

SEQENS

OUR SCIENCE FOR YOUR FUTURE

CDMO services for Pharmaceuticals

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The background of the slide is a blurred industrial scene. In the foreground, a large, cylindrical metallic vessel is visible, secured with several hexagonal bolts. Above it, there are various pipes, valves, and mechanical components. The background shows a complex network of industrial structures, including scaffolding and more piping, all slightly out of focus. The overall color palette is dominated by cool blues and greys, with some warmer tones from the industrial lighting in the background.

About us

SEQENS

SEQENS Key figures

A European fine-chemistry group delivering scalable molecule development and manufacturing across Pharma Solutions and Specialty Ingredients

Seqens has achieved a premium positioning through high quality grades and market recognition

Trusted partner CDMO, with ongoing efforts to build-up awareness & recognition

Tier 1 Fine Chemist, with strong market recognition

Premium player w. high quality grades on Consumer Healthcare, and on Phenol & Solvents (incl. IPA)



15⁽³⁾
Production sites



c.800m€
Revenues



c.2,700
Employees



1,500+
Customers

PHARMA⁽¹⁾



A CDMO platform



Pharma ingredients



#1 player in **Aspirin** and **SA intermediates**



Top 3 **Paracetamol**, **PAP integrated supplier**

SPECIALTY
ING.⁽²⁾



Custom solution

High-end Markets



Ingredients catalog

Strongly positioned



SPS

Local positioning
Premium
Diversification



SEQENS at a glance

Pharma



A CDMO platform

- APIs & intermediates
- **Multi-purpose** cGMP production units
- State-of-the-art R&D and technologies
- Custom polymers



Pharma & Healthcare ingredients

- **80+** active ingredients/ **120** intermediates
- **+500** DMFs
- **#1** Aspirin chain player
- **Top 3** Paracetamol supplier

Chemistry



Specialty ingredients

- **Custom & catalog** specialty ingredients
- Compliant with markets standards including pharmaceuticals, cosmetics, batteries, defense, coatings, and lubricants.
- Custom polymers

Biomedicines



Cell & Gene therapies

- A European leader in cell and gene therapy manufacturing.

Why choosing SEQENS?



Partner of choice

We put our expertise and know-how at the service of your success



Capacities

Our industrial capabilities allow us to meet all challenges with performance and innovation



Flexibility

We adapt our services to your specific needs and market developments



Proximity

Our local presence and customer-first mindset guaranteeing personalized and responsive support every step of the way

“

Customer Feedback⁽¹⁾

“Our collaboration with Seqens goes back several years. Seqens' teams are very responsive, ready to find solutions, and demonstrate a high level of expertise. For a biotech company like us, having a partner that combines quality work with strategic expertise has always been an important advantage.”

– CEO, Biotech, Europe

“Having worked for more than 7 years with Seqens, for the development of syntheses of active ingredients as well as for the production of GMP batches of these, I strongly recommend Seqens as a partner.”

– SVP, Head of Non-Clinical Development, Biotech, Europe

“Seqens makes sure to assess what you need and push for optimization, Seqens delivers quality work on time, and the relationship with the Seqens contact is excellent”

– CEO, Biotech, North America

“Seqens is a reliable supplier, has perfectly qualified product and high-level reputation in the market.”

– Head of Procurement, Mid Pharma, Asia

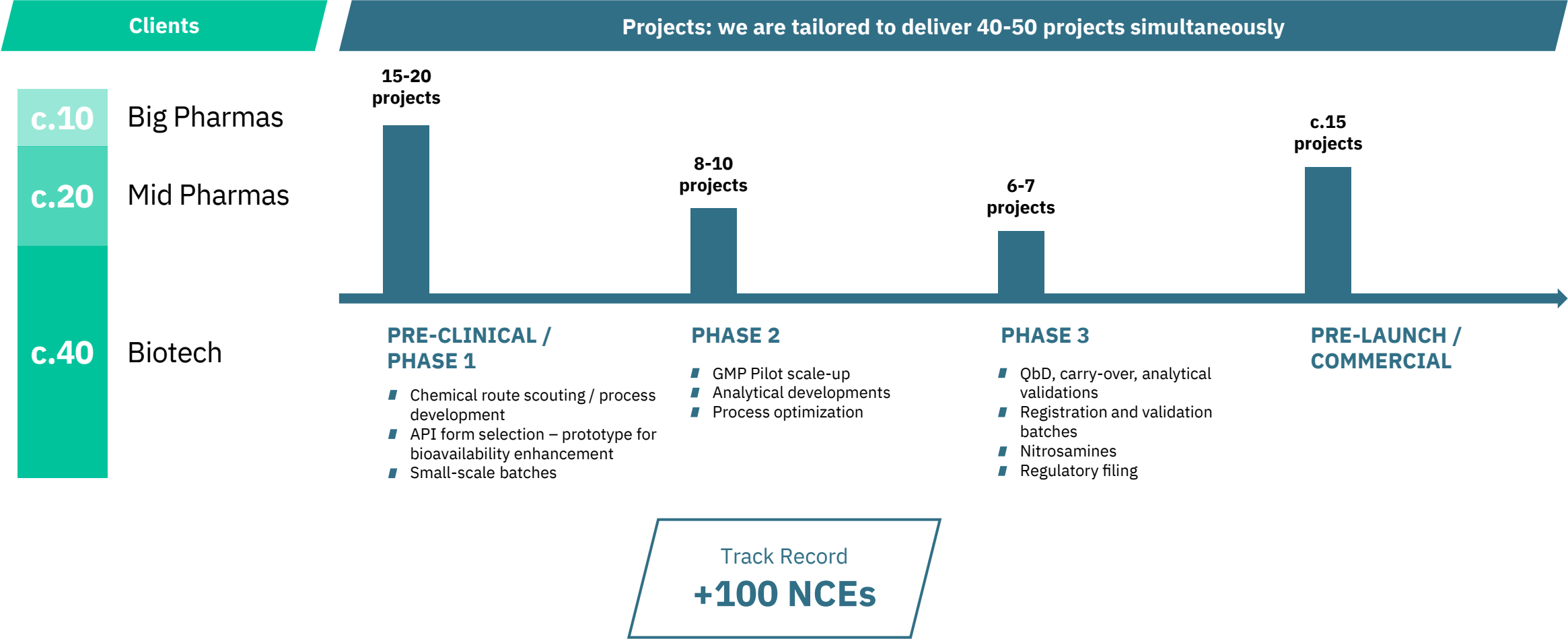
“Our contacts within R&D have been responsive to questions and have demonstrated creative solutions to issues encountered.”

– Head of CMC, Biotech, North America

(1) Source: 2024 and 2025 Customer Satisfaction Surveys

”

We are partnering with selected Big Pharmas and a large number of Biotechs in Europe and North America, for their projects from the pre-clinical to the commercial phases



Consolidating our sustainability leadership

Step toward our ambition

CO₂ emissions	-46,2%	Absolute CO ₂ emissions of scopes 1+2 to be reduced between 2021 and 2031 (SBTi approved)
	-27,5%	Absolute CO ₂ emissions of scopes 3 to be reduced between 2021 and 2031 (SBTi approved)
Sustainable products	100%	Assess the CSR impact of our new products by 2026
Safety	-50%	Reduce workplace accident frequency rate to 2 by 2026

2026 focus activities

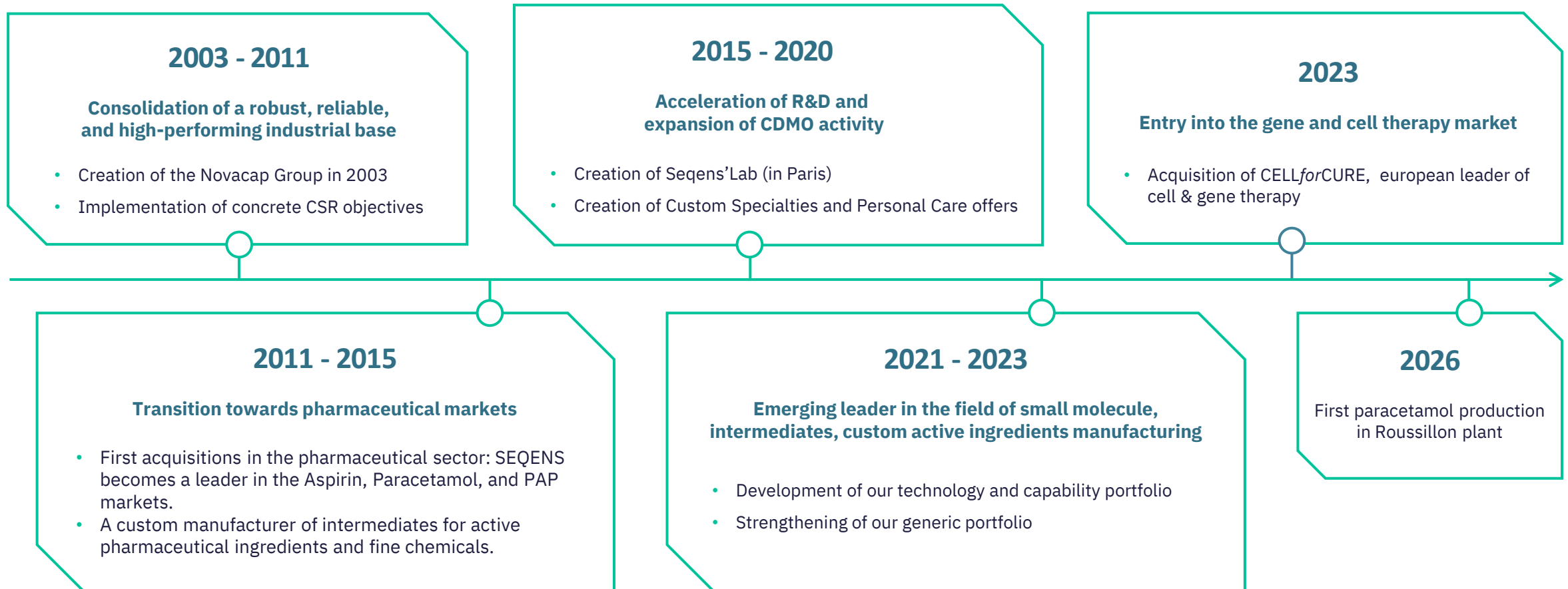
- Reduce the environmental impact of our industrial and R&D sites (energy, water, waste, emissions, etc.)
- Reduce upstream CO2 emissions by focusing on circular economy (waste) and bio-sourcing
- Deployment of tools to assess the environmental and social impact of products
- Preparation of the CSRD (Corporate Sustainability Reporting Directive)

Our most important distinctions

91% of our sites are gold or platinum



More than 20 years of history



SEQENS is supported by SK Capital

alongside five principal strategic shareholders



SK Capital Partners is a private investment firm focused on the specialty materials, chemicals, and pharmaceutical sectors. The companies within its portfolio currently generate approximately \$11 billion in annual revenue and employ over 15,000 people worldwide.



ARDIAN

EXIMIUM



SEQENS CDMO offer

Focus on SEQENS' Pharmaceuticals Activities

Small Molecule Drug Substance

- Custom APIs
- Custom Intermediates (non-GMP & GMP)
- Regulatory Starting Materials
- Potent APIs & Intermediates
- Generic APIs

Polymers (catalog & custom) for Drug Delivery and Medical Devices

Key figures



700+
Clients



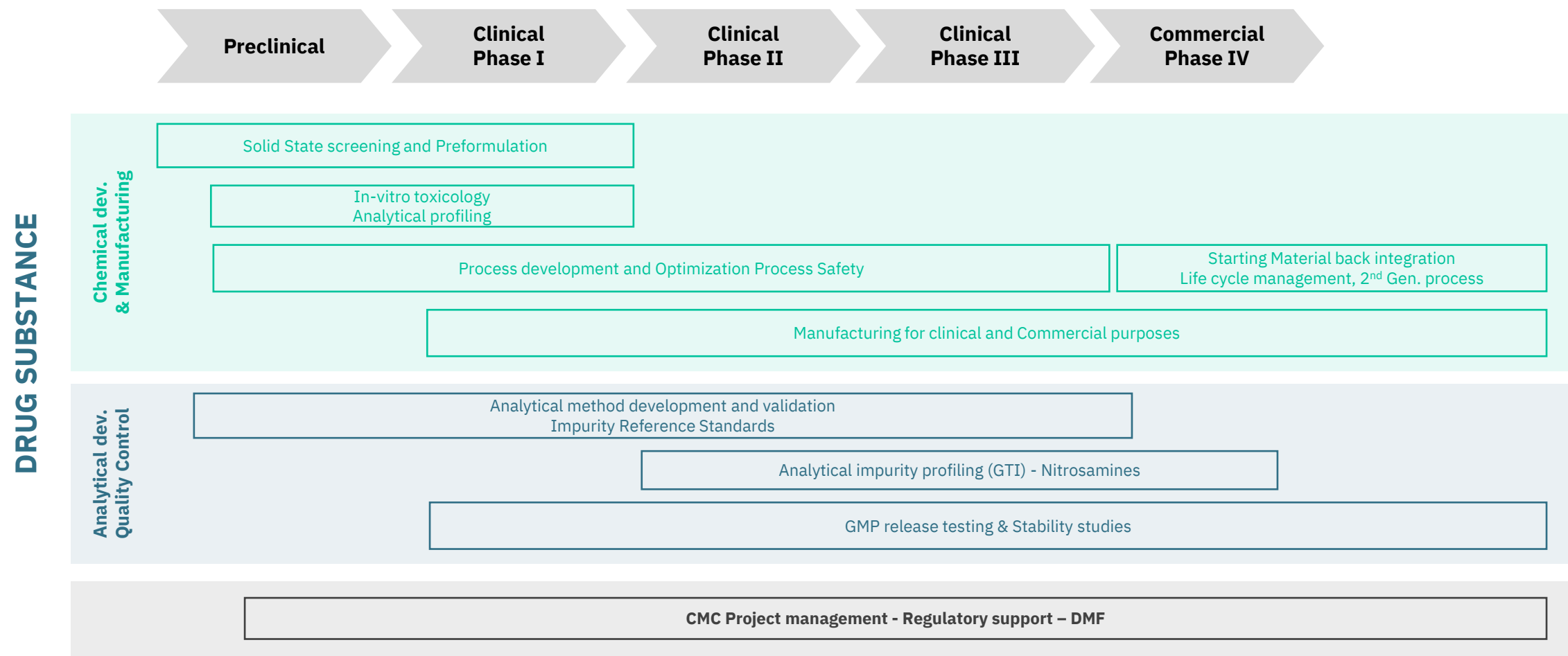
c.1700
Employees



6
Manufacturing Sites (4 cGMP sites)

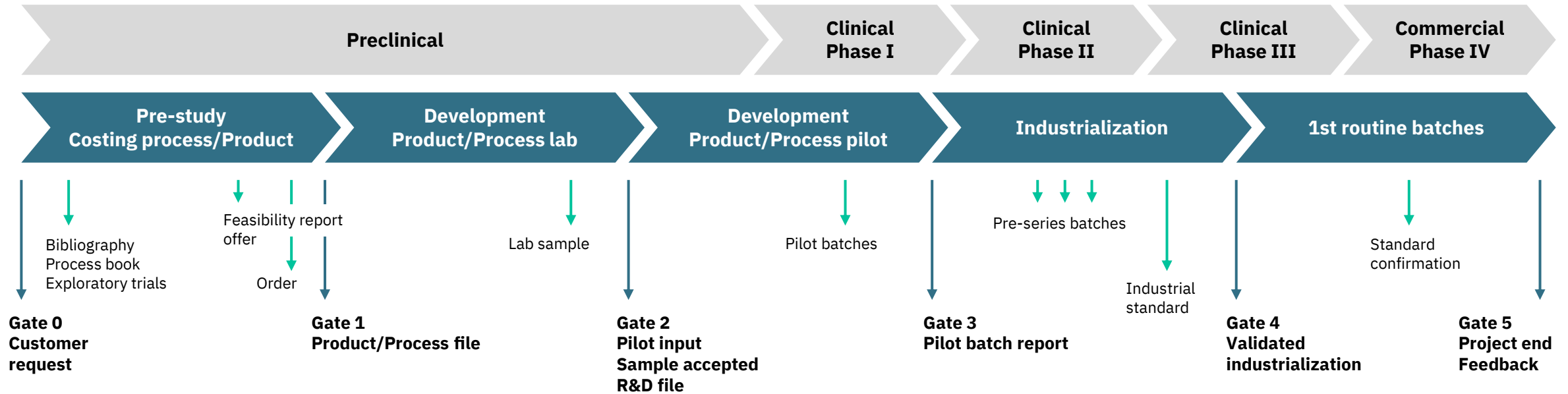
Drug Substance Contract Development and Manufacturing services

Full services to support new assets throughout clinical phases



SEQENS Stage Gate process

CMC Project manager assigned for all the development



- Mirror organization with our customers
- One single interlocutor
- Support throughout project life cycle
- Clear Communication and interactivity with technical teams
- Anticipation & risk management (right on time)

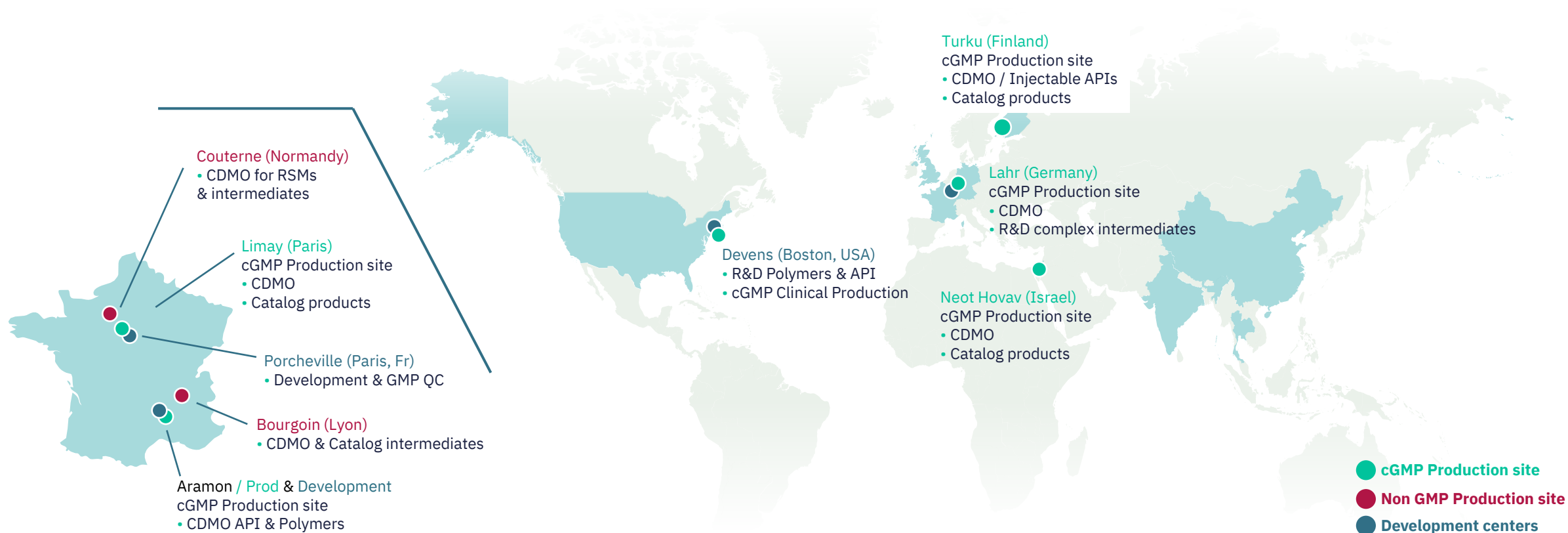
A global and flexible Drug Substance CDMO manufacturing network

in Europe & US Pharma intermediates and small molecules APIs

Several cGMP sites

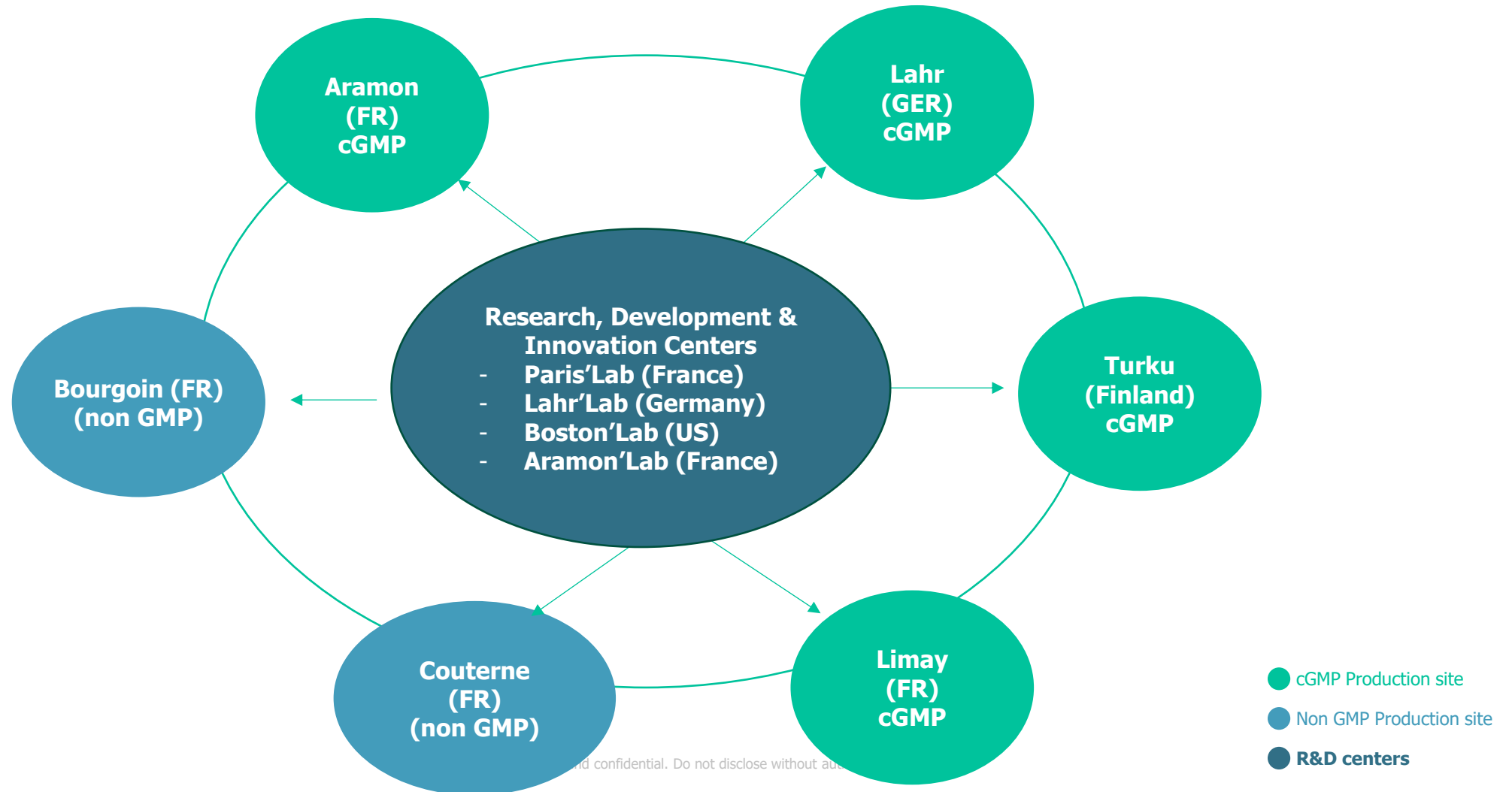
~ 1200 m³ reactor capacity

(o/w 700 m³ GMP)



Your Trusted CDMO Partner for Advanced, Scalable Pharmaceutical Manufacturing

- Robust infrastructure for API development, scale-up, and commercial production.
- Fully integrated network ensures efficient tech transfer, process continuity, and back-integration of intermediates and RSMs.



R&D – Integrated R&D network to support Innovation

Paris'Lab (France)

- ✓ **30 000 SQM** Science platform
- ✓ **140** Scientists (50% Ph.D.)
- ✓ **1** kilo lab

Small molecules, HTE, Flow chem, Solid state, Analytical platform including NMR, X-Ray & Genotoxic impurities, ICH stability chamber, ...



Boston'Lab (USA)

- ✓ **1 500** SQM R&D center
- ✓ **25** Scientists (>50% Ph.D.)
- ✓ **10** kilo labs
- ✓ **1** GMP Suite

Polymers, lipids & Small molecules, analytical platform incl. GPC-SEC, reology, LC-MS, ICH Stability chambers,...



Aramon'Lab (France)

- ✓ Commercial plant hosting R&D Labs
- ✓ **10** Scientists (50% Ph.D.)
- ✓ **2** kilo labs
- ✓ **1** GMP suite - ISO 7

Versatile polymerization equipment incl. Melt, hydrosoluble, ethylene oxide under high pressure and analytical characterization: 500 mHz NMR, GPC-MALS, Reology,...



Lahr'Lab (Germany)

- ✓ Commercial plant hosting R&D Labs
- ✓ **26** Scientists (>30% Ph.D.)
- ✓ **1** GMP kilo lab

Small molecules, analytical platform incl. LC-MS, Orbitrap, ICH Stability chambers,...



Detailed description of the offer of Development services

SOLID STATE & EARLY FORMULATION

Solid State / API Characterization

- Structural solid state analysis
- Physicochemical characterization, Solubility, Dissolution
- Biological characterization: Permeability
- DCS/BCS classification

API Form selection

- Polymorph, salt and co-crystal screening
- High Throughput Experimentation (HTE)

Particle engineering (size reduction)

Crystallization process development

Early Formulation

- Excipients compatibility
- Bioavailability enhancement, Controlled release
- Amorphous solid dispersion (Hot Melt Extrusion & Spray Drying), size reduction, lipid-based formulations, suspensions
- Polymers & Lipids used as excipients
- Early-phase forms delivery, stability & release testing
- Drug Product partnerships



Seqens
SOLID STATE &
EARLY FORMULATION

TOXICOLOGY (ADME TOX)

In silico Safety by design (QSAR)

In vitro Toxicology screening

Regulatory *in vitro* toxicology (GLP Formulation): genotoxicity

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SYNTHESIS & MANUFACTURE

Process Research (Route scouting)

Production of lab sample for *in vitro* testing

Non GMP tox batches

Process safety studies

Process development & optimization

- HTE – Big Kahuna – Unchained Labs
- Multi-step agile chemistry
- Quality By Design (QbD)
- Fermentation (USP/DSP)
- Multicatalysis (Bio-catalysis, photo-catalysis, metallo-catalysis, organo-catalysis)
- Flow chemistry
- Polymerization / Lipid chemistry
- Synthetic biology
- Purification (selective crystallization / chromatography, distillation)
- Particle engineering including size reduction

Early-stage Synthesis (GMP) – Drug Subst. First To Human batches

Manufacturing

- Kilo-lab
- Scale-up to commercial
- Starting Materials back integration
- Double sourcing
- 2nd Generation process development
- High Potent APIs



Seqens
POLYMERS



Seqens
MULTICAT



SeqensFAST
Continuous Process

ANALYTICAL SERVICES

Analytical methods

- Development
- QbD Development
- Validation

Impurity Reference Standards synthesis and Qualification

Analytical impurity profiling (GTI)

- Forced degradation studies
- Identification
- QSAR (*in silico*)
- Genotoxicity (*in vitro*)
- Quantification

Nitrosamines

- Risk assessment consulting
- Screening of positive Nitrosamines
- Quantification of Nitrosamines and Nitroso drug substance related impurities (NDSRI)
- Synthesis of NDSRI standards
- Ultra traces quantification of nitrites in excipients

Cleaning validation

- Method development
- Validation
- Swabbing recovery validation
- Testing

GMP Release testing (Raw materials, In-Process and Drug substance)

Stability studies

- Analysis
- Storage
- Forced degradation

Extractables and Leachables studies



Seqens
ANALYTICS

REGULATORY SERVICES

Consulting services for program management & Regulatory Affairs

Chemistry - A large range of capabilities and expertise

Industrial and Technology Capabilities (cGMP/non-GMP)

Batch reactions
520 m³ GMP capacity and 293 m³ pre-GMP
From -80 °C to + 250 °C
capacity typical batch; size 300 kg
5 R&D center with 20 m³ pilot capacity

Corrosive media and API handling
Hastelloy capacity (reactor, filtration, centrifugation & dryer) up to 2.5 m³ / 100 kg

High process window
High pressure autoclaves up to 90 bars and 230 °C
Total capacity of 18.5 m³ (2.5 m³ for general application, 16 m³ for H₂) up to 100 bars

Biocatalysis and fermentation
Catalogue Enzymes (>500) and microorganism (4500) collection
Fermentation capacity (up to 300 L)
Fermentation process development of small / long peptide and metabolites
Downstream processes up to pilot scale

Continuous processes
Si carbide plate (0.6l) and HC 276 coil (2.1l)
-20 to + 200 °C, up to 20 bars.
Capacity of 50t / year

Solid isolation / engineering
Horizontal & vertical centrifuges, pressure & vacuum filters, rotavapor
Hammer & Knife Milling, Sieving, Spray drying, Freeze drying, Jet milling
Total capacity 115 units (up to 300 kg)

Advanced Polymers and Lipids

GMP Custom Polymers & Lipids, Excipients
Pressure polymerizations (up to 4 bar)
Excipients for drug delivery
Medical Devices: Scaffolds for cell recolonization, implants, Biomaterials diagnostic

Special Equipment
Industrial Ion Exchange (Resin)
Reverse Osmosis
Industrial Flash Chromatography
Short path / Thin layer distillation (up to 20 theoretical steps)
Tangential flow Filtration
Freeze Drying

Quality APIs

Analytical impurity profiling, cleaning validation, nitrosamine, stability study.
GMP release testing (e.g. for Injection, inhalation, ophthalmic and oral use)

Highly potent APIs handling

Controlled room (ISO7) and OEB4 handling
Up to 20 m³ capacity, High level of automation

Special permits

Capabilities and permit to handle controlled substances (e.g. narcotics, psychotropic drugs etc.)

Synthetic Expertise

Specific processes
Heterocyclic reactions
Protected Amino Acid Derivatives
Polymerization reactions
Enantiopure Synthesis
Resolution, asymmetric synthesis (by organic or biochemistry)

Polymerization
Custom & Catalogue polymers
(e.g. Polyacrylates, Polyesters, Polyamide, Polysiloxanes, PEG (Ethylene oxide), PEKK, PEEK)

Gas reaction
Carboxylation (CO₂)
Carbonylation (CO)
Hydrogenation (H₂)
Ethylene oxide
Hydrogen chloride (HCl)
Chlorine (Cl₂)

Reduction processes
LiAlH₄
DIBAL-H
NaBH₄

High pressure high temperature reactions

Hydrogenation
Reductive amination
Carbonylation & Hydroformylation
Pressure Aminolysis

Hazardous Reactions

Cyanations (NaCN, TMSCN, NH₄SCN)
Diazotization
Phosphoryl chloride chemistry
Peroxide Handling
Deprotonation with NaH/LiH
Bromination with Br₂, Chlorination with Cl₂

Functionalization processes

Friedel Craft C-C (Aromatic alkenes/ketones, Alkyl, alkene)
C-N bond formation (quaternary amine salt, amide)
C-O bond formation (Etherification, epoxide)
(Trans)Esterification (fatty acid, polyglycol fatty acid, estolide, dialkyl carbonate)

Organometallic reactions

Grignard, Lithium, Zinc, copper chemistry
Cross coupling reaction (Suzuki, Borane, Heck, Sonogashira), Proprietary library catalyst

Chemistry - Advanced Polymers and Lipids Expertise



Drug Delivery

- Controlled-release
- API Solubility & Bioavailability Enhancer
- Therapeutic Polymers & Pro-drugs
- RNA/DNA delivery

GMP Custom Polymers & Custom Lipids
Catalog **Bioresorbable** Polymers: **Expansorb**



Medical Devices

- Biomaterials for Implants
- Scaffolds for cell recolonization
- Diagnostic medical devices

GMP or non-GMP Custom Polymers & Custom Lipids
Catalog **Bioresorbable** Polymers: **Expansorb**
Catalog **Implantable** Polymers: **IMPEKK**

Polymers

Type of Polymerizations	Ring opening polymerizations <i>(including Melt ROP)</i>			Radical Polymerizations (controlled and uncontrolled)	Polycondensation
Compositions & Post treatments	Chemical synthesis			Polymer post-treatments	
	Block copolymer	Graft Polymerization	Gradient Copolymers	GMP Filtration/ Purification / Drying	

Lipids

Type of Lipids	Ionizable Lipids	Cationic Lipids	Neutral Lipids	Pegylated Lipids	Lipid Intermediates
Purification	Flash Chromatography	Hight Pressure Chromatography	Solvent Evaporation	Crystallization and Drying	Salt Screening

Characterization for In process controls and/or Release testing

- NMR 500 Mhz
- Spectroscopy: NIR, FTIR, UV-VIS
- Thermal analysis : DSC, TGA
- Particle size: Laser light diffraction, Dynamic light scattering
- Viscosimetry
- Rheology
- Liquid, Gaz and Ion chromatography: RID, ELSD, UV-VIS, CAD, MS, HRMS, FID, MS
- Size Exclusion Chromatography: MALS, MALS/RALS, RI, UV

Analytical techniques: available for non-GMP testing and GMP QC

HPLC / UPLC	GPC / SEC	Spectroscopy	Physical characterization
Ultraviolet (UV) Refractive Index (RI) Photodiode Array (PDA) Conductivity Detector (CD) Evaporative Light Scattering (ELSD) Charged Aerosol (CAD) Mass Single and Triple Quad Mass QTOF Mass Orbitrap	Injectors: Head-Space Injector Split/Splitless Liquid Injector Split/Splitless Liquid Injector (PTV) Detectors: Katharometer (TCD) Flame Ionization (FID) MALS / RALS Mass Single & Triple Quads (Electronic Impact & Chemical Ionization) Orbitrap	NMR 400 MHz NMR 500 MHz FTIR UV/VIS Fluorimetric (FLD)	XRPD Empyrean LDPSD Mastersizer 3000 Air Jet Siever DLS Zetasizer Pro Red Morpho-Analyzer Light Microscopy Raman Microscopy Scanning Electron Microscopy Hot Stage Microscopy Specific Surface Area (BET) Dynamic Vapor Sorption DSC TGA Flash Point Melting Point Mettler Polarimeter Refractometer (Liquid & Powder) Densimeter Turbidimeter Osmometer Rotational Viscometers Rheometer
Waters / Agilent / Shimadzu / Thermo-Dionex / Merck-Hitachi	Agilent / Shimadzu / Perkin-Elmer	Bruker / Perkin-Elmer / Agilent	Malvern-Panalytical / Hosakawa Alpine / Mettler / TA Instrument

A broad range of RA capabilities to add value for new and existing customers

- Extensive expertise in CMC dossier preparation and addressing inquiries from global health authorities
- API, Excipients and Intermediates
- DMF preparation and filing across multi countries
- Effective cross-functional coordination
- Dedicated Regulatory Affairs Contact by project
- Early-stage technical involvement to establish key parameters



20 YEARS expertise of RA Management Team (PhD and PharmD)



10 PEOPLE team of highly trained regulatory experts



500+ Active DMF in 75 Countries
US: 94 - Europe: 91 - Canada: 40 - Japan: 30
Proven DMF filing track records in China, Korea, Brazil

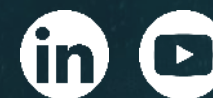


100% of successful registrations

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THANK YOU



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