Corden Pharma

Oligonucleotides

Technology Platform

Need small quantities of GMP oligonucleotides at a reasonable price?

Expect excellent process knowledge from early-phase to commercial?

Searching for one partner for drug substance and drug product from early-stage to global commercial supply?

Looking for rapid scale-up services?

Seeking a more efficient, cost-effective way to manage several third party suppliers?

Aiming for fully-transparent process development and documentation?

Seeking phase appropriate process and analytical development?

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. 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 & Drug Product teams to decrease your development time to market.

Your Benefits — Our Strengths

Fast & Lean Process Development Approach

Scientific Expertise
Your project will benefit from our efficient, time-saving development of thousands of process steps using Quality by Design.

Meet Collective Sustainability Goals

Toxicology Knowledge
Gain assurance from our in-depth knowledge in handling a wide range of toxicological active compounds, including highly potent APIs, to protect people, products & the environment.

Foster Entre-preneurial Spirit

Flexibility & Transparency
Benefit from our collaborative commitment to react with flexibility & 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
Discover how our fully integrated supply services, ranging from GMP starting materials to Drug Substance, Fill & Finish Drug Products and Packaging, enable faster times to clinical trials & market with reduced costs.

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.

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.

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.

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 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.

Aseptic Fill & Finish at CordenPharma Caponago (IT).

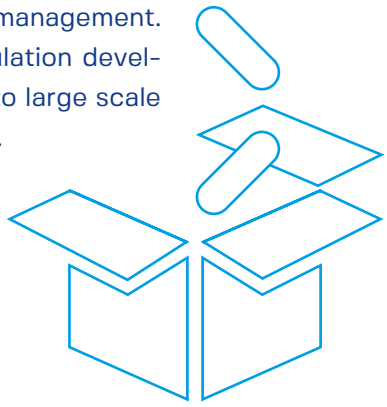
The Backbone of Synthesis – Oligonucleotide APIs

Our scientists have mastered the core principles of synthesizing advanced Oligonucletoide APIs, and bring them to bear on every project, large or small. The Oligonucleotide platform supplies you with specialized combined expertise from early stage to commercial supply of advanced Oligonucleotide APIs.

Our expert chemistry teams design and produce custom oligonucleotides tailored to your specific quality standards. From DNA and RNA to modified nucleotides and backbones, we deliver sequences of various lengths and complexities.

Not sure where to start? Our team of experts are here to guide you. We start with your sequence to develop the manufacturing process and quality standards in a phase appropriate manner to get you into the clinic as quickly as possible.

Furthermore, your benefit expands to the seamless tech transfer of your project within our facility network for the production of Drug Products and 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 / labelling, and clinical trial kit management. We additionally supply LNP formulation development services as well as small to large scale GMP LNP manufacturing services.



Our Proven Oligonucleotide Capabilities

Mid-scale oligonucleotide manufacturing suite at CordenPharma Colorado.

Development Capabilities

- Full Developmental Capabilities at up to 10 mmol scale
- Synthesis on Cytiva Akta OligoSynt™ units
- Purification using AktaPure™ systems with up to 3.5cm columns
- TFF using Sartorius Sartoflow™
- Lyophilization

Synthesis Capabilities

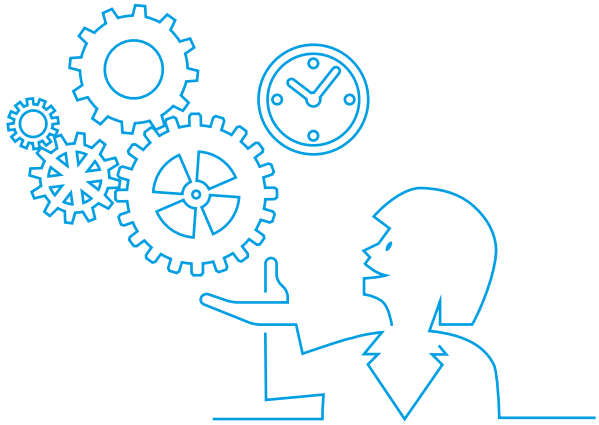
- Able to manufacture from 10-160 mmol scale under GMP in flexible manufacturing suites
- Synthesis on Cytiva Akta OligoPilot™ units
- Purification with a range of techniques and diluents using 5- 25cm columns
- TFF with cross-membrane flow at 4-6L/min/m^2
- Lyophilization – extensive capacity available
- Expansion coming in 2025 to add larger scale capabilities

Analytical Capabilities

- Various UPLC, HPLC and IC capabilities with AEX, UV/Vis, MS & Conductivity detectors
- GC-MS, ICP-MS
- LC Q-TOF MS, LC/MS, UV/Vis
- Capillary Electrophoresis
- Microbial Testing – Endotoxin & Bioburden

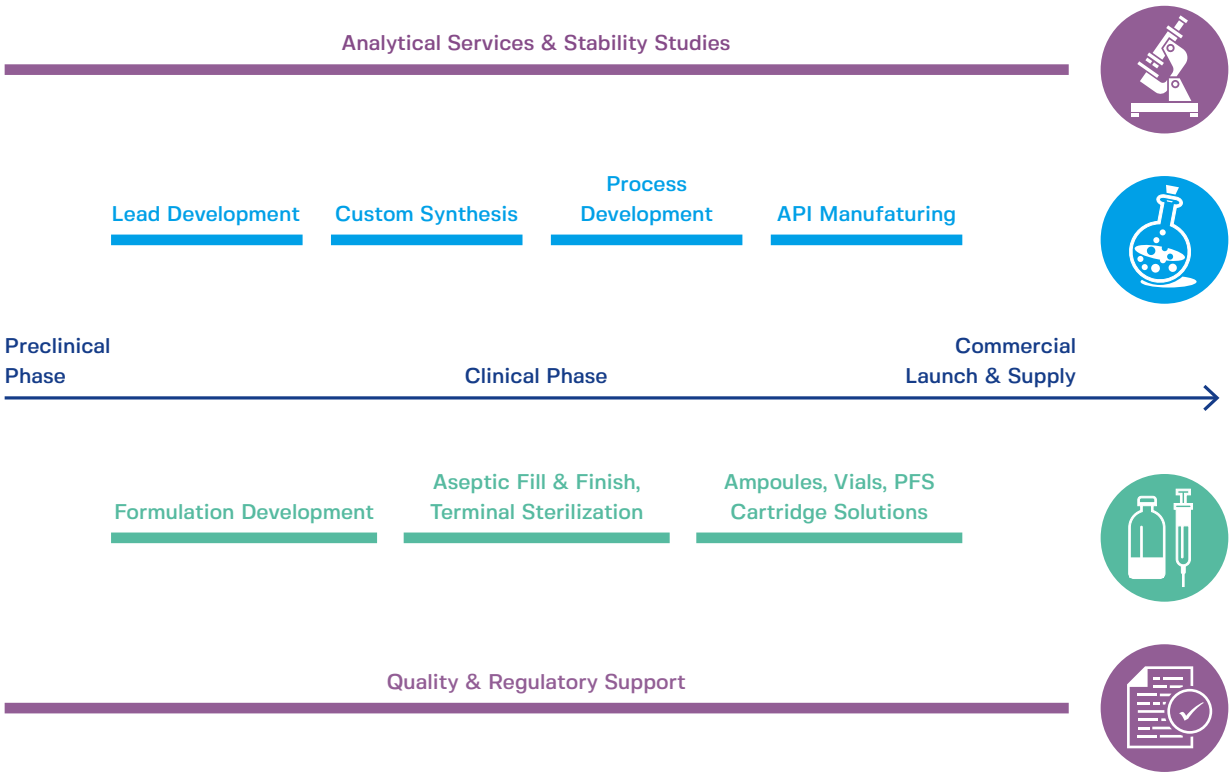

Ear protection must be worn
PEPPERL+FUCHS

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 forward 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)	Caponago (IT)
	EMA, EU local	●	●
	FDA	●	●
	PMDA	●	●
	TGA	●	●
	Health Canada	●	●
	ANVISA	●	●

Our Manufacturing Sites

Manufacturing Sites	Products	Services
● CordenPharma Colorado, USA (Sites 1 + 2)	Oligonucleotides	→ R&D, non-GMP and GMP-Production → Extensive purification and isolation capacity → Full analytical development and support
● CordenPharma Caponago, IT	Integrated Supply	→ Injectable Drug Products & LNP formulation → Vial, Pre-filled syringe and cartridge capability


Corden
Pharma

CordenPharma
International

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cordenpharma.com


Peptides


Oligonucleotides


Lipids &
Carbohydrates


Injectables


Highly Potent
& Oncology


Small Molecules