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



300

and engineers

Pre-GMP sites for RSMs & Building-blocks



80+ DMFs for commercial APIs



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

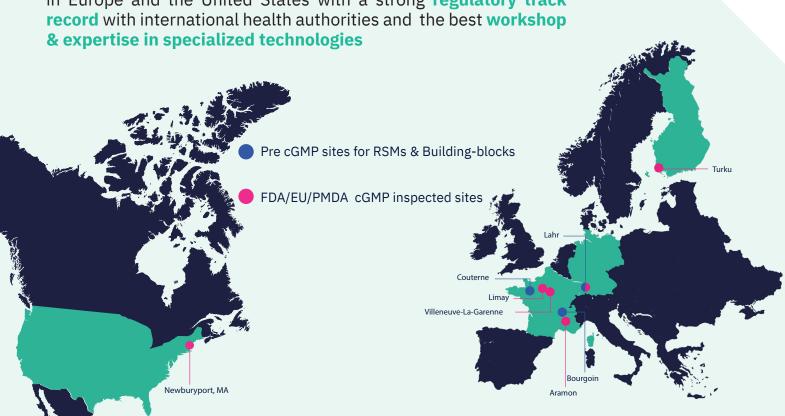
API for injectable and ophthalmic FDF

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



DEVENS

SEQENS'Lab

prot

Small molecules & polymers



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

Controlled substances (Schedule II-V)

Small molecules & polymers



2,000 M² 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

Biocatalysis



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

- Biocatalysis
- Tailor made enzymes

Products Under Development*

roduct	Therapeutic Area	Stage	Dossier availability		
isopyramide Phosphate	Antiarrhythmic	Dossier preparation	2022		
iglustat	Type 1 Gaucher Disease	Dossier preparation	looking for partnership		
ethenamine Hippurate	Antibacterial (urinary)	Dossier preparation	looking for partnership		
orketamine	Pain management	Dossier preparation	2022		
-Baclofen	Muscle relaxant, Antispastic	Dossier preparation	2021		
-Ketamine HCl	Depression, Pain management	Dossier preparation	2022		
odium Benzoate	Urea cicle disorders /Schizophrenia	Dossier preparation	2022		
rinzolamide	Ophthalmic	R&D	2023		
arbidopa	Add-on treatment for Parkinson's	R&D	2023		
arunavir	HIV infection	R&D	2023		
mtricitabine	HIV-1 infection	R&D	2023		
avipiravir	Antiviral	R&D	2023		
lycopyrrolate Bromide	Respiratory System	R&D (specific PSD for inhalation)	2021		
lycopyrrolate Tosylate	Anticholinergic, Hyperhidrosis	R&D	2022		
acaftor	Cystic fibrosis	R&D	2022		
irabegron	Urinary disorder	R&D	2023		
ropofol	Anesthesia	R&D	2023		
uxolitinib	Myelofibrosis	R&D	2023		
afinamide	Add-on treatment for Parkinson's disease	R&D	2022		
amoxifen Citrate (Ph.Eur,)USP	Oncology	R&D	2023		
ofacitinib	Ulcerative colitis	R&D	2023		
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API Product list - manufactured in the US and in EU

		EU	EU	US	US DMF for	Can.	Jap.	Korea	China	
Product	Quality	CEP	DMF (ASMF)	DMF	reference **	DMF	DMF	DMF	DMF	Therapeutic Area
Apraclonidine HCl	USP			/						Cardiovascular System
Articain (Carticaine) HCl	Ph.Eur					*				Nervous System
Baclofen	Ph.Eur, USP				/					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 Desipramine HCl	Ph.Eur, USP Ph.Eur, USP								*	Cardiovascular System Nervous System
2,4-Dichlorobenzyl alcohol	Ph.Eur		/							Antiparasitic products, insecticides and repellents
Enclomiphene citrate	Ph.Eur		/							Genito-urinary system and sex hormones
Glycopyrrolate Bromide	Ph.Eur, USP				/					Respiratory System Anticholinergic, Hyperhidrosis
Heptaminol Base	Ph.Eur									Cardiovascular System
Heptaminol HCl	Ph.Eur	/								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	1			/					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									Nervous System
Promethazine Base	Ph.Eur		/							Respiratory System
Pyridostigmine Bromide	USP				/					Nervous System
Racecadotril	Ph.Eur	1								Alimentary tract and metabolism
Sodium Phenyl Butyrate	USP				*					Alimentary tract and metabolism
Tamoxifene Citrate	JP									Oncology
Tazarotene	Ph.Eur, USP									Dermatologicals
Terazosin HCl Anhydrous	USP									Genito-urinary system and sex hormones
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	/								Cardiovascular System
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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 Sequens

Segens is an integrated global leader in pharma 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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SEQENS MINERAL SPECIALTIES











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Early stage





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Drug delivery



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🛑 On site laboratories

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Biocatalysis services



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