



## CDMO OFFER

Manufacturing & Development Capabilities

Date:

Speaker:

Place / event :



Beyond our medicines, *lives*

# Ethypharm, a specialty pharma company with European roots, focused on the Central Nervous System and Hospital Injectables



## Specialty pharma

- **CNS:** 3 main areas of expertise - pain, addiction and depression.
- **Hospital injectables:** a portfolio of injectable medicines for emergency and hospital use.
- A **direct presence in the top 5 European markets.**
- A longstanding **direct presence in China.**



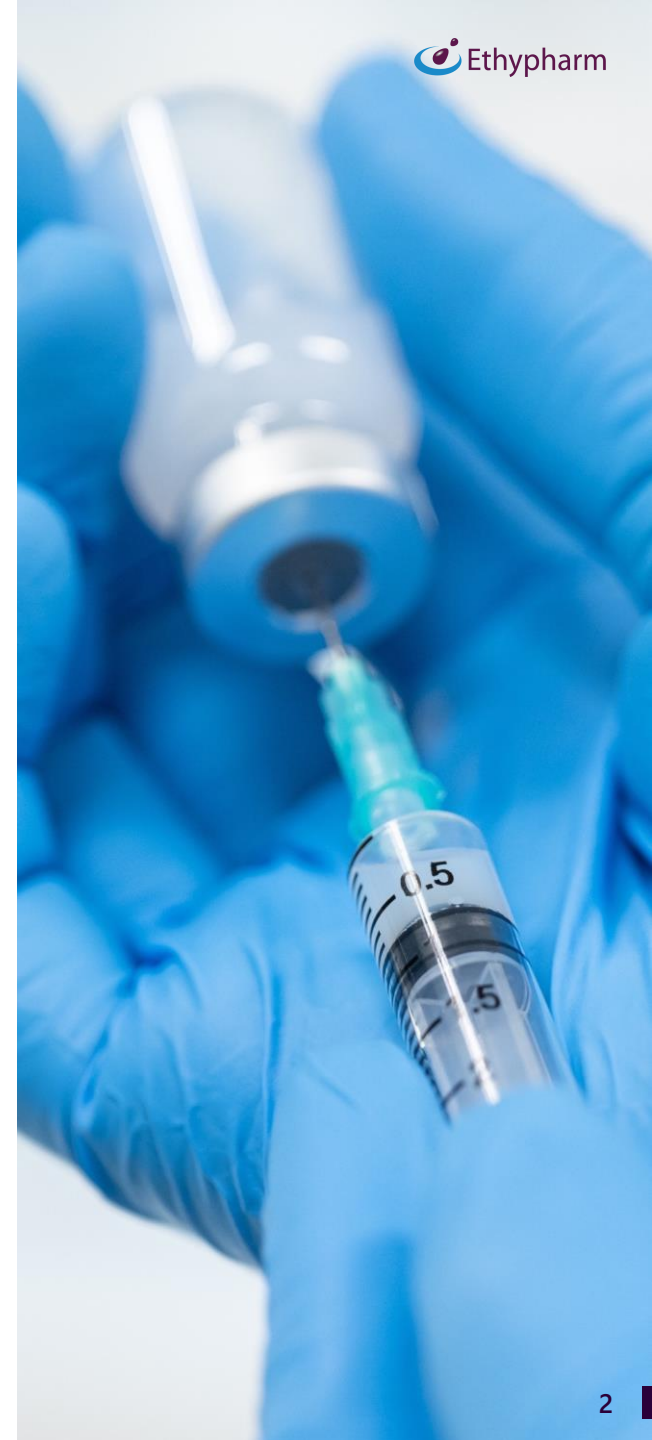
## Distribution & Licenses

- Global reach through distributors and licensees.
- 171 partners in 54 countries.
- Broad catalog of Injectables and dry forms.



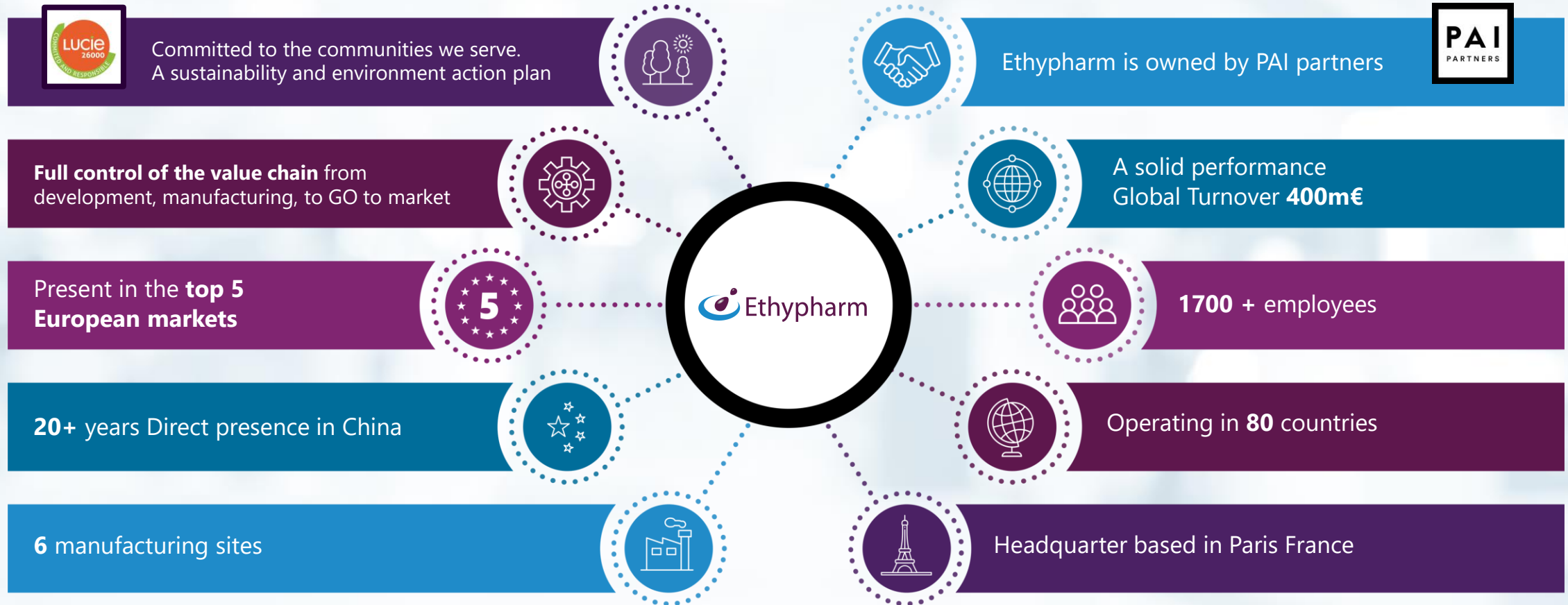
## CDMO

- A team of development experts alongside your project.
- 6 state-of-the art manufacturing plants with high quality standards
- A wide range of dosage forms & packaging.




# Ethypharm in a nutshell

(2022 figures)



# 6 states-of-the-art manufacturing plants to produce your product

## GLOBAL HEADQUARTERS

- Saint-Cloud, France  

## MANUFACTURING SITES

- Romford, UK  
- Châteauneuf-en-Thymerais, France  
- Le Grand-Quevilly, France  
- Bernedo, Spain  
- Casarrubios, Spain  
- Shanghai, China  



# Sterile forms



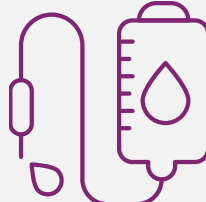
**AMPOULES**

- Terminal sterilization
- Aseptic filling



**PRE-FILLED SYRINGES**

- Terminal sterilization
- Aseptic filling



**FLEXIBLE IV BAGS**

- Terminal sterilization



**LYO IN VIALS**



**SOLUTION /  
SUSPENSION IN VIALS**



# Non Sterile forms



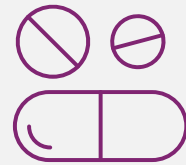
## NON-STERILE ORAL SOLUTIONS

### API:

- Conventional
- Controlled Substances

### Technologies:

- Glass & HDPE Bottles



## TABLETS / CAPSULES / PELLETS

### API:

- Conventional
- Controlled & Highly Potent Substances

### Technologies:

- Oral Solid Dosage
- Solid Dosage Form

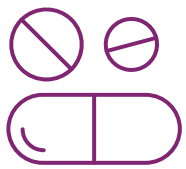


# A 40+ years expertise in Controlled Drugs manufacturing

With over 40 years of experience in handling narcotics, in the manufacturing and testing of controlled drugs (Morphine, Fentanyl, Buprenorphine, Naloxone) and high potent drugs (oncology, orphan drugs), we prioritize compliance and the highest levels of security to ensure the safe and responsible management of controlled substances.

Our robust compliance protocols and access-protected security systems are designed above compliance with regulatory requirement to provide peace of mind to our partners, customers and operators.

Our state-of-the-art facilities are equipped with advanced technologies and systems that adhere to the strictest industry standards. This enables us to maintain the integrity of the products throughout their journey within the supply chain.



**TABLETS / CAPSULES / PELLETS**



**ORAL SOLUTION**



**AMPOULES**



# An agile Development team to meet your demand



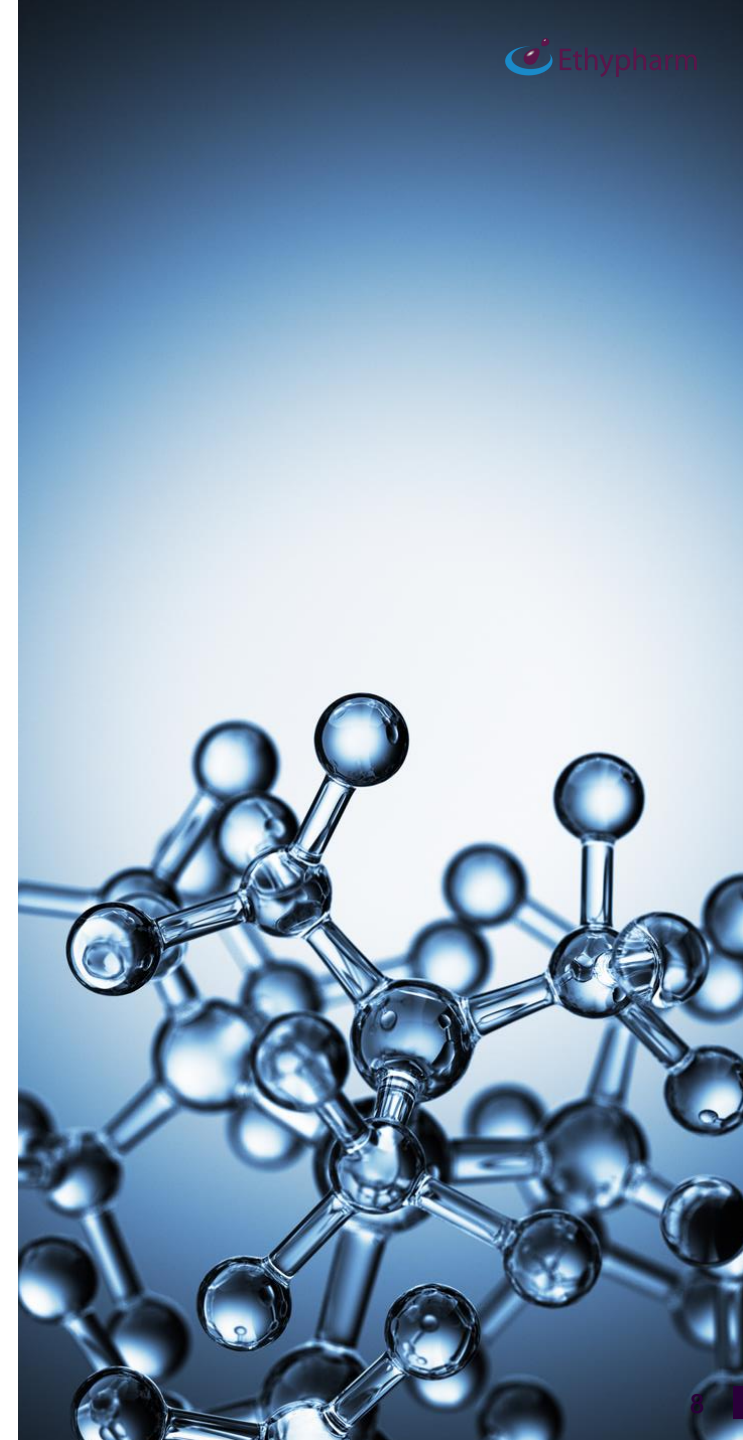
- **Full range of innovative development solutions** from API sourcing to support on regulatory strategy definition and on submission (formulation - pilot - regulatory batches manufacture - analytical method development and validation - ICH stability studies.../ tailor made solutions)
- **Oral solids and liquids - sterile products:** PFS - Ampoules – Flexible IV bags - Vials - Lyos
- **Dedicated experimented teams** and laboratories
- GMP clinical batches capabilities for EU and US markets
- Huge understanding **of international guidelines**
- **Flexibility - reliability**



**3 development centers  
across Europe**



**An experienced multi-disciplinary team to drive development projects from evaluation, pharmaceutical and analytical development, clinical, scale-up, until Marketing Authorization and Commercial launch.**





# Our Technologies & Know-how



Flashtab®



Flashtab®  
& Tmask®



# Our Technologies & Know-how



Nanosizing®

## NANOSIZING

- > improves bioavailability
- > reduces food effect

300 à 400 µm    1 à 20 µm    < à 250 nm

**MICRONIZED**                      **NANONIZED**

**FASTER DISSOLUTION**

NANONIZED  
MICRONIZED

**IMPROVED BIOAVAILABILITY**

NANONIZED  
MICRONIZED

**SOLUBILITY**

	HIGH	LOW
HIGH PERMEABILITY	I	II
LOW PERMEABILITY	III	IV

**POORLY SOLUBLE DRUGS**  
(class II of the Biopharmaceutical Classification System)

# Our Technologies & Know-how

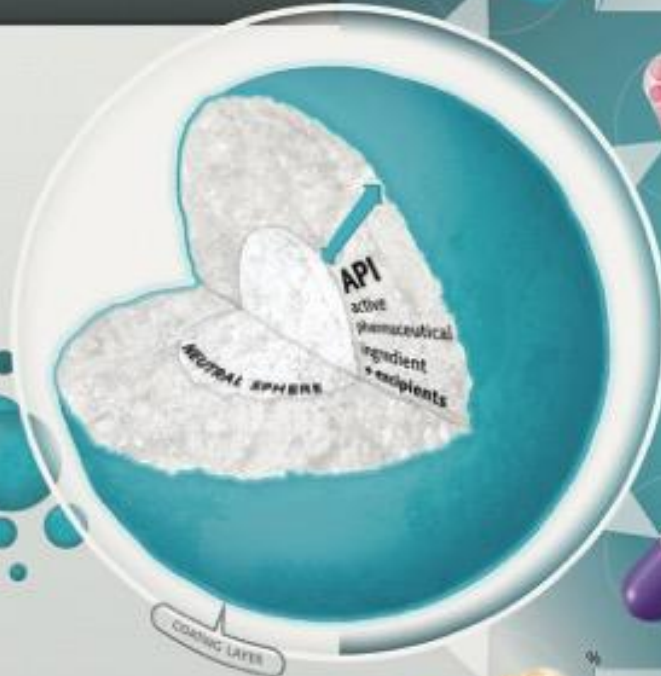
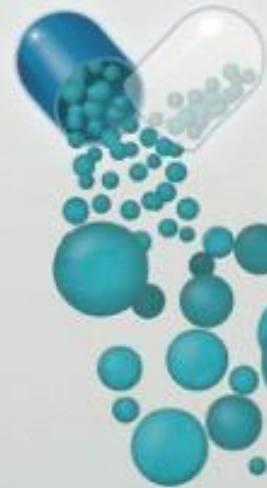


Multicaps®



MULTICAPS®

- > versatile and flexible
- > adapted to fixed combinations



# Our Technologies & Know-how



Transmucosal®

**TRANSMUCOSAL**

- > improves bioavailability
- > allows fast onset of action

TRANSMUCOSAL ROUTE

AVOIDS FIRST PASS METABOLISM EFFECT

RAPID ACTION

RELEASED

TRANSMUCOSAL ROUTE

ORAL ROUTE

TIME (min)

Ethypharm

# Our Technologies & Know-how



Locktab®

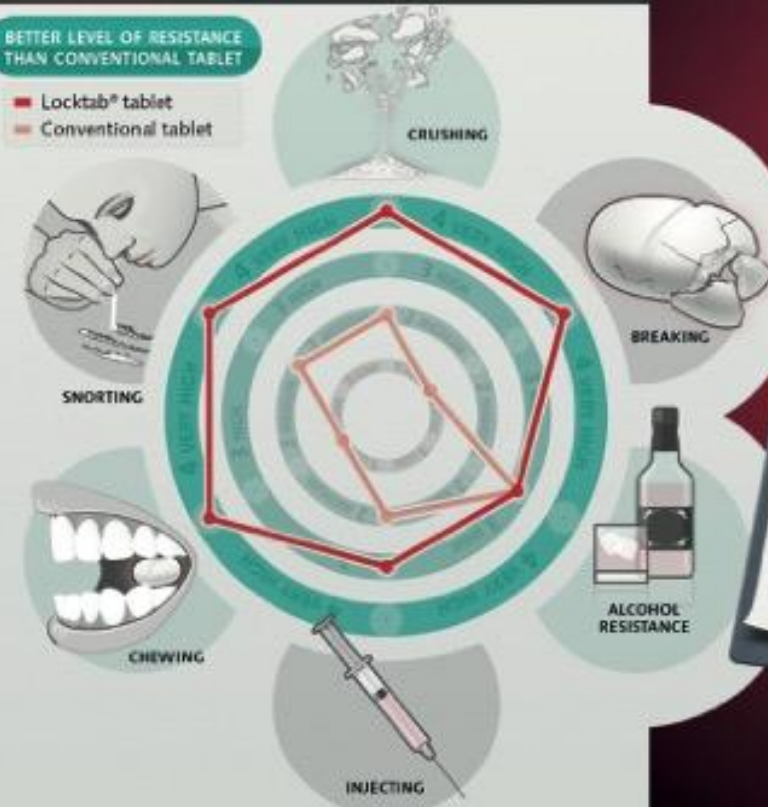


## LOCKTAB®

- > tamper resistant oral formulation
- > dedicated to drugs with abuse potential


BETTER LEVEL OF RESISTANCE THAN CONVENTIONAL TABLET

- Locktab® tablet
- Conventional tablet





CRUSHING



BREAKING




ALCOHOL RESISTANCE



INJECTING



CHEWING



SNORTING



- BREAKING**  
Locktab resists to pressures higher than 4MPa
- CRUSHING**  
Locktab cannot be easily crushed using household tools
- CHEWING**  
Locktab is almost impossible to chew
- INJECTING**  
Locktab's gelification makes injection almost impossible
- ALCOHOL RESISTANCE**  
Locktab avoids dose-dumping in alcohol
- SNORTING**  
Locktab gelifies in small amounts of liquid, rendering snorting almost impossible

TAMPER RESISTANT



# 6 state-of-the-art manufacturing facilities and a network of external partners offering full services

Our 6 plants in France, UK, Spain operate as full-service CDMOs vertically integrated from active substance to finished products with a strong service portfolio including controlled drugs handling, development, scale-up, regulatory services, production process design.



## United Kingdom, France & Spain

Supplying the European, US & international markets



## China

Supplying the local market and Asian region



Compliance with the **highest quality standards and regulations** with a proven experience and track record with MHRA, NMPA, ANSM, USFDA and AEMPS



U.S. FOOD & DRUG ADMINISTRATION

ANSM  
Agence nationale de sécurité du médicament et des produits de santé

MHRA  
Medicines and Healthcare Products Regulatory Agency



AEMPS  
agencia española de medicamentos y productos sanitarios

MFDS  
식품의약품안전처  
Ministry of Food and Drug Safety



NATIONAL MEDICAL PRODUCTS ADMINISTRATION  
国家药品监督管理局

# Châteauneuf-en-Thymerais

Headcount:  
**272** 

**Authorizations:**



**KOREA**



**USA**



**FRANCE**

**Product Forms:**  
Complex Oral Solid Dosage  
(controlled release,  
immediate release)

**Number of units produced:** **1.5**   
Billion doses +

**Strong expertise**  manufacturing and testing of  
controlled release Oral Solid  
Dosage and large volume batches

**Equipment:**

- 6 Fluid Bed Coaters (batch size 300-600 kg)
- 20 Conventional coating pans
- 3 Tableting
- 4 Capsule filling



# Grand-Quevilly

Headcount:  
**282**

**Authorizations:**

**KOREA**

**USA**

**FRANCE**

**Product Forms:** modified release solid oral doses /High potent / Narcotics

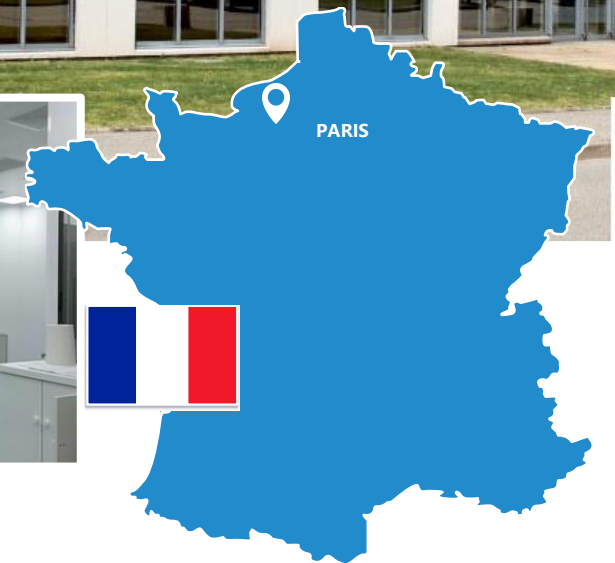
**Number of units produced:** **850** Million doses +

**Strong expertise** Manufacturing and testing of Complex oral Solid Dosages (Immediate Release, Prolonged Release) ; Controlled Drugs and high potent drugs

**Equipment:**

- 7 Conventional and perforated coating pan
- 5 Fluid bed coater
- 2 High shear granulators
- 3 Tableting machine
- 4 Capsule filling
- 2 Nanosizers

Dedicated Manufacturing Units for High potent product (granulator / drying, tablet press / coating pan / capsule filling)





# Bernedo

Headcount:

**130**



Authorizations:



agencia española de  
medicamentos y  
productos sanitarios

SPAIN

**Product Forms:**

Terminally sterilized  
flexible IV bags  
(PVC or PVC-FREE)



**Number  
of units  
produced:**

**9.700**

Million bags



**Strong  
expertise**



Focused in development manufacturing  
and controlling sterile products (IV  
Flexible Bags).

**Equipment:**

- 3 Semi-automatic Filling Machines (flexibility)
- 3 Autoclaves
- 3 Overwrapping Machines.



# Casarrubios

Headcount: **95**

**Authorizations:** agencia española de medicamentos y productos sanitarios  
SPAIN

**Product Forms:** sterile injectables forms vials & ampoules   
**Number of units produced:** **8.9** Million doses

**Strong expertise** **Development and commercial production of ampoules (Aseptic filling and terminal sterilization)**  
Vial (liquids & Lyo)

**Equipment:** 1 filling line for ampoules (1ml to 25ml)  
1 filling line for vials (6ml to 22ml)  
4 Lyos



# Romford

Headcount:  
**404**  +

**Authorizations:**

 <b>FDA</b> U.S. FOOD & DRUG ADMINISTRATION	 <b>MHRA</b> Medicines and Healthcare Products Regulatory Agency	 <b>SFDA</b> Saudi Food & Drug Authority	 식품의약품안전처 Ministry of Food and Drug Safety	 Pharmacy and Poisons Board
USA	UK	SAUDI ARABIA	KOREA	KENYA

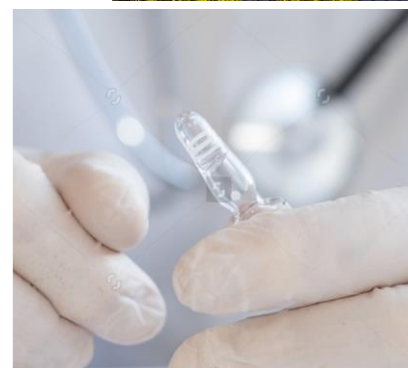
**Product Forms:** Terminally sterilised ampoules, aseptic and Terminally Sterilised PreFilled Syringes, Oral Liquids 

**Number of units produced:** **1.3** Million   
**50** Million 

**Strong expertise**  Handling controlled drugs, Sterile processes

**Equipment:**

- 4 ampoule filling machines (1ml to 20ml)
- 3 automatic inspection machines
- High Speed ampoule packing
- Oral Liquid Filling and Packing
- Aseptic PFS Filling
- Autoclaves and Dry Heat Oven





SCAN ME TO KNOW MORE  
ABOUT OUR CDMO OFFER



Ethypharm your  
partner of choice

Your CDMO Contact

If you want to partner with us,  
contact us on:  
CDMO: [Cheval.isabelle@ethypharm.com](mailto:Cheval.isabelle@ethypharm.com)  
D&L: [Partnerwithus@ethypharm.com](mailto:Partnerwithus@ethypharm.com)

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

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