SEQENS

CONTINUUM OF PROGRESS

Catalog & Custom offer for

Drug Delivery Solutions

SEQENS CDMO, a global Contract Development and Manufacturing Organization

With 25 years of experience in process development, scale-up and ongoing cGMP manufacturing of small molecule APIs, we support emerging, specialty and large pharmaceutical customers for their drug substance or drug delivery needs.

Continuum in the API life cycle

- Early phase development
- Late phase to commercial
- Second generation process
- Generic APIs

Continuum in the API value chain

- cGMP and non-cGMP intermediates
- RSMs
- API manufacturing
- Excipients for drug delivery
- Controlled substances

Continuum in technological capabilities

- From batch to flow chemistry
- Solid state characterization and optimization
- Hydrogenation and high pressure
- Large volume potent capabilities (0.1 µ/m3)
- Biocatalysis

SEQENS

CONTINUUM OF PROGRESS

Continuum in production capabilities

- cGMP and non-cGMP kilo Labs
- cGMP and non-cGMP pilots units
- 2 Pre GMP production sites
- 6 cGMP / FDA inspected API production sites

Continuum in human regulatory

- Chemistry, Manufacturing and Controls
- Complementary chemistry and chemical engineering expertise for process industrialization
- Process safety
- SEQENS'LAB, a unique Center of Excellence and dynamic multidisciplinary ecosystem dedicated to innovation and development

Continuum in geographical coverage

- R&D centers in EU and US
- Manufacturing sites accross 3 continents
- Global network of sales offices
- Solutions for dual sourcing

Foster growth with Seqens

Four custom development and manufacturing organizations – PCAS in France and Finland, Chemie Uetikon in Germany, PCI Synthesis in the United States and Wavelength in Israel & India – have joined forces as Seqens CDMO to offer world-class drug Substance development and manufacturing services to the pharmaceutical industry.

Assets & Competencies

8
cGMP/FDA inspected sites WW

1,000 m³
600 m³ cGMP

3
Pre-GMP sites for RSMs & Building-blocks

200+
DMFs for commercial APIs

250
scientists, experts and engineers

7
R&D Centers worldwide

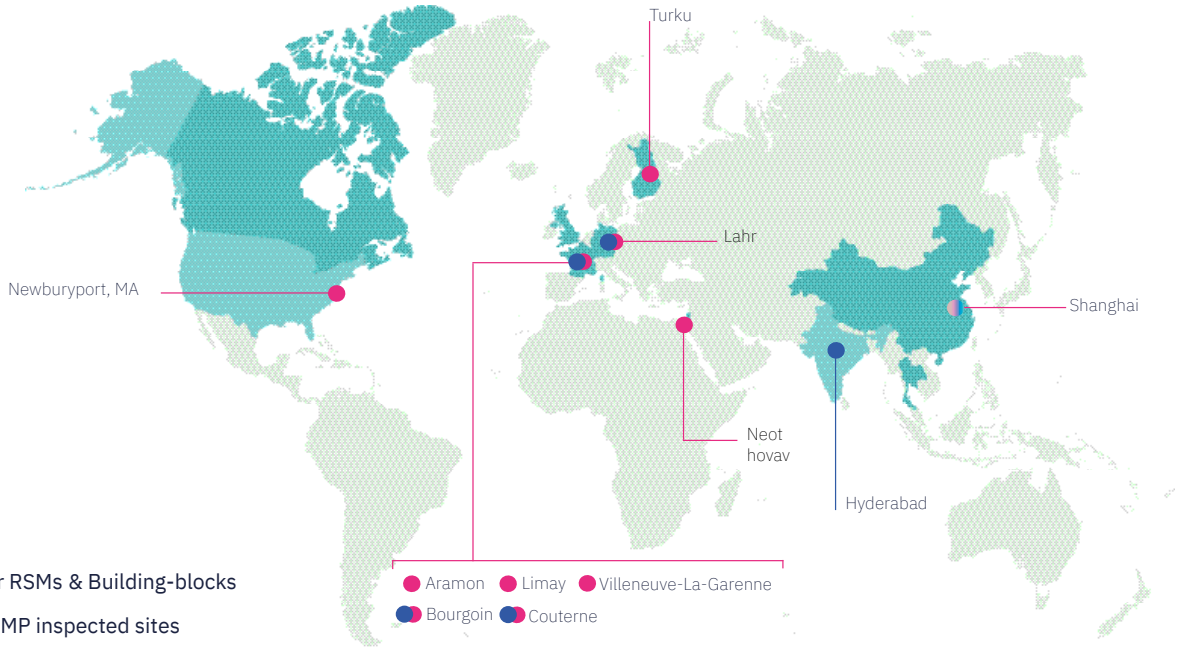
- Over 35 years of API production experience
- In-house back integration of intermediates and starting materials for safe supply
- Global sales and distribution network
- Excellent regulatory compliance track record at all GMP sites

A wide range of technologies

- High Pressure Reaction
- Low temperature technology
- Enzymatic Chemistry
- Potent API capabilities: OEL<100 ng/m³
- API for injectable and ophthalmic FDF
- Controlled Substances
- Flow chemistry
- Micronisation & spray drying services

An international network

Benefit from a manufacturing network of **7 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**

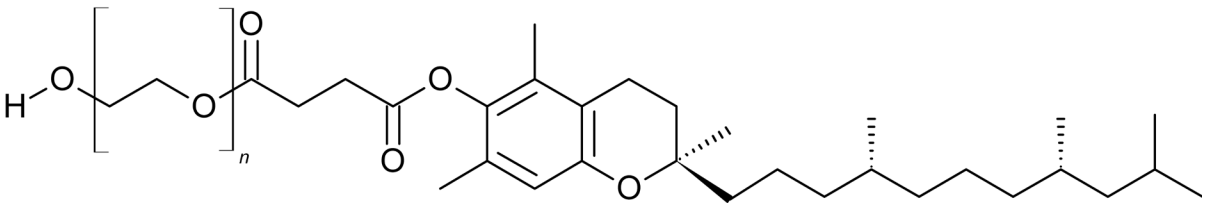


VITAMIN E TPGS

Application field of Vitamin E-TPGS: Pharmaceutical, Nutraceutical, Food and beverage, Cosmetic and Personal Care, Animal nutrition.

Chemical structure

Chemical Name: D-α tocopheryl polyethylene glycol 1000 succinate
Synonym/acronym : TPGS, Tocophersolan, Tocofersolan



Properties of Vitamin E TPGS

Vitamin E TPGS, a non-ionic surfactant, water soluble derivative of natural Vitamin E, is a multirole excipient for pharmaceutical drug delivery innovation.

Improving bioavailability

- Absorption enhancer
- PgP inhibitor

Surfactant properties

- Drug solubilizer
- Emulsifier
- Vehicle for lipid based formulation (SEDDS* and SMEDDS**)
- Plasticizer for hot Melt Extrusion
- Stabilizer for
- amorphous solid
- dispersion

Source of Vitamin E

- API for Vitamin E (water soluble source of vitamin E)
- Antioxydant

** SEDDS: Self-Emulsifying Drug Delivery*

*** SMEDDS: Self-MicroEmulsifying Drug Delivery System*

Type of formulation and administration pathway

Formulation

- Tablet
- Capsule (hard and soft)
- Soft gel
- Solution
- Cream

Administration

- Oral
- Mucosal (buccal,
- vaginal, nasal etc.)
- Parenteral
- Ophthalmics
- Dermal

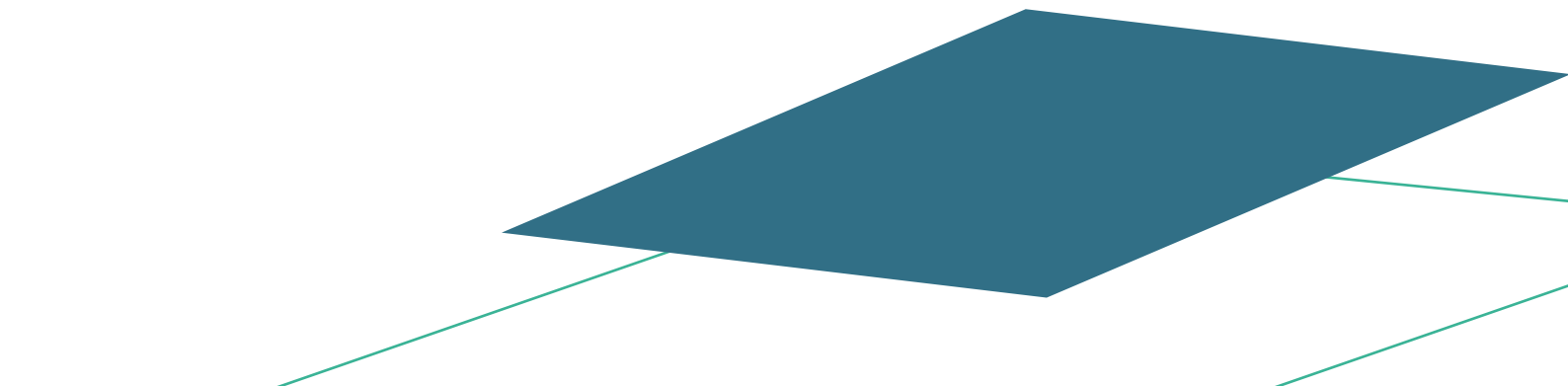
Regulatory Status

- Active DMFs i.e. US type IV (Excipients)
- NF compliant (USP)
- Produced in Europe (Germany)
- GMP compliance (EU, USFDA)

Physical and chemical properties

Chemical Abstract Index Name
Poly(oxy-1,2-ethanediyl), α-[4-[[(2R)-3,4-dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-2H-1-benzopyran-6-yl]oxy]-1,4-dioxobutyl]-ω-hydroxy-

Empirical Formula: $C_{33}O_5H_{54}(CH_2CH_{2O}O)n$
CAS : 9002-96-4
Molecular weight: ~1.5 kDa
Melting Point: 36-42 °C
Physical form: waxy solid with low melting point
Color: white to light tan
Vitamin E content (D-α-tocopherol): 25 % minimum weight basis; standard range 25-30 %

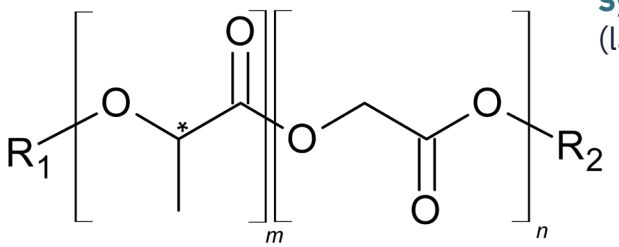


EXPANSORB®

EXPANSORB® GMP PLA & PLGA copolymers are obtained by copolymerization of the corresponding cyclic dimers lactide and glycolide. PLGAs are among the best-in-class functionnal excipients for controlled-release of injectable drugs, included in multiple commercial formulations, and commonly used material for resorbable medical devices.

Chemical structure

(PLA : n=0)



PLGA

Chemical Name: poly (lactic acid) / poly (lactic-co-glycolic) acid
Synonym/acronym: PLGA, PLAGA, poly (lactide-co-glycolide)

Properties & applications of GMP-grade PLGA

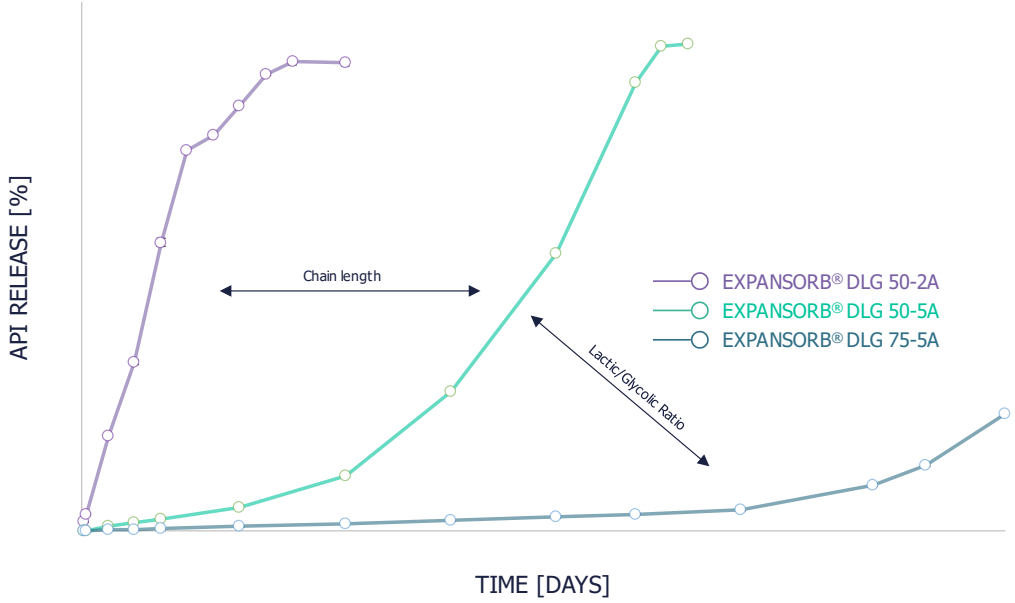
Properties

- Excellent biocompatibility, controllable biodegradability / bioresorbability
- Highly tunable properties :
  - LA/GA ratio
  - Lactide enantiomer ratio (D,L)
  - Chain length
  - End-chain
  - Copolymerization...

Applications

- FDA-approved excipient
- Controlled release formulations (nanoparticles, microparticles)
- Implantable systems for drug delivery
- Resorbable materials for medecine surgery
- Matrix for tissue engineering

Take the control of your drug release !

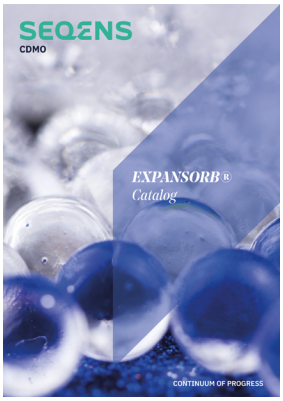


Seqens Unique Offer

20+ years expertise on PLGA manufacturing within several on-the-market formulations

- Active DMFs i.e. US type IV (Excipients)
- Dedicated onsite R&D capabilities to any fine tuning from lab to industrial scale
- Regulatory services support : IMPD, DMF Filing
- Produced in Europe (Aramon, France)
- GMP compliant (EU, USFDA)
- Classic and ultrapure ***low-monomer and powder*** grades available.

New !
Ultrapure LMP Grade available !
With <0,5% monomer content



Ask for our EXPANSORB® catalog

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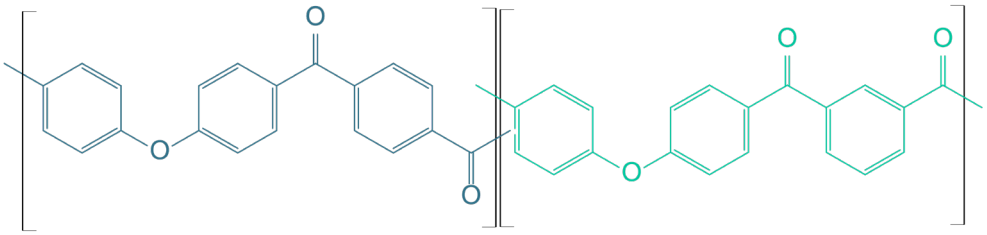
IMPEKK™

PEKK produced by Seqens "IMPEKK™ polymer" is a high performance thermoplastic designed for permanent surgical implants such as spinal, cranial, orthopedics and dental implants. Its tailored crystallization speed enables IMPEKK™ polymer to be perfectly suited for Additive Manufacturing.

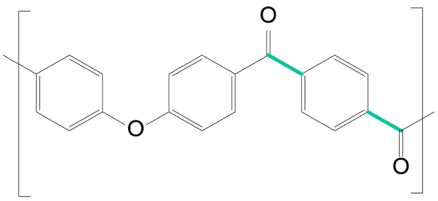
Chemical structure of Poly-Ether-Ketone-Ketone (PEKK)



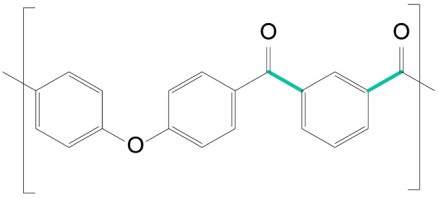
Key properties

The presence of 2 ketone groups compared to other PAEK polymers (Poly-Aryl-Ether-Ketone) gives IMPEKK™ polymer greater polarity and allows for better acceptance of functional fillers, providing a wide range of formulation choices for implantable medical device manufacturers. IMPEKK™ polymer is composed of ether (flexibilizing) and ketone (rigidifying) groups. The more ketone groups there are, the higher the Tg (Glass Transition temperature) and the better the mechanical properties. IMPEKK™ is a copolymer that includes terephthaloyl and isophthaloyl units. This modularity allows fine tuning of crystallization rate and Melting point temperature (Tm).

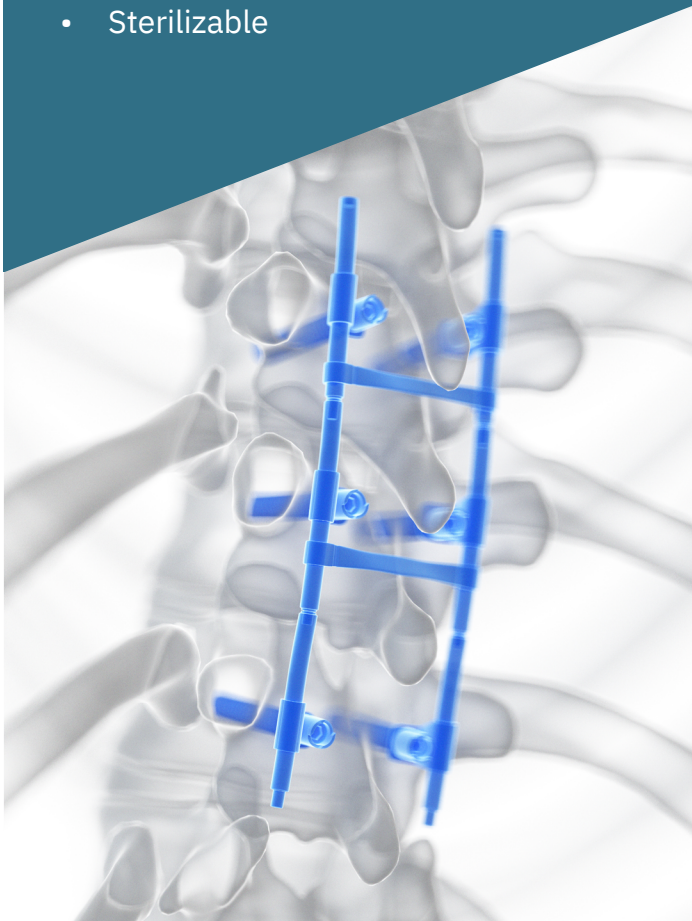
- Elastic modulus close to cortical bone
- X-ray translucency
- Chemical inertness
- Oustanding compressive strength
- High Tg
- Excellent tribological properties
- Excellent barrier properties
- Toughness
- Sterilizable



Terephthaloyl *Para linkage*



Isophthaloyl *Meta linkage*



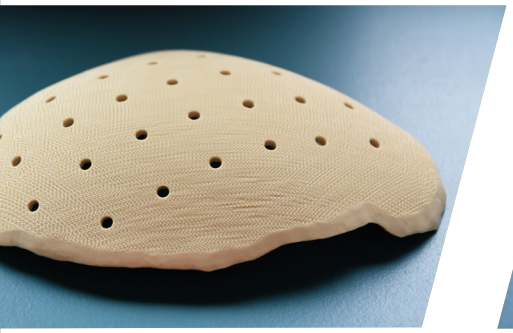
Applications

Amenable to all polymers processing techniques (Injection Molding/Extrusion): **IMPEKK™ 1G-T** (granules for Testing and Development)

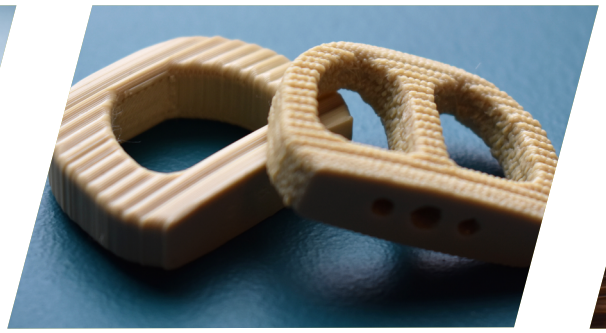
	Norm	IMPEKK™ 1G-T
Appearance	/	Golden Yellow or White to cream solid
Polymer type	/	Semi-crystalline
Melting range/point (°C)	DSC DIN EN ISO 11357	345-375/358
Glass Transition (°C)	DSC DIN EN ISO 11357	160-170
Tensile test at Break (MPa)	DIN EN ISO 527-1	115
Tensile Modulus (GPa)	DIN EN ISO 527-1	3,7
Impact Strength	DIN EN ISO 179-1eU	180 kJ/m²
Impact Strength (notched)	DIN EN ISO 179-1eA	5,7 kJ/m²
Density	DIN EN ISO 1183	1,30 g/cm³
% Tere/Iso	/	80/20
Crystallization speed	/	Very fast
Processing temperature (°C)	/	385°C
Availability	/	Q3/22

Particularly suited for Additive Manufacturing: **IMPEKK™ 3D-F-T** (filaments for Testing and Development)
IMPEKK™ 3D can be printed both amorphous and semi-crystalline.

	IMPEKK™ 3D-F-T
Appearance	Golden Yellow or White to cream solid
Polymer type	Pseudo-amorphous
Diameter	1,75 mm
Packaging	500 g spool
Availability	Available



PEKK-based Cranial Implant printed by Kumovis



PEKK-based Spinal Cage Implants printed by Kumovis

IMPEKK™ 3D-F-T Filament

If you are interested in our IMPEKK™ for implantable medical application, please contact us for more information: **alexandra.ngawazenang@seqens.com**

Custom material for Drug delivery, Medical Materials & Biomedical Applications

Seqens can offer a full range of services to develop and produce materials for medical applications.

Seqens Unique Offer

- Excellence in lipids and polymers chemistry since 1962
- Materials involved on several commercially available formulations or medical devices
- Dedicated polymer workshops units and lipid production capabilities in Europe and US
- Full project management with regular reporting under strict confidentiality
- In-house development and scale-up capacities from kilolab to big industrial scales
- Full regulatory support : IMPD, DMF Filing
- Analytical resources and manufacturing units operating according to ICHQ7 and GMP guidelines on QA authorities (european, FDA...) inspected sites

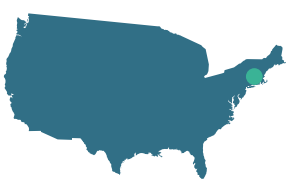
SOME EXAMPLES OF OUR EXPERTISE ON CUSTOM MATERIALS

- Lipids & polymers for RNA encapsulation
- Molecules for glycemia measurement in diabete medical devices
- Resin for injectable formulation
- Filter aid for peptids
- Hydrophilic coating solution for catheters
- Chromatographic resins synthesis and modification

Focus on 4 of SEQENS' expert DDS R&D centers

BOSTON'LAB

Small molecules & polymers



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

ARAMON'LAB

Drug Delivery Polymers

- DD&MM Polymers dedicated R&D team
- 2 kilolab suites (1 dedicated for melt polymerisation)
- 7 scientists with >50% PhD

LAHR'LAB

Accelerated R&D

- Industrialization center
- Lab Surface : 700sqm
- 3 Kilo-lab Suites

SEQENS 'Lab

Small molecules & Polymers

- 4 kilo-labs
- 2 cGMP pilot plants with 11 multipurpose reactors (total capacity of 12 m³)
- Temperature range: -15/+150°C (hastelloy reactor: -80/+200°C)
- 110 Scientists with > 50% PhD

Notes

About Seqens

Seqens is a worldwide leader in the development and production of active ingredients, pharmaceutical intermediates and specialty ingredients leveraging on 24 manufacturing sites, 10 R&D centers and 3,200 employees in 10 countries.

As an integrated player across the value chain - from raw materials to active ingredients and from research and development to industrialization - SEQENS offers a broad portfolio of active ingredients, pharmaceutical intermediates and specialty ingredients, develops and industrializes the most demanding molecules, and relies on its ability to innovate, develop and implement the best available technologies.
Driven by a culture of excellence and a strong entrepreneurial spirit, but also strong values such as unity, tacity, agility and reactivity, our employees are committed to providing more than 1000 customers in the word with the highest level of service and quality while acting ethically in accordance with our strong Environmental, Social and Governance program.

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.

3200 people

300 scientists, experts and engineers

10 R&D centers

1000 clients in more than **80** countries

24 manufacturing sites

DISCOVER SEQENS PHARMA SOLUTIONS PRODUCTS & SERVICES OFFER

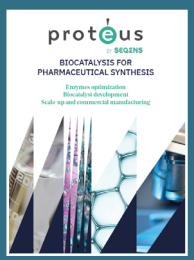
SCAN ME

Custom manufactuting

Early stage manufacturing

Intermediates

Drug Delivery Solutions



Biocatalysis services

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