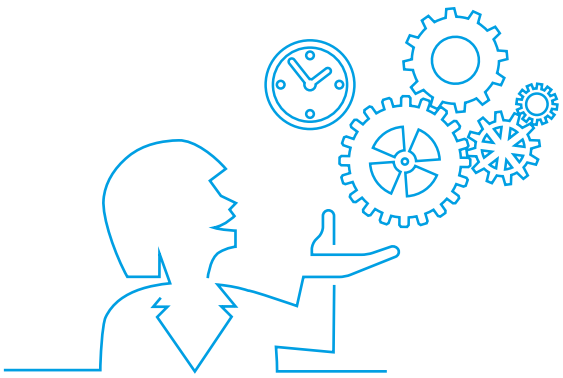
Our team at CordenPharma Chenôve (FR) performed rapid & efficient development, scale–up and manufacturing of a small molecule process from a medicinal chemistry route to a 100 kilogram scale in a short period. The original process the customer brought to us was a classic medicinal chemistry route that 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

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

Sampling of a final API to support homogeneity testing plan at CordenPharma Switzerland.

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

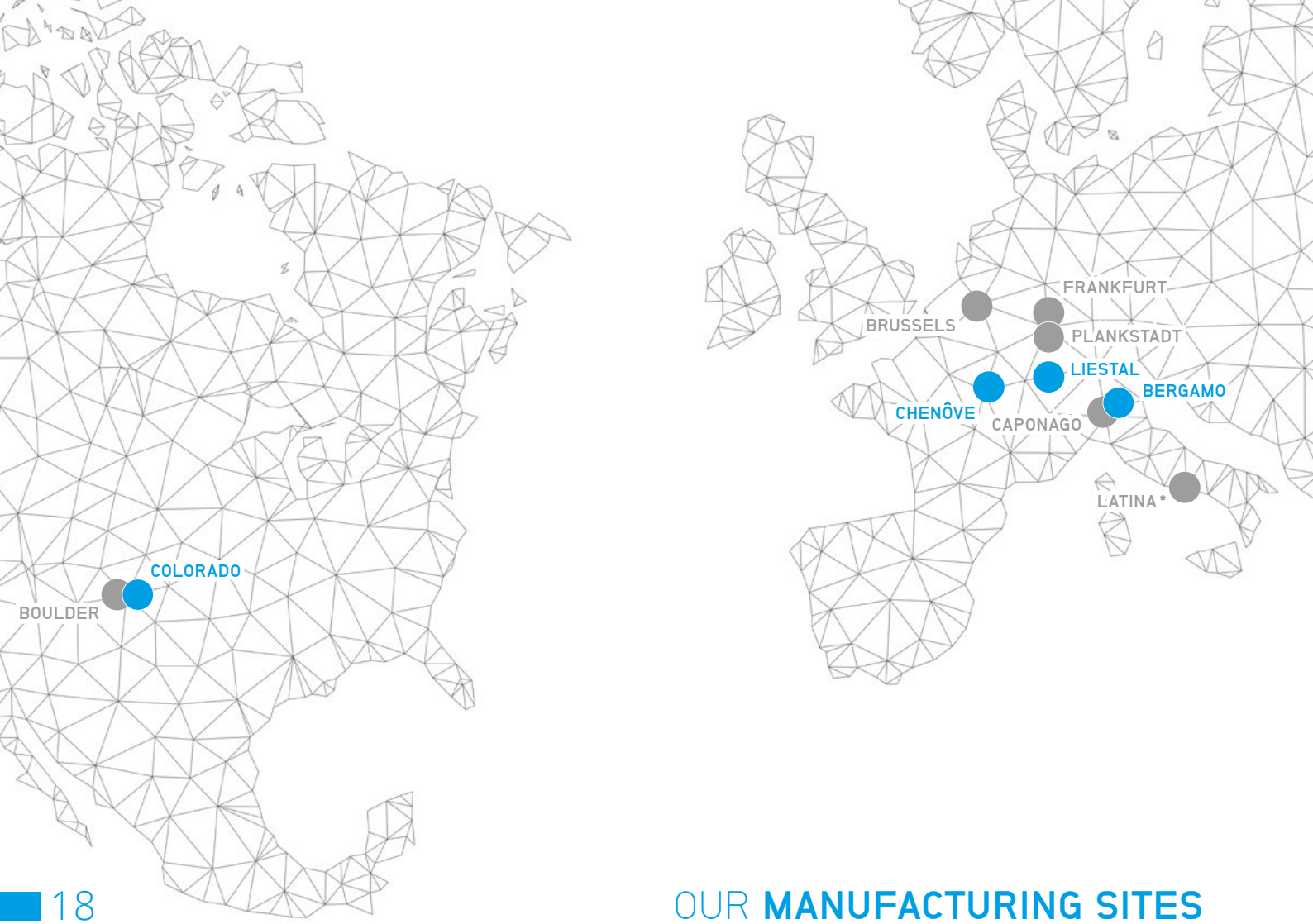
You will benefit from the ongoing support of CordenPharma's Continuous Improvement Program, based on the consistent completion of corrective and preventive actions arising from self-initiated proactive third party group-wide gap assessments, agency inspections, as well as internal, annual corporate & 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	COLORADO (US)	LIESTAL (CH)	CHENÔVE (FR)	BERGAMO (IT)
	EMA, EU local	●	●	●	●
	FDA	●	●	●	●
	PMDA	●	●	●	●
	TGA	●		●	●
	Health Canada	●	●	●	●
	ANVISA	●			●
	IMPROMTORG		●		



OUR **MANUFACTURING SITES**

MANUFACTURING SITES	PHASE	REACTOR RANGES	SPECALITIES
CordenPharma Switzerland, Liestal, CH	Preclinical to Small–Scale Commercial	Kilo Lab 60 – 2,500 L –90°C to 160°C Hydrogen @20bar	Small Molecule Development Centre Hydrogentation & Purification Capabilities
CordenPharma Chenôve, FR	Preclinical to Medium–Scale Commercial	Kilo Lab 600 – 5,000 L –20°C to 160°C	Flow Chemistry Expertise Micronization Capabilities
CordenPharma Colorado, USA	Phase III to Large–Scale Commercial	Kilo Lab 100 – 18,000 L –100°C to 140°C Hydrogen @10bar	Cryogenic RXNs Hydrogenation Extensive Purification Micronization Capabilities
CordenPharma Bergamo, IT	Phase III to Large–Scale Commercial	1,000 – 28,000 L –20°C to 290°C Hydrogen @15bar	Large–Scale / Competitive Pricing Hydrogenation Micronization Capabilities

* Corden Pharma Latina S.p.A. was acquired by a Third Party (not affiliated to CordenPharma)

CORDENPHARMA
INTERNATIONAL

Otto-Hahn-Straße
68723 Plankstadt
Germany

www.cordenpharma.com