SEQENS CDMO

TRUSTED SUPPLIER of Active Pharmaceutical Ingredients



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 Segens CDMO to offer world-class Drug Substance Development and Manufacturing services to the pharmaceutical industry.

SEQENS CDMO ASSETS & COMPETENCIES



cGMP/FDA inspected sites in EU & the US



1.000 m³ 600 m³ cGMP



Pre-GMP sites for RSMs & Building-blocks



80+ DMFs for commercial APIs



300 and engineers



R&D Centers in EU & US









track record at all GMP sites

A wide range of technologies

High Pressure Reaction

Potent API capabilities: OEL<100 ng/m³

Low temperature technology

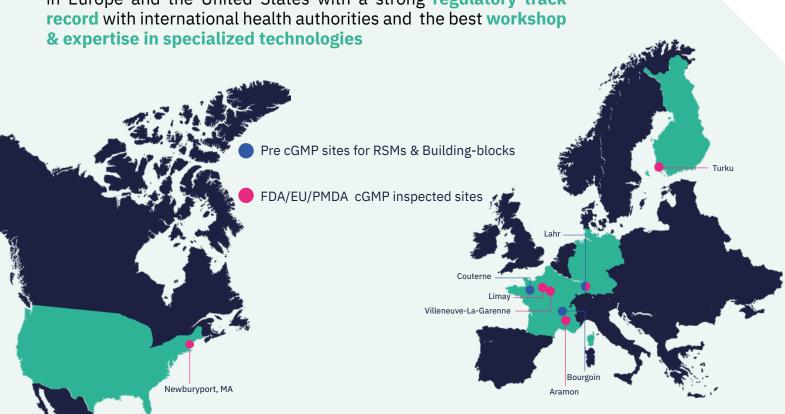
API for injectable and ophthalmic FDF

Flow chemistry

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 worldwide filing capacity and experience: more than 80 active DMFs
- Customized particle size distribution In-house IP team for the design of noninfringing patent process
- Solid state development team: Expertise in



BOSTON'LAB

SEQENS'Lab



Biocatalysis

Early phase project

Small molecules & polymers





2,000 M² lab-floor 6 Kilo Labs 110 Scientists with > 50% PhD

1,000 M² lab-floor 5 Kilo Labs 30 Scientists with > 50% PhD



Solid state characterization

Flow chemistry

Capacity to produce from a few milligrams to 100 kg per batch

1,000 M² Lab floor 8,000 Micro-organisms library 350 Enzymes available for testing 20 Scientists with > 30% PhD

Biocatalysis

Tailor made enzymes

Controlled substances (Schedule II-V)

Products Under Development*

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



API Product list - manufactured in the US and in EU

Product	Quality	EU CEP	EU DMF (ASMF)	US DMF	US DMF for reference **	Can. DMF	Jap. DMF	Korea DMF	China DMF	Therapeutic Area
Apraclonidine HCl	USP		(' ' ' ' ' '	/						Cardiovascular System
Articain (Carticaine) HCl	Ph.Eur					*				Nervous System
Baclofen	Ph.Eur, USP	1			/					Muskulo-skeletal System
Ciclopirox	Ph.Eur, USP				/					Dermatologicals
Ciclopirox Olamine	Ph.Eur, USP	/								Dermatologicals
Cinacalcet	Ph.Eur, USP		/		/					Systemic hormonal preparations
Clomifene Citrate	Ph.Eur, USP, JP	1				*				Genito-urinary system and sex hormones
Clonidine Base	USP				/				_	Cardiovascular System
Clonidine HCl	Ph.Eur, USP								*	Cardiovascular System
Desipramine HCl	Ph.Eur, USP		_							Nervous System Antiparasitic products, insecticides
2,4-Dichlorobenzyl alcohol										and repellents Genito-urinary system and sex
Enclomiphene citrate	Ph.Eur	_			_	_	_		_	hormones Respiratory System Anticholinergic,
Glycopyrrolate Bromide	Ph.Eur, USP									Hyperhidrosis
Heptaminol Base	Ph.Eur	_								Cardiovascular System
Heptaminol HCl	Ph.Eur	1		_	_	_	_			Cardiovascular System
Ketamine HCl	Ph.Eur, USP									Nervous System
S-Ketamine HCl	Ph.Eur	/								Nervous System
Mepenzolate Bromide	JP									Alimentary tract and metabolism
Mepivacaine HCl	Ph.Eur, USP	/		*		*				Nervous System
Methimazole (Thiamazol)	Ph.Eur, USP				/					Systemic hormonal preparations
Mequitazine	EP (int.), JP		/							Respiratory System
Olopatadine HCl	Ph.Eur, USP				/					Respiratory System
Oxeladin Citrate	Ph.Eur									Respiratory System
Oxybutynin Base	Ph.Eur, USP			/	/	/				Genito-urinary system and sex hormones
Oxybutynin HCl	Ph.Eur, USP	1			/	/	/		/ *	Genito-urinary system and sex hormones
Phenylacetic acid sodium salt (sodium phenylacetate)	USP						/ *			Alimentary tract and metabolism
Pholcodine	Ph.Eur	/								Respiratory System
Pindolol	Ph.Eur, USP				/					Cardiovascular System
Piperidolate HCl	JP, USP									Alimentary tract and metabolism
Podophyllotoxin	USP				/					Dermatologicals
Praziquantel	Ph.Eur, USP	•		/	/	/				Antiparasitic products, insecticides and repellents
Promazine HCl	Ph.Eur	1								Nervous System
Promethazine Base	Ph.Eur									Respiratory System
Pyridostigmine Bromide	USP				/					Nervous System
Racecadotril	Ph.Eur	/								Alimentary tract and metabolism
Sodium Phenyl Butyrate	USP				/ *					Alimentary tract and metabolism
Tamoxifene Citrate	JP									Oncology
Tazarotene	Ph.Eur, USP				/					Dermatologicals
Tetrahydrozoline	Ph.Eur, USP, JP	*								Sensory organs
Timolol Hemihydrate	Ph.Eur, USP				/					Sensory organs
Timolol Maleate	Ph.Eur, USP	1		/	/	/	/			Sensory organs
Trimeprazine (Alimemazine) Tartrate	Ph.Eur, USP	•								Respiratory System
Troxerutine	Ph.Eur	1								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 Regulatroy 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 Segens

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

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ESSENTIAL DRUG SUBSTANCES

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protous SEQENS'Lab Small molecules & polymers

LAHR ARAMON Accelerated R&D Drug delivery polymers

Biocatalysis

BOSTON

Early phase projects

MONTREAL Electronics

MIDDLESBROUGH Cosmetics & fine chem











DISCOVER SEQENS PHARMA SOLUTIONS PRODUCTS & SERVICES OFFER



Custom



Early stage





Drug delivery



services



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Contact: PAPI@segens.com

69130 ECULLY CEDEX FAX. +33 (0) 4 26 99 18 38

WWW.SEQENS.COM



