

# CORDENPHARMA CAPONAGO

EXPERTS TAKING CARE



*CordenPharma Caponago*  
Viale dell'Industria, 3  
20867 Caponago  
Italy  
Phone +39 02 95452 1  
Fax +39 02 95452 300  
sales@cordenpharma.com

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



## Our History

- 1970 Foundation by ICI Pharma
- 1987 Expansion by Astra Zeneca to accommodate Diprivan (propofol)
- 1992 First FDA approval
- 2009 Latest Anvisa (Brazilian) approval
- 2009 Acquired by ICIG to become CordenPharma Caponago S.p.A.
- 2011 Latest EMA & FDA combined approval
- 2012 Italian MoH Veterinary approval

# CORDENPHARMA CAPONAGO

Your CMO Partner

>25 Years of Experience

CordenPharma Caponago, located just east of Milano, Italy, provides pharmaceutical customers over 25 years of experience in manufacturing sterile liquid dosage forms for injectable use, with specialized expertise in sterile emulsion technology. Core capabilities

include formulation and process development, industrial engineering and scale-up, complex technology transfer as well as new product launches. Regarded as one of most competent sites for sterile emulsion technology worldwide, CordenPharma Caponago covers

all steps in the process from emulsion preparation, filling, and terminal sterilisation to inspection, labeling and packaging. We follow your drug product distribution and complex supply chain every step of the way.



# US



## Compliance Worldwide

- EMA (AIFA)
- FDA
- ANVISA
- PMDA
- TGA
- Health Canada





# WHAT WE DO

**Sterile Injectable  
Emulsions & Solutions**

**Pre-filled Syringes**

With more than 25 years of experience in manufacturing sterile injectables, Cordenpharma Caponago offers one of the largest and most competent facilities worldwide for the manufacturing of solutions and emulsion in ampoules, vials and large pre-filled syringes. CordenPharma Caponago has been successfully inspected by the FDA since 1992 with a track record of success handling terminally-sterilized products via steam and/or superheated water sterilization cycles. Our state-of-the-art inspection lines, equipped with multiple cameras specifically designed to inspect emulsions, provide fully-automated inspections for 100% of the emulsions produced.

## CORE CAPABILITIES

- cGMP manufacturing of parenteral dosage forms in ampoules and vials
- Proven expertise in sterile emulsion technology
- Pre-filled syringes (10 to 50 ml) handling
- Proven expertise in development, technology transfer, scale-up, and new product launch support
- Extensive packaging and logistics services for the global market with over 95% customer satisfaction
- Management and distribution of clinical trial medication
- Expertise in supplying products to the Japanese market

## SERVICES

CordenPharma Caponago's broad range of services includes project management, development and validation of analytical methods, and regulatory support in preparation of IMPD and CMCs writing. On behalf of our customers we manage registration dossier filings in multiple countries, including deficiencies, and maintain relationships with various regulatory agencies throughout the process of obtaining marketing approval.



**Our experts manage  
over 170 SKUs and  
serve more than 70  
markets worldwide.**





## EQUIPMENT

- 3 process rooms equipped with APV high-pressure homogenizers
- 3 Filling lines for vials (fully-integrated lines including washing, depyrogenation, filling, stoppering and crimping)
- 1 Filling line for ampoules (fully-integrated line including washing, depyrogenation, filling and sealing)
- 1 Filling line for pre-filled syringes (fully-integrated line including washing, depyrogenation, plunger insertion, filling, stopper insertion and crimping)
- Automatic inspection machine for 20 ml ampoules and vials
- Semi-automatic inspection machines for vials (20 ml, 50 ml, 100 ml)
- Automatic inspection machines for PFS (20 ml, 50 ml)

## ANNUAL CAPACITY

- Vials - 60 million units
- Ampoules - 18 million units
- Pre-filled Syringes - 9 million units

## CLINICAL TRIAL SUPPLIES MANAGEMENT

CordenPharma Caponago supports your drug product clinical trials by providing clinical trial supply services. Our dedicated areas handle blinding operations, placebo & comparators, labeling and randomization, as well as secondary packaging. During the clinical trial, our experts also provide warehousing, distribution, return, reconciliation and destruction of supplies.

## SECONDARY PACKAGING

- Annual capacity >20 million finished packs
- Distribution of more than 150 SKUs in 70 markets worldwide
- Experience in supplying the Japanese market
- Packaging equipment:
  - 20 ml ampoules / vials packaging line
  - 50/100 ml vials packaging line
  - Semi-automatic line for multipacks



## EXPANSION CAPACITY

CordenPharma Caponago has immediate capacity for expansion in a fully-independent building containing new validated space with areas suitable for the installment of production lines and primary / secondary packaging lines. Fully-equipped chemical and microbiological laboratories, inclusive of stability chambers, are also available. The building is additionally outfitted with services such as air conditioning, heating, a water treatment system, nitrogen and a compressed air line.