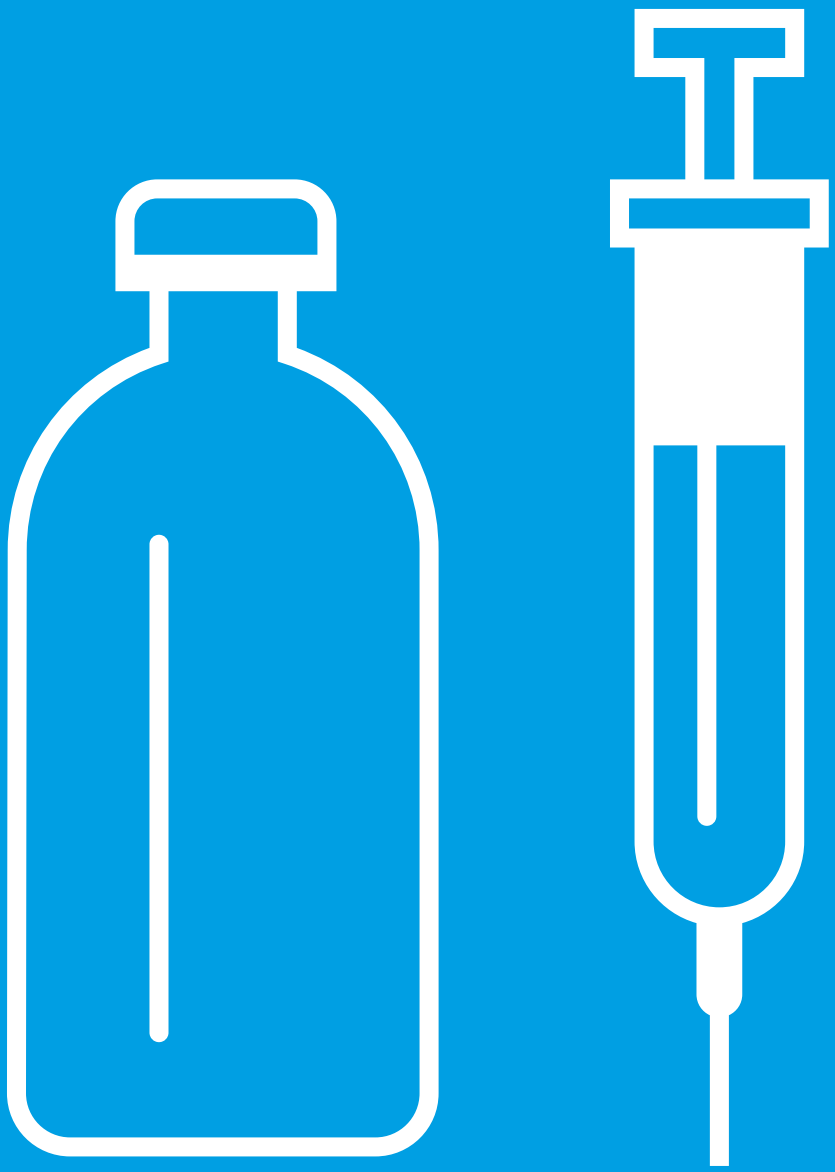
CORDENPHARMA

INJECTABLES
TECHNOLOGY PLATFORM



CORDENPHARMA

Searching for ONE PARTNER for drug substance & drug product from early-stage to global commercial supply?

Looking for a wide variety of injectable drug product devices from ampoules, vials & cartridges to Pre-filled Syringes (PFS)?

Expect proven process knowledge from early phase to commercial?

Need support in managing the complexity of your injectable combination product (device + drug)?

Require formulation capacities for aseptic fill & finish or terminal sterilization?

Want to be in line with injectable compliance & manufacturing best practices?

Seeking complete feasibility & stability testing services?

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. 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 five Technology Platforms, we have fostered an efficient exchange between API & Drug Product teams to decrease your development time to market.

YOUR BENEFITS – OUR STRENGTHS

Versatile Support Throughout Your Injectable Drug Product Life–cycle

Wide & Balanced Range of Injectable Services
Benefit from our integrated injectable services from early formulation development & clinical testing through filing & commercial supply.

Access to Broad Manu–facturing Capabilities

Terminal Sterilization and Aseptic Fill & Finish Technologies
Receive adaptable support for multiple programs at any scale & stage of drug development & commercialization.

Insight Into the Complexity of Combination Device & Drug Products

Sound Industry Knowledge of Combination Product Requirements
Let the right partner navigate industry changes to support your development goals & efficiently commercialize your combination injectable device–drug product.

Expertise in Peptide & Small Molecule Formulation

From Drug Substance to Drug Product
Access a wide range of formu–lated drug products using our capability to support you from early clinical to commercial.

Reliable Delivery of Selected Dosage Form

Full Range of Filling Volumes
Utilize a broad range of in–jectable drug product dosage forms, from ampoules & vials to Pre–Filled Syringes (PFS) & cartridges.

Early–stage Non–GMP Drug Development Formulation

End–to–end Formulation Development
Be early to market by making use of our R&D lab for effi–cient development & seamless transfer between non–GMP & GMP formulated drug products.

Focus on Reliable Safety Expertise

Quality Is the Foundation of Every Step Your Project Takes
Rely on the integrity of our robust quality, regulatory compliance & manufacturing standards from initial process development through product delivery, supported by sub–stantial global regulatory & filing experience (EMA, FDA, PMDA).

Valued Packaging & Logistics Services

Flexible Packaging & Secure Serialization Techniques
Profit from our dedicated capabilities for secondary packaging such as single– & multi–containers (vials, PFS, ampoules & cartridges). Cur–rent serialization technologies with highly flexible distribution systems cover all your pharma–logistic needs.

Faster Time to Market with Reduced Cost

Streamlined Fully–Integrated Supply
Discover how our ONE PARTNER fully–integrated supply services, ranging from back–integration of non–GMP raw materials to Drug Substance, Fill & Finish Drug Products and Packaging, enable faster times to clinical trials & market with reduced costs.

Foster Entrepre–neurial Spirit

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

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.

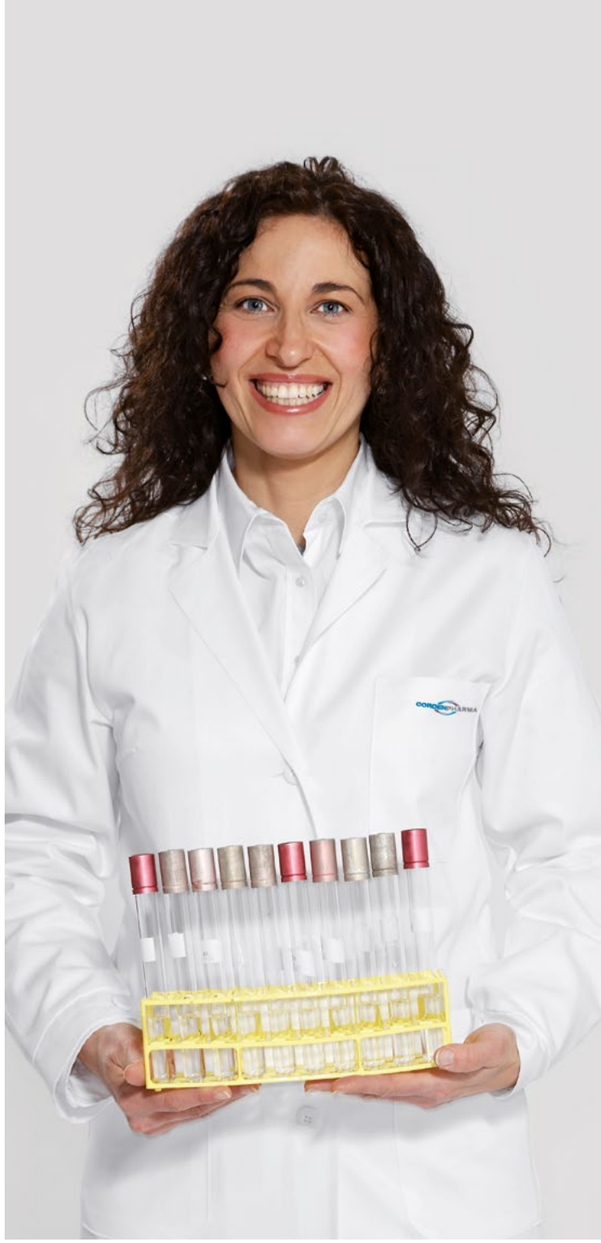
Aseptic Fill & Finish at CordenPharma Caponago (IT).

The Concept of Flexibility – Injectable Drug Products from Clinical to Commercial

When partnering with CordenPharma for the supply of Injectable Drug Products, experience flexibility from different perspectives.

We offer you a broad spectrum of injectable services starting from early formulation development to full commercial scale, covering both terminal sterilization & aseptic filling technologies for Pre–filled Syringes (PFS), vials, ampoules, cartridges and lyophilized vials, with a range of filling volumes including the capability for combination products. With various processes and filling lines, and an overall annual capacity of ~100 million units, CordenPharma's Injectable platform offers the flexibility to support multiple programs and customers in parallel, at any scale and stage of drug development & commercialization.

Beyond the Injectables Platform, your benefit expands to the seamless tech transfer of your API project (either Peptide or Small Molecule) within our facility network, which spans the manufacturing of drug substances to drug products, including packaging, labeling and clinical trial kit management services.

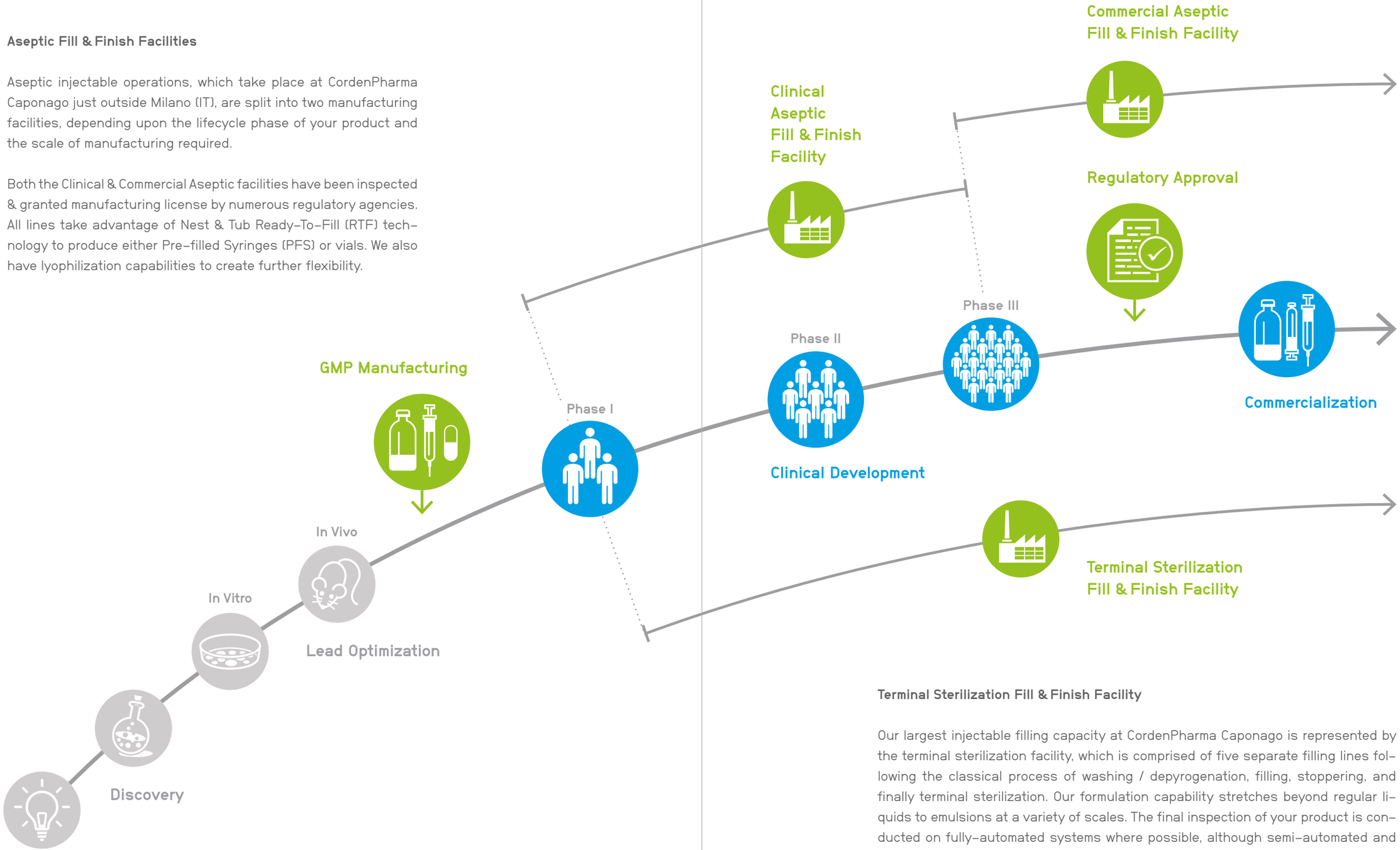


OUR CAPABILITIES FOR INJECTABLE MANUFACTURING

Aseptic Fill & Finish Facilities

Aseptic injectable operations, which take place at CordenPharma Caponago just outside Milano (IT), are split into two manufacturing facilities, depending upon the lifecycle phase of your product and the scale of manufacturing required.

Both the Clinical & Commercial Aseptic facilities have been inspected & granted manufacturing license by numerous regulatory agencies. All lines take advantage of Nest & Tub Ready-To-Fill (RTF) technology to produce either Pre-filled Syringes (PFS) or vials. We also have lyophilization capabilities to create further flexibility.



Terminal Sterilization Fill & Finish Facility

Our largest injectable filling capacity at CordenPharma Caponago is represented by the terminal sterilization facility, which is comprised of five separate filling lines following the classical process of washing / depyrogenation, filling, stoppering, and finally terminal sterilization. Our formulation capability stretches beyond regular liquids to emulsions at a variety of scales. The final inspection of your product is conducted on fully-automated systems where possible, although semi-automated and manual inspections are possible where the drug product formulation dictates it.

EARLY–DEVELOPMENT TO CLINICAL STAGES

Research & Development Operations

At CordenPharma Caponago, a dedicated team of skilled professionals awaits you to help develop your injectable formulation, tailored to your specific needs. Whether the team is simply executing a technology transfer of your existing formulation, refining an existing formulation or developing a custom formulation from scratch, the formulation & analytical team are fully prepared to establish an agreed scope of work, followed by execution within approved parameters to deliver your product.

With experience developing formulations for vials, Pre–filled Syringes (PFS), cartridges or ampoules for either aseptic or terminal sterilization applications, your project will benefit from a wide range of experience working with small molecules, peptides or biomolecules to develop liquid, lyophilized or emulsion products, along with all the required development documentation to support either a clinical or commercial application.

Our focus at the development phase is to use previously conducted studies to create a tailored program specific to your product lifecycle stage. Operating within a dedicated, newly renovated R&D laboratory, our development team will rapidly & efficiently move your project through this phase into production.

Pre–Filled Syringe robotized filling line and weighing / priming station at CordenPharma Caponago (IT).

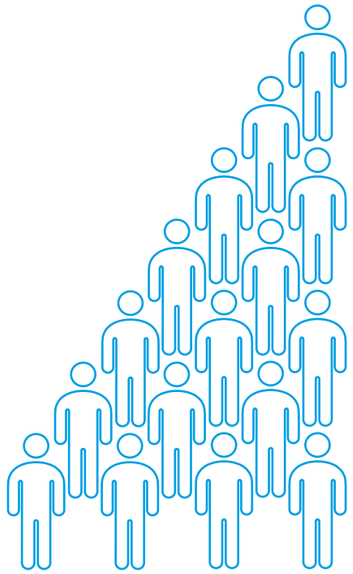
R&D analytical development scientist controlling an ongoing test at CordenPharma Caponago (IT).

Clinical Aseptic Fill & Finish Facility

Take advantage of a broad range of formulation options within our Clinical Aseptic facility at CordenPharma Caponago. Built in 2015, the plant was granted a license and approval in early 2016 by AIFA (Italian Regulatory Authority) for the manufacture of formulation development and clinical manufacturing.

Our dispensing & compounding area has the flexibility to conduct batch formulation with either fixed stainless steel vessels or cutting–edge disposable formulation technologies as required.

The filling area takes advantage of Nest & Tub technology to produce either vials or Pre–filled Syringes (PFS) in a range of sizes. To optimize full flexibility for your product application, the filling line can either run using classical mechanical pumping heads or the latest peristaltic technology – whichever your product requires to be successful.

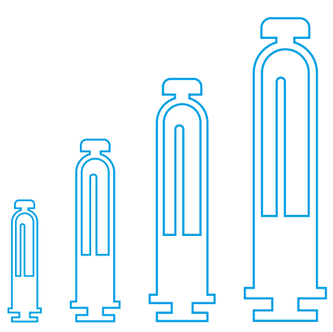


COMMERCIAL INJECTABLE MANUFACTURING

Commercial Aseptic Fill & Finish Facility

Within CordenPharma Caponago's Commercial Aseptic processing facility, you will find the perfect fit for your drug product from a matrix of Pre–Filled Syringes (PFS), Cartridges or Vials of various sizes. Targeting production volumes from a few thousand to millions of units per year, this facility allows maximum flexibility via two independent & qualified filling lines, the first of which was approved in 2018 by AIFA (Italian Regulatory Authority) and the USFDA.

Formulation of your commercial product can occur in either installed stainless steel vessels or the latest disposable technologies. The compounding areas are equipped with gloveboxes to enable the handling of the most sensitive APIs under inert or moisture–controlled environments as required.



Our filling lines adopt an open RABS set–up, employ the latest robotic technology, and adopt Nest & Tub RTF concepts in order to gain efficiency & assurance of quality. We also utilize either mechanical or peristaltic pumps, depending upon your product requirements. Liquid filled vials can also undergo lyophilization via the installed & integrated freeze dryer (~5sqm). Finally, your filled products are inspected in a dedicated inspection area that will have its automation finalized in late 2019.

ASEPTIC FILL & FINISH	AMPOULES	VIALS	PFS	CARTRIDGES
Sterile Liquids (Solution)		●	●	●
Sterile Powder Lyophilized (Solution)		●		

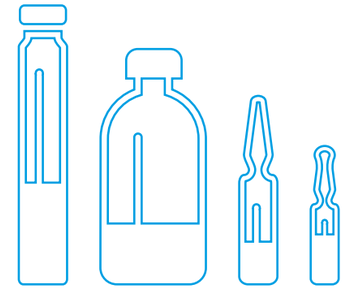
Commercial Terminal Sterilization Facility

With our Terminal Sterilization facility, you can access our largest onsite manufacturing capacity, comprised of five separate filling lines following the classical process of washing / depyrogenation, filling, stoppering and finally, terminal sterilization utilizing either clean steam or super–heated water. This facility has over twenty–five years of experience in terminal sterilization, and has been successfully inspected by all the major regulatory authorities.

Our formulation capacity via installed stainless steel formulation vessels ranges from 50 L to 1250 L of either solution or emulsions via numerous independent formulation rooms. To create the emulsion formulations, we adopt a high–pressure homogenizer that can operate across the full range of formulation scales.

Final inspection is conducted on fully–automated inspection systems where possible, although semi–automated and manual inspections are possible.

All production areas (both Terminal Sterilization & Aseptic Filling) are fully–supported by on–site Chemical & Microbiological laboratories, which are set–up to manage a large variety of quality tests.



TERMINAL STERILIZATION	AMPOULES	VIALS	PFS	CARTRIDGES
Solution	●	●		●
Emulsion	●	●		●
Suspension	●	●		●

FLEXIBLE PACKAGING SERVICES

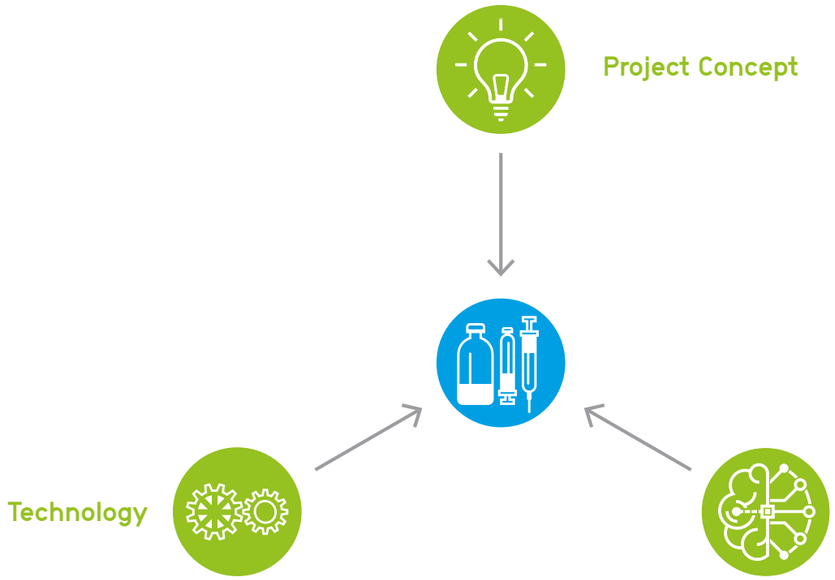
Injectable Packaging Capabilities

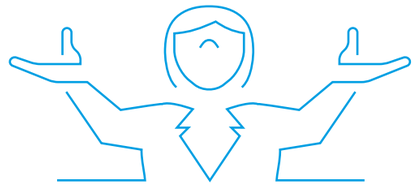
A common service for all our injectable manufacturing areas (Aseptic & Terminal Sterilization) is our extensive packaging capabilities. Your commercial projects will greatly benefit from fully-automated individual or multi-pack configurations with full serialization technology in compliance with the latest US & EU regulations.

Additionally, we have a dedicated Clinical Trial packaging area where your drug products are packaged according to your specific clinical trial & management requirements.

Aseptic filling line at CordenPharma Caponago (IT).

SOLUTIONS FOR **COMBINATION DRUG PRODUCTS**



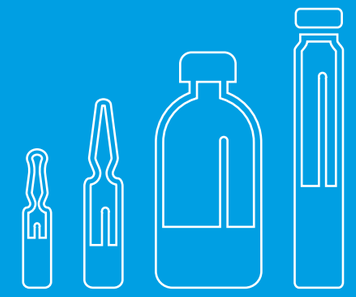


Innovative Injectable Combination Drug Products

In recent years, regulatory bodies have introduced new rules & regulations around combining injectable drug products with devices, commonly referred to as «Combination Drug Products».

As the regulations continue to evolve, CordenPharma is working diligently with our customers at the forefront of this new field, developing a sound understanding of the integration between pharmaceutical formulation science and device engineering competencies.

We have established the necessary background knowledge, while keeping abreast of the latest developments, to ensure your product efficiently advances through this new regulatory landscape.



«To see the whole team successfully come together on this project was really exciting for me because this was a very technically challenging project, factoring in many different aspects, including the new Combination Product regulations.»

Silvia Lissoni, Business Development & Tech Transfer Manager, CordenPharma Caponago

The team at CordenPharma Caponago supported the clinical supply of an innovative drug product, aseptically filled in syringes. Initially the R&D team had to modify the process to establish a stable formulation, which was afterwards demonstrated via an engineering batch confirming all the critical parameters. The manufacturing of clinical batches was soon after carried out in the Clinical Development Facility to enable the Customer's clinical trial fast-track progress.

Then, the process was transferred to the Commercial Facility, where scale-up & registration batches were successfully completed – all to support the customer's NDA filing & future commercial launch.

This experience reinforces CordenPharma Caponago's capabilities to cover the entire clinical lifecycle for a challenging injectable project from clinical stage to launch preparation. In addition to our expertise in developing injectable fill-finish processes, the customer appreciated the seamless collaboration within the different departments of the site, which proved critical to achieving such successful and repeatable results.

ONE PARTNER PROCESS & PROJECT MANAGEMENT

Streamlined Process Collaboration

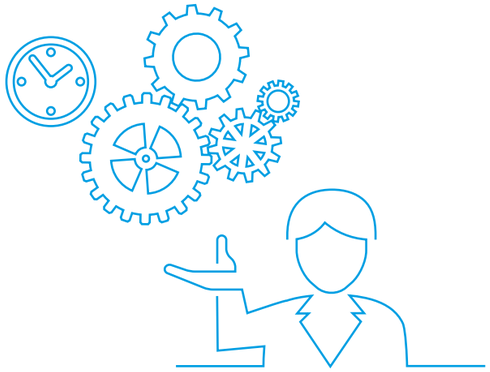
Our approach to every project begins with fostering a constant exchange between the applicable API & Drug Product Process Development teams involved. Ongoing alignment with analytical, quality and compliance support guarantees you fast and consistent results, independently of where your project starts.

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 Caponago (IT).

Aseptic operator loading tools for sterilization at CordenPharma Caponago (IT).



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

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 ongoing 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

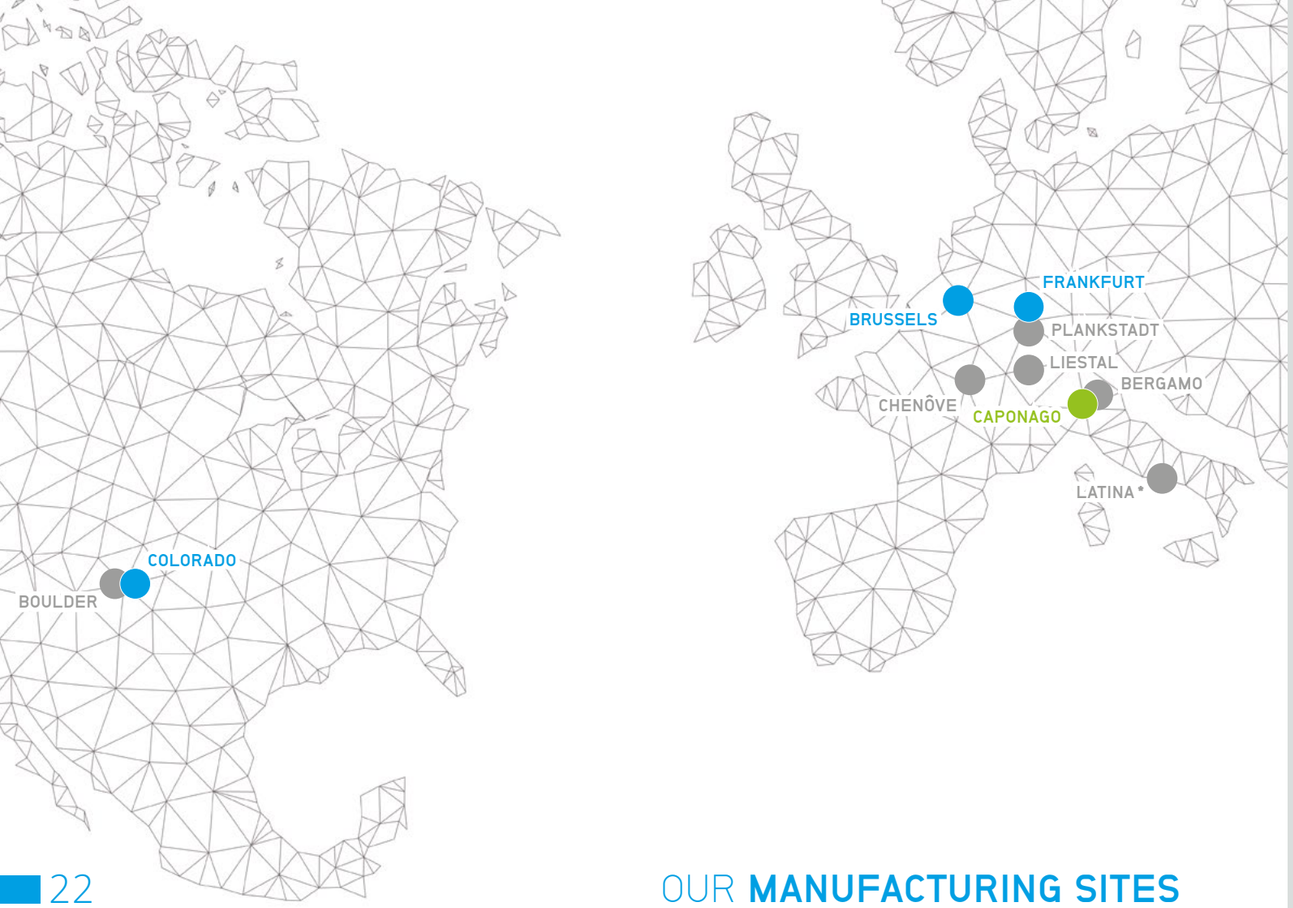
You will benefit from the ongoing support of CordenPharma's Continuous Improvement Program, based on the consistent completion of corrective and preventive actions arising from self–initiated proactive third party group–wide gap assessments, agency inspections, as well as internal, annual corporate & 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 communica–tion, 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 Operat–ing Procedures (SOPs), master work instructions, plans & forms to meet all the requirements for your pharmaceutical success.

MARKET	AGENCY	CAPONAGO (IT)	BRUSSELS (BE)	COLORADO (US)
	EMA, EU local	●	●	●
	FDA	●	●	●
	PMDA	●	●	●
	TGA	●		●
	Health Canada	●		●
	ANVISA	●	●	●
	IMPROMTORG			



OUR **MANUFACTURING SITES**

MANUFACTURING SITES	PRODUCTS	SERVICES
CordenPharma Caponago, IT	Injectable Drug Products	Injectable Drug Products Fill & Finish Aseptic & Terminal Sterilization
CordenPharma Brussels, BE	Integrated Peptide API Supply	Solid-Phase (SPPS) & Liquid-Phase (LPPS) Peptide Synthesis & Production R&D, non-GMP and GMP-Production
CordenPharma Colorado, USA	Integrated Peptide API Supply	Largest Peptide Production & Purification Capacity Worldwide R&D, non-GMP & GMP Production
CordenPharma Frankfurt, DE	Integrated Peptide API Supply	R&D & non-GMP Production

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

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INTERNATIONAL

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