

# SEQENS

CDMO

TRUSTED SUPPLIER *of*  
*Active Pharmaceutical Ingredients*



APIs



CONTINUUM OF PROGRESS

# Foster growth with Seqens

Three custom development and manufacturing organizations – PCAS S.A. in France and Finland, Chemie Uetikon in Germany and PCI Synthesis in the United States – have joined forces as Seqens CDMO to offer world-class Drug Substance Development and Manufacturing services to the pharmaceutical industry.

## SEQENS CDMO ASSETS & COMPETENCIES

 **6**  
cGMP/FDA inspected sites in EU & the US

 **1,000 m<sup>3</sup>**  
600 m<sup>3</sup> cGMP

 Over 25 years of API production experience

 **2**  
Pre-GMP sites for RSMs & Building-blocks

 **80+**  
DMFs for commercial APIs

 In-house back integration of intermediates and starting materials for safe supply

 **300**  
scientists, experts and engineers

 **3**  
R&D Centers in EU & US

 Global sales and distribution network

 Excellent regulatory compliance track record at all GMP sites

## A wide range of technologies

High Pressure Reaction

Potent API capabilities: OEL < 100 ng/m<sup>3</sup>

Flow chemistry

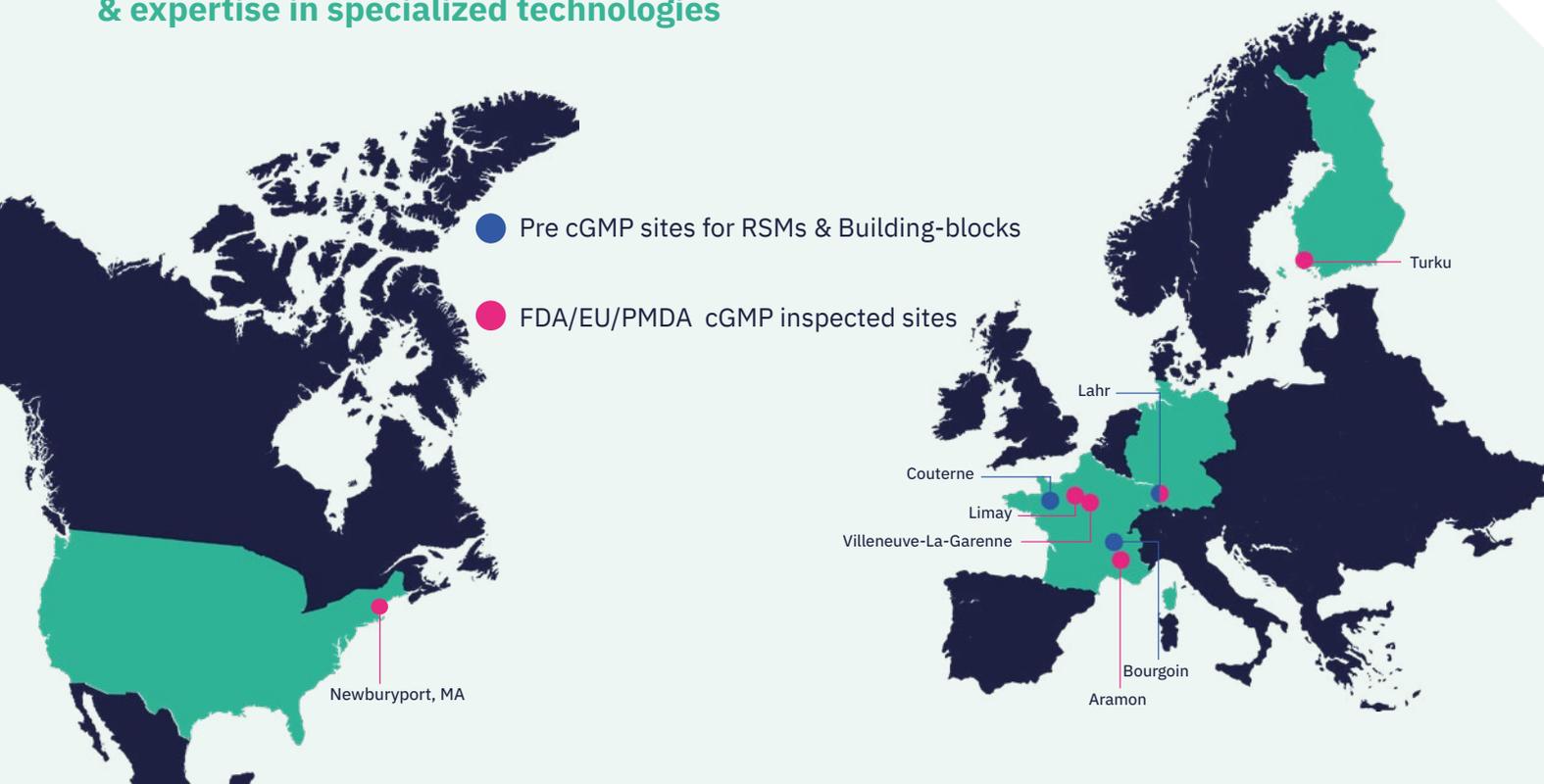
Low temperature technology

API for injectable and ophthalmic FDF

Ethylene Oxide under GMP

## SEQENS CDMO, AN INTERNATIONAL NETWORK

Benefit from a manufacturing network of **6 cGMP** plants located in Europe and the United States with a strong **regulatory track record** with international health authorities and the best **workshop & expertise in specialized technologies**



# 3 Research & Development centers for new API projects launch *in Europe and the US*

/// In-house Regulatory Affairs team with world-wide filing capacity and experience : more than 80 active DMFs

/// Solid state development team: Expertise in polymorphism

/// Customized particle size distribution

/// In-house IP team for the design of non-infringing patent process



## BOSTON'LAB

Early phase project



1,000 M<sup>2</sup> lab-floor  
5 Kilo Labs  
30 Scientists  
with > 50% PhD

/// Controlled substances  
(Schedule II-V)

## SEQENS'Lab

Small molecules & polymers



2,000 M<sup>2</sup> lab-floor  
6 Kilo Labs  
110 Scientists  
with > 50% PhD

/// Crystallization  
/// Solid state characterization  
/// Flow chemistry  
/// Capacity to produce from a few milligrams to 100 kg per batch

## protéus BY SEQENS

Biocatalysis



1,000 M<sup>2</sup> Lab floor  
8,000 Micro-organisms  
library 350 Enzymes  
available for testing  
20 Scientists  
with > 30% PhD

/// Biocatalysis  
/// Tailor made enzymes

# Products Under Development\*

| Product                                | Therapeutic Area                         | Stage                             | Dossier availability |
|--|--|-----------------------------------|----------------------|
| <b>R-Baclofen</b>                      | Muscle relaxant, Antispastic             | Dossier preparation               | 2021                 |
| <b>Darunavir</b>                       | HIV infection                            | R&D                               | 2023                 |
| <b>Dorzolamide</b>                     | Ophthalmic                               | R&D                               | 2023                 |
| <b>Emtricitabine</b>                   | HIV-1 infection                          | R&D                               | 2023                 |
| <b>Glycopyrrolate Bromide</b>          | Respiratory System                       | R&D (specific PSD for inhalation) | 2021                 |
| <b>Glycopyrrolate Tosylate</b>         | Anticholinergic, Hyperhidrosis           | R&D                               | 2022                 |
| <b>Ivacaftor</b>                       | Cystic fibrosis                          | R&D                               | 2022                 |
| <b>Mirabegron</b>                      | Urinary disorder                         | R&D                               | 2023                 |
| <b>Propofol</b>                        | Anesthesia                               | R&D                               | 2023                 |
| <b>Ruxolitinib</b>                     | Myelofibrosis                            | R&D                               | 2023                 |
| <b>Safinamide</b>                      | Add-on treatment for Parkinson's disease | R&D                               | 2022                 |
| <b>Tamoxifen Citrate (Ph.Eur, )USP</b> | Oncology                                 | R&D                               | 2023                 |
| <b>Tofacitinib</b>                     | Ulcerative colitis                       | R&D                               | 2023                 |



# API Product list – manufactured in the US and in EU

| Product                                    | Quality         | EU CEP | EU DMF (ASMF) | US DMF | Bra. DMF | Can. DMF | Jap. DMF | Korea DMF | China DMF | Therapeutic Area                                    |
|--|-----------------|--------|---------------|--------|----------|----------|----------|-----------|-----------|---|
| <b>Apraclonidine HCl</b>                   | USP             |        |               | /      |          |          |          |           |           | Cardiovascular System                               |
| <b>Articain (Carticaine) HCl</b>           | Ph.Eur          | /      |               | /      |          | /*       |          | /         |           | Nervous System                                      |
| <b>Baclofen</b>                            | Ph.Eur, USP     | /      |               | /      |          | /        |          |           |           | Muskulo-skeletal System                             |
| <b>Ciclopirox</b>                          | Ph.Eur, USP     |        |               | /      |          | /        |          |           |           | Dermatologicals                                     |
| <b>Ciclopirox Olamine</b>                  | Ph.Eur,         | /      |               |        |          | /        |          |           |           | Dermatologicals                                     |
| <b>Cinacalcet</b>                          | Ph.Eur, USP     |        | /             | /      |          | /        |          |           |           | Systemic hormonal preparations                      |
| <b>Clomifene Citrate</b>                   | Ph.Eur, USP, JP | /      |               | /      | /        | /*       | /        |           |           | Genito-urinary system and sex hormones              |
| <b>Clonidine Base</b>                      | USP             |        | /             | /      |          | /        |          |           |           | Cardiovascular System                               |
| <b>Clonidine HCl</b>                       | Ph.Eur, USP     | /      |               | /      |          | /        |          |           | /*        | Cardiovascular System                               |
| <b>Desipramine HCl</b>                     | Ph.Eur, USP     |        |               | /      |          |          |          |           |           | Nervous System                                      |
| <b>2,4-Dichlorobenzyl alcohol</b>          | Ph.Eur          |        | /             |        |          |          |          |           |           | Antiparasitic products, insecticides and repellents |
| <b>Enclomiphene citrate</b>                | Ph.Eur          |        | /             | /      |          |          |          |           |           | Genito-urinary system and sex hormones              |
| <b>Glycopyrrolate Bromide</b>              | Ph.Eur, USP     | /      |               | /      | /*       | /        | /        | /*        | /         | Respiratory System Anticholinergic, Hyperhidrosis   |
| <b>Heptaminol Base</b>                     | Ph.Eur          |        |               |        |          |          |          |           |           | Cardiovascular System                               |
| <b>Heptaminol HCl</b>                      | Ph.Eur          | /      |               |        |          |          |          |           |           | Cardiovascular System                               |
| <b>Ketamine HCl</b>                        | Ph.Eur, USP     | /      |               | /      |          | /        | /        | /         |           | Nervous System                                      |
| <b>S-Ketamine HCl</b>                      | Ph.Eur          | /      |               | /      |          | /        |          | /         |           | Nervous System                                      |
| <b>Mepenzolate Bromide</b>                 | JP              |        |               |        |          |          | /        |           |           | Alimentary tract and metabolism                     |
| <b>Mepivacaine HCl</b>                     | Ph.Eur, USP     | /      |               | /*     |          | /*       |          |           |           | Nervous System                                      |
| <b>Methimazole (Thiamazol)</b>             | Ph.Eur, USP     | /      |               | /      |          | /        | /        | /         | /         | Systemic hormonal preparations                      |
| <b>Mequitazine</b>                         | EP (int.), JP   |        | /             |        |          |          | /        | /*        |           | Respiratory System                                  |
| <b>Olopatadine HCl</b>                     | Ph.Eur, USP     |        | /             | /      |          | /*       |          |           | /         | Respiratory System                                  |
| <b>Oxeladin Citrate</b>                    | Ph.Eur          |        | /             |        |          |          |          |           |           | Respiratory System                                  |
| <b>Oxybutynin Base</b>                     | Ph.Eur, USP     |        | /             | /      |          | /        |          | /         |           | Genito-urinary system and sex hormones              |
| <b>Oxybutynin HCl</b>                      | Ph.Eur, USP     | /      |               | /      | /        | /        | /        | /*        | /*        | Genito-urinary system and sex hormones              |
| <b>Pholcodine</b>                          | Ph.Eur          | /      |               |        |          |          |          |           | /         | Respiratory System                                  |
| <b>Pindolol</b>                            | Ph.Eur, USP     | /      |               | /      |          | /        |          |           |           | Cardiovascular System                               |
| <b>Piperidolate HCl</b>                    | JP, USP         |        |               |        |          |          | /        |           |           | Alimentary tract and metabolism                     |
| <b>Podophyllotoxin</b>                     | USP             |        |               | /      |          |          |          |           |           | Dermatologicals                                     |
| <b>Praziquantel</b>                        | Ph.Eur, USP     | /      |               | /      |          | /        |          |           |           | Antiparasitic products, insecticides and repellents |
| <b>Promazine HCl</b>                       | Ph.Eur          | /      |               |        |          |          |          |           |           | Nervous System                                      |
| <b>Promethazine Base</b>                   | Ph.Eur          |        | /             |        |          |          |          |           |           | Respiratory System                                  |
| <b>Pyridostigmine Bromide</b>              | USP             |        |               | /      |          |          |          |           |           | Nervous System                                      |
| <b>Racecadotril</b>                        | Ph.Eur          | /      |               |        |          |          |          |           |           | Alimentary tract and metabolism                     |
| <b>Sodium Phenyl Butyrate</b>              | USP             |        |               | /      |          | /        | /        |           |           | Alimentary tract and metabolism                     |
| <b>Tamoxifene Citrate</b>                  | JP              |        |               |        |          | /        |          |           |           | Oncology  |
| <b>Tazarotene</b>                          | Ph.Eur, USP     |        | /             | /      |          | /        |          |           |           | Dermatologicals                                     |
| <b>Tetrahydrozoline</b>                    | Ph.Eur, USP, JP | /      |               |        |          |          |          | /*        |           | Sensory organs                                      |
| <b>Timolol Hemihydrate</b>                 | Ph.Eur, USP     |        |               | /      |          |          |          |           |           | Sensory organs                                      |
| <b>Timolol Maleate</b>                     | Ph.Eur, USP     | /      |               | /      |          | /        | /        | /         |           | Sensory organs                                      |
| <b>Trimeprazine (Alimemazine) Tartrate</b> | Ph.Eur, USP     | /      |               | /      |          |          | /        |           |           | Respiratory System                                  |
| <b>Troloxerutine</b>                       | Ph.Eur          | /      |               |        |          |          |          |           |           | Cardiovascular System                               |

The Regulatory dossier of APIs produced on the Limay site, Villeneuve-la-Garenne (VLG Chem) and Aramon (Expansia) are registered under the PCAS name.

The Regulatory dossier of APIs produced on the Lahr site are registered under the Uetikon name.

The Regulatory dossier of APIs produced on the Newburyport are registered under the PCI name.

\* In progress. \*\* US DMFs that have passed the Completeness Assessment and are available for reference by ANDAs under GDUFA.

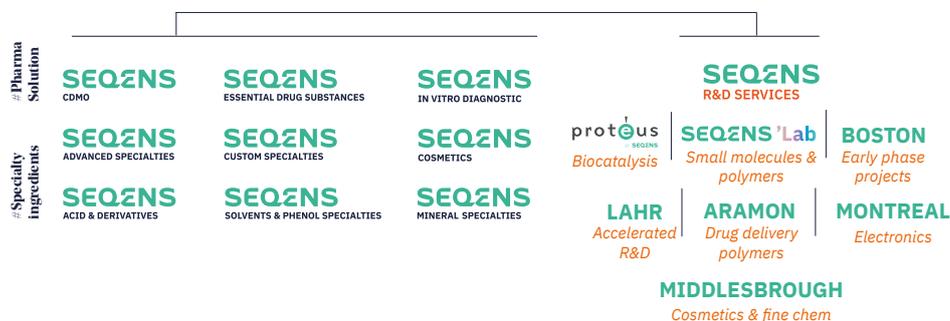
Availability of APIs is subject to patent restriction in countries where applicable patents are in effect.

# About Seqens

Seqens is an integrated global leader in pharmaceutical solution and specialty ingredients, delivering outstanding performance, unrivalled market responsiveness and custom-made solutions to its customers.

In the pharmaceutical industry, Seqens supports its customers in developing, scaling up and manufacturing drug substances from the pre-clinical phase to the commercial phase. Seqens also offers a large portfolio of APIs and proprietary products.

## SEQENS



3200 people



300 scientists, experts and engineers



7 R&D centers



1000 clients in more than 80 countries



24 manufacturing sites

## DISCOVER SEQENS PHARMA SOLUTIONS PRODUCTS & SERVICES OFFER



Custom manufacturing



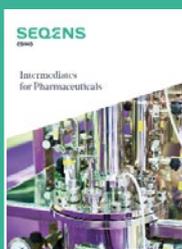
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Early stage manufacturing



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Intermediates



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Drug delivery



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Biocatalysis services



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