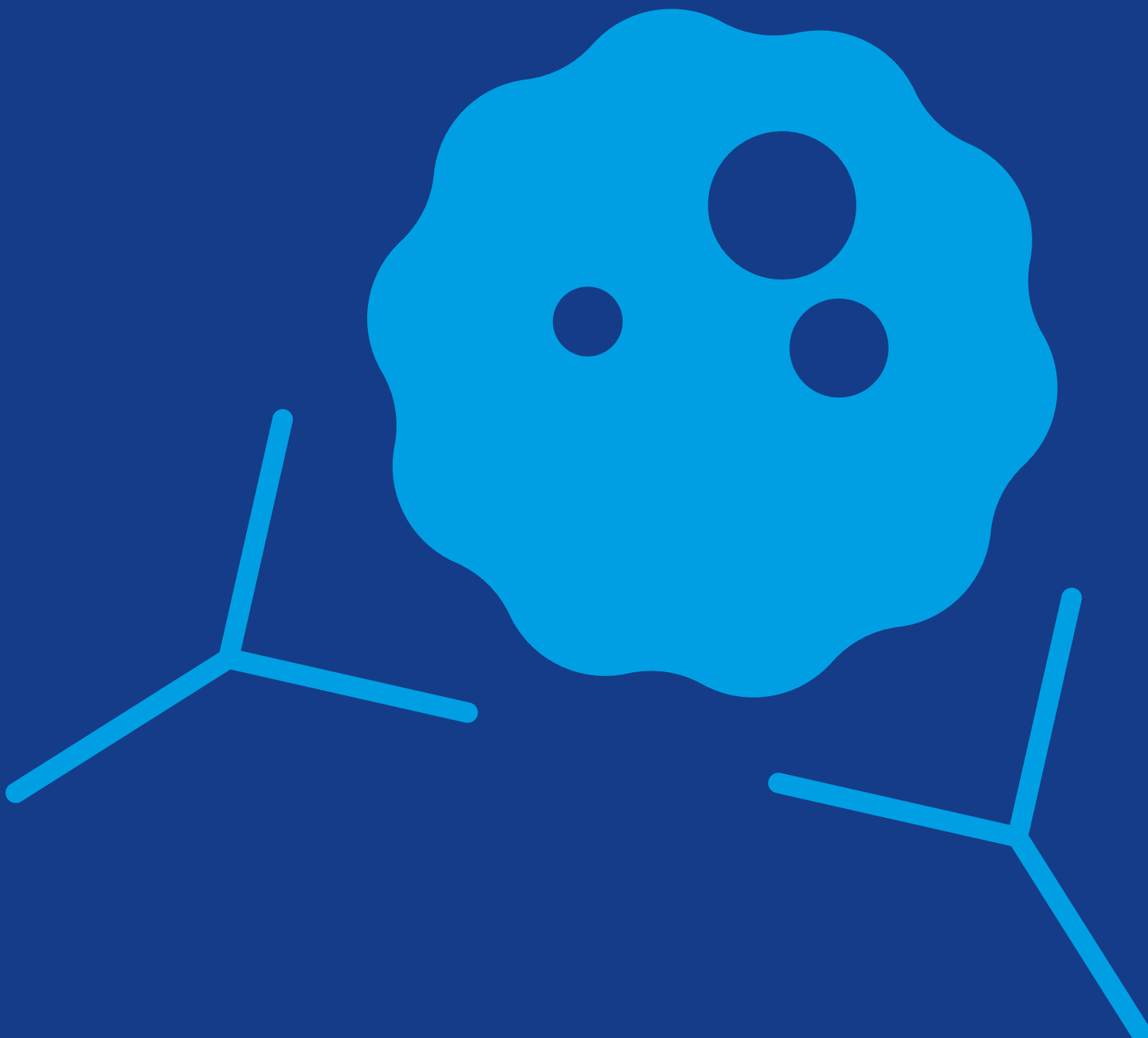
Corden Pharma

Highly Potent & Oncology

Technology Platform



Having solid state or bioavailability issues?

Want a CDMO with extensive expertise, knowledge & capabilities?

Looking for one partner to supply both APIs & Drug Products in clinical & commercial quantities?

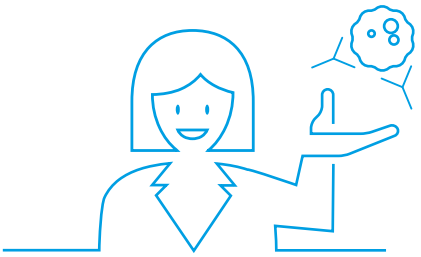
Seeking safe handling of Highly Potent & Oncology APIs, Oral Solid Dosage & Sterile Liquid Vials?

Searching for expertise in complex chemistry or formulations?

Care about successful regulatory track record in all major markets with an emphasis on quality?

Expect Quality by Design principles to be applied to the development of an API or Drug Product?

Looking for highly potent purification technolgies?



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 lifecycle at all stages, from clinical to commercial, from API to Drug Product, supported by dedicated regulatory and project management services. Straightforward communication with one supplier alleviates the need for excess resources required to manage multiple providers. The reduced complexity results in cost and time savings. Our organizational structure provides you with one point of contact to help navigate your way to project completion. 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 & Oral Solid Dose / Injectable Drug Product teams to decrease your development time to market.

Your Benefits — Our Strengths

Ease of Scale-up & Manufacturing

Scientific Expertise
Benefit from our extensive expertise & capabilities in process development, scale-up & manufacturing.

Proven Containment Technology

Highly Potent Manufacturing
Take advantage of our long manufacturing history of highly potent APIs & Drug Products with data-supporting containment practices.

Foster Entrepreneurial Spirit

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

Commitment to Sustainability

Responsible Global Environment
Count on our long-standing dedication to protect the environment, use resources wisely and promote innovation in the communities where we operate.

Organizational Integrity

Quality is at the Core of Everything We Do
Rely on our commitment to provide the highest quality & ensure product integrity for you and the patients you serve. Adherence to these principles is the responsibility of all employees at every level of the organization.

Faster Time to Market

One Partner
Gain access to our integrated network of extensive capabilities for faster timelines to clinical supply & market.

Transparent Communications

Aligned Project Management
Work closely with our dedicated project managers to ensure seamless communication between you & the technical team. We strive to manage & track progress to achieve your project objective.

Access Our Expertise

Knowledge Sharing
Increase your product value & working knowledge by accessing our expertise throughout the execution of your project.

Robust Highly Potent Manufacturing

Industry-Leading Containment Practices
Maximize engineering control effectiveness through the intangible elements of a robust highly potent containment program. We identify, adopt & develop best practices to ensure the safety of our products & workers.

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.

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 Chain solution spanning your complete product life cycle at all stages, from manufacturing of back-integrated complex registered starting materials to cGMP intermediates, APIs, Oral Solid Dosage forms, Injectable Drug Products & Packaging through clinical development & commercial supply > resulting in reduced time, risk & cost. Your project is all the while supported by dedicated regulatory & project management expertise at every step along your outsourcing path.

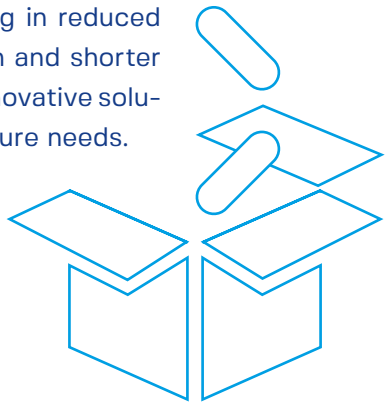
Formulation Development at CordenPharma Plankstadt (DE).

One Source for Highly Potent & Oncological Products

The Highly Potent & Oncology platform offers over 30 years of experience in the development and production of highly potent compounds. Our extensive capabilities enable us to support your project from clinical through commercialization.

Our API facilities can scale-up from laboratory-scale to 12,000 L vessels. The Oral Solid Dosage Drug Product manufacturing capabilities start with 100 g of blend and gradually increase according to the demand of your project, and we can even address bioavailability-challenged APIs with enabling technologies such as spray drying, hot melt extrusion, micronization, and nanomilling. Our clinical and commercial injectable Drug Product facility can aseptically manufacture highly potent solutions in vials.

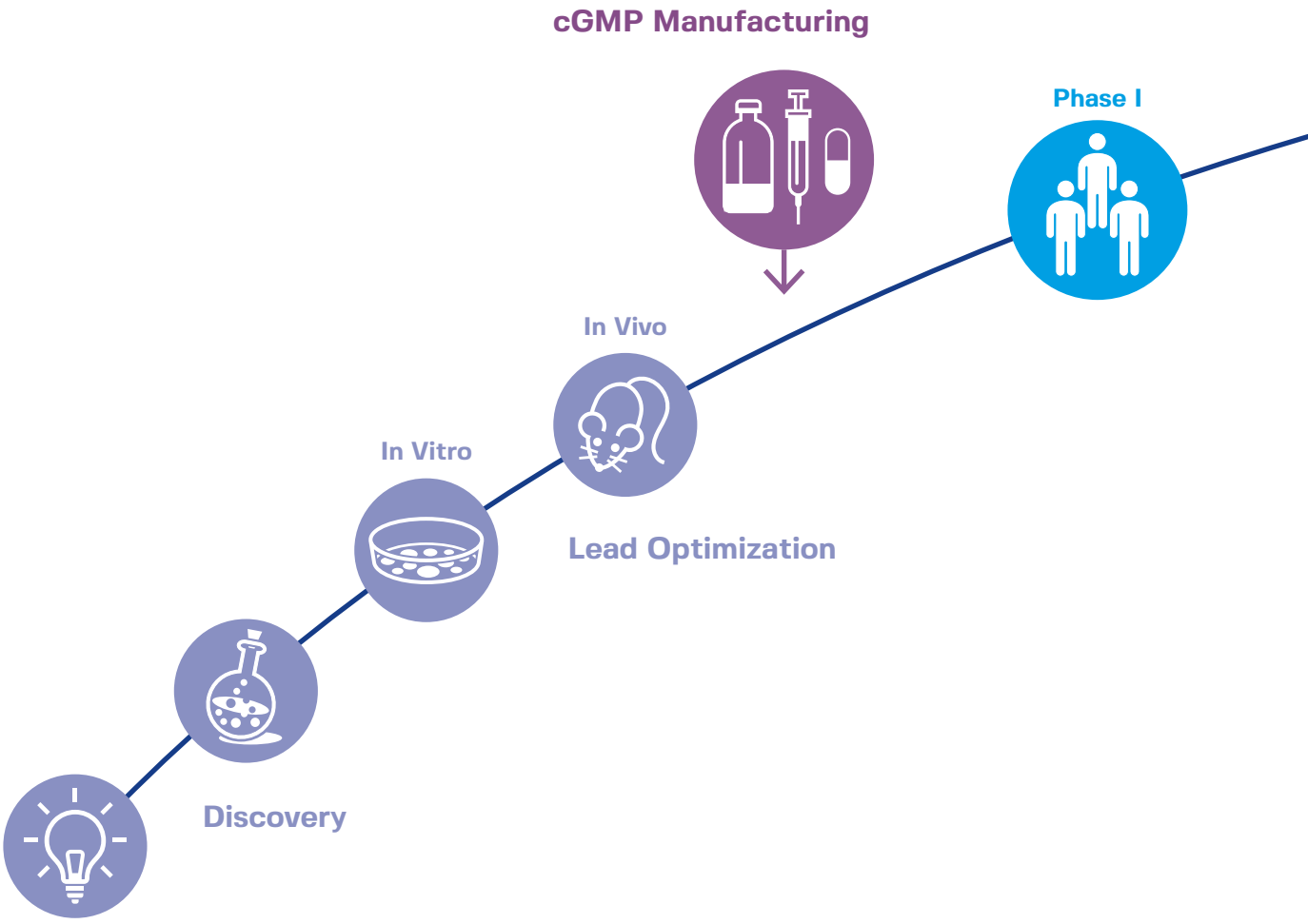
This continuum of capabilities from APIs to finished dosage Drug Products, including ready-for-market packaging, labeling and serialization, allows you to either pick and choose your required services, or take advantage of our Integrated Supply Chain from development to commercialization. The level of integration is flexible and customizable, resulting in reduced complexity, de-risked supply chain and shorter lead-times. We deliver agile and innovative solutions to meet your current and future needs.



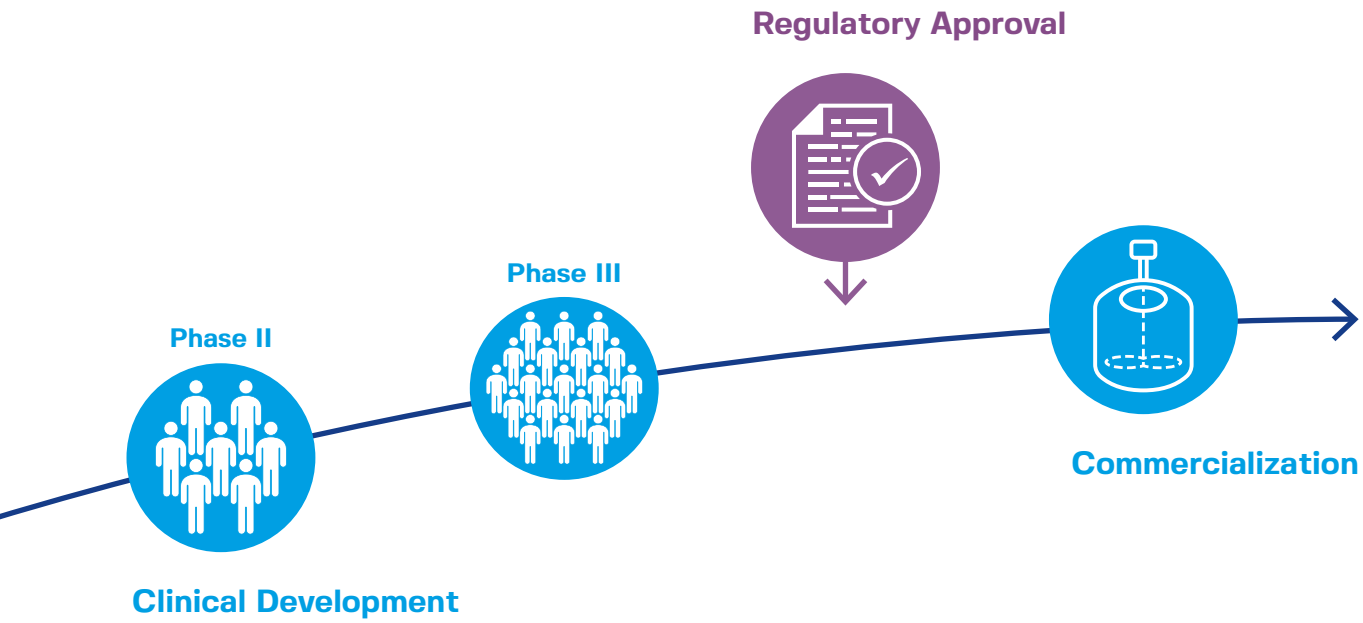
The Experts of Highly Potent & Oncology

Our Core Highly Potent & Oncology Services

- Fast & phase-appropriate development & manufacturing services for both APIs & Oral Solid Dose / Injectable Drug Products
- QbD development philosophy
- Scale-up & tech transfer expertise
- Broad technology & know-how portfolio
- Integrated API, OSD & Injectable Drug Products
- Packaging, labeling & serialization for OSD & Injectable Drug Products
- Regulatory expertise & successful track record in all major markets
- Industry leaders in highly potent manufacturing



View of our Highly Potent & Oncology facility CordenPharma Colorado (USA).

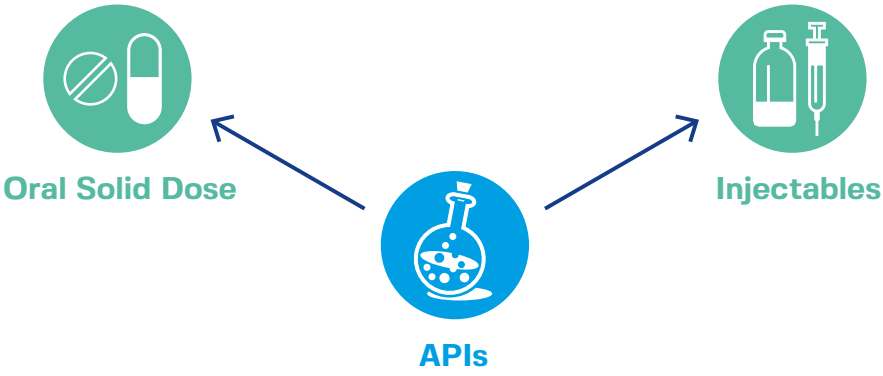


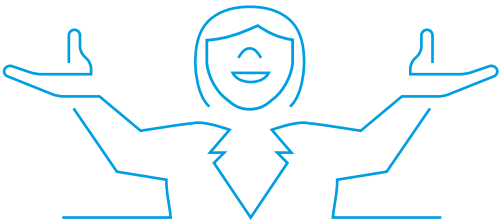
Dedicated to Maintaining The Highest Safety & Environment Standards

We have successfully implemented innovative solutions to ensure containment of highly potent compounds designed to protect workers, products and the environment, allowing us to safely handle the most potent compounds developed (OELs of picograms per cubic meter).

This level of containment is achieved through an integration of hard elements, such as engineering controls, and softer components (e.g. company culture, process development, occupational health pre-planning & containment execution cycle) that are proven to enhance our containment capabilities as part of a robust industrial hygiene program.

Capabilities of Highly Potent & Oncology APIs





The Backbone of Highly Potent & Oncology APIs

Our facilities in Colorado, US (CordenPharma Colorado) focus on the development and manufacturing of Highly Potent APIs from laboratory scale to commercialization for all potencies, including picogram level. This is possible due to a series of engineering controls and a well-defined, robust industrial hygiene program. Your API development & manufacturing projects will benefit from our Highly Potent API services, which include highly potent small molecules and peptides (solution- & solid-phase) at all scales, as well as extensive purification expertise and highly potent chromatography. The facilities have been accredited by SafeBridge®.

HPAPI Capabilities

- → Complex synthesis, small molecules & peptides
- → Products of all potency
- → API development
- → Clincial supply & commercial supply
- → Linker-payloads for drug conjugates
- → Highly potent chromatography (normal &reverse phase)
- → Highly potent lyophilization
- → Full analytical capabilities
- → Compliant with all major markets

Capabilities of Highly Potent & Oncology Drug Products

The Backbone of Highly Potent & Oncology Drug Products

CordenPharma Caponago, located just outside of Milan (IT), has expertise in the manufacturing of highly potent Sterile Liquids in Vials. The site offers technology transfer & manufacturing, and is comprised of two independent facilities, one for clinical supplies up to 10,000 units per batch, and the other facility with two commercial-scale filling lines, one fully dedicated to vials:

- Aseptically-filled solutions in vials
- Handling of highly potent small molecules, peptides, and biological entities
- Commercial-scale vial filling
- Full analytical capabilities
- Supply compliant with all major markets

Discover our Drug Product Services

Injectable highly potent manufacturing at CordenPharma Caponago (IT).

cGMP clinical supply suite at CordenPharma Plankstadt (DE).

CordenPharma Plankstadt, located one hour from Frankfurt (DE), has a broad range of capabilities and specializes in the development and manufacturing of Highly Potent & Oncology Oral Solid Dosage forms. This facility provides a complete offering from small scale as low as 100 g for formulation development of prototypes to clinical scale (1-60 kg) and up to 150 kg per batch commercial scale. This continuum allows us to support every phase from the initial formulation development to commercial scale manufacturing:

- Coated & Uncoated Tablets, Minitablets
- Hard Gelatin & HPMC Capsules
- Powders, Granules, Pellets
- Conventional processing technologies including Roller Compaction, High Shear & Fluid Bed Granulation (aqueuos and solvent processes)
- Solutions for APIs with Bioavailability Challenges including Hot Melt Extrusion, Spray Drying, Micronization, and Nanomilling
- Immediate & modified release formulations
- Pediatric formulations & Taste masking
- Labeling, packaging & distribution services
- Full analytical capabilities
- Supply compliant with all major markets

Our finished dose facilities meet the serialization compliance requirement 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.

In addition to these facilities, the platform has access to the other sites within the CordenPharma network able to manufacture cGMP intermediates and non-potent APIs. We also assist in sourcing your complex regulatory starting materials through our Global Procurement Team.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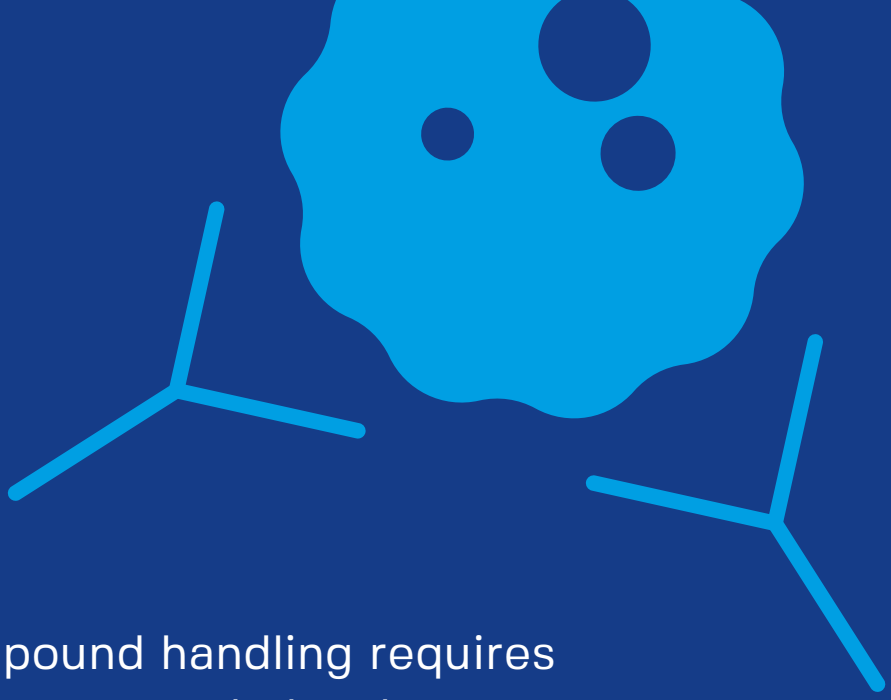


«Potent compound handling requires more than just a good glovebox. It demands a commitment to your coworkers, customers and ultimately, the patients that will receive the medicine.»

Charles Tucker, Ph.D. - Director Research & Development, CordenPharma Colorado

The employees at CordenPharma have made that commitment. We've developed not only the infrastructure to handle compounds, but the procedures, training and culture to support that work, even as advances in drug discovery push the envelope of selectivity, bioavailability, and potency every day.

When a customer approached us with a compound that had an exposure limit measured in picograms per cubic meter, we knew we had to up our game. With a dedicated effort between Industrial Hygiene, Operations & Engineering, we were able to demonstrate that we could contain the compound to that level. Our customer was be able to progress the program to deliver a life-changing treatment to their patients, and we were able to prove to ourselves through vigilance and dedicated effort that we can handle the challenge.

One Partner Process & Project Management

Streamlined Process Collaboration

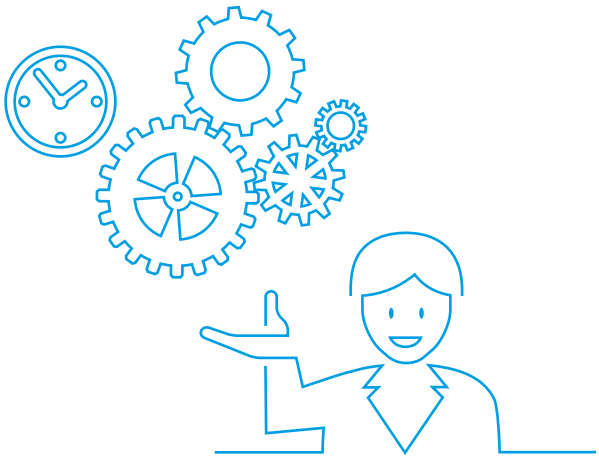
Our approach to every project begins with fostering a constant exchange between the applicable API & Drug Product Process Development teams involved. Ongoing alignment with analytical, quality and compliance support guarantees you fast and consistent results, independently of where your project starts.

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.

The project management team from CordenPharma Plankstadt (DE)

Oral Solid Dose early development facility at CordenPharma Plankstadt (DE).



Your One Partner Benefits:

- → Single point of contact throughout your project for both APIs & Drug Products
- → Flexible & responsive organizational structure
- → 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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«We were presented with a challenging formulation for a Phase I clinical highly potent tablet. Because the initial clinical data looked very promising, the project was fast-tracked and the process successfully scaled-up under cGMP conditions without technical scale-up batches.»

Oliver Schinzinger, Ph.D. - Director Pharmaceutical Development, CordenPharma Plankstadt

This was possible due to the application of QbD (Quality by Design) principles and our risk-based, systemic approach to development, which started with pre-defined objectives emphasizing product & process understanding and process control based on sound science.

We reached alignment with our customer on the Quality Target Product Profile (QTPP) and required timelines for this development program. Then we performed a thorough risk assessment and identified all critical parameters. The parameters identified were studied and an appropriate control strategy was put in place. Scale-up was successful and Phase III product was supplied on time, in spec and in full. We are hoping this becomes one of many commercial projects at CordenPharma Plankstadt.

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 compliance enhancing IT-solutions.

CordenPharma Continuous Improvement Program

Your project 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, 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)	Caponago (IT)	Plankstadt (DE)
	EMA, EU local	●	●	●
	FDA	●	●	●
	PMDA	●	●	●
	TGA	●	●	●
	Health Canada	●	●	●
	ANVISA	●	●	●

Our Manufacturing Sites

Manufacturing Sites	Products	Services
● CordenPharma Colorado, USA (Sites 1 & 2)	APIs	→ Highly Potent & Oncology Small Molecules & Peptides → Chromatography → Lyophilization → Small-Scale to Commercial
● CordenPharma Caponago, IT	Injectable Drug Products	→ Highly Potent & Oncology Liquid Filled Vials → Small-Scale to Commercial
● CordenPharma Plankstadt, DE	Oral Solid Dosage Drug Products	→ Highly Potent & Oncology Oral Solid Dosage Forms → Small-Scale to Commercial


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International

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cordenpharma.com


Peptides


Oligonucleotides


Lipids &
Carbohydrates


Injectables


Highly Potent
& Oncology


Small Molecules