ACTIVE PHARMACEUTICAL INGREDIENTS | API | CDMO | CHEMISTRY
HPAPI | BIOTECHNOLOGY | END TO END SERVICE

Olon Group is a global leader in the development and production of active pharmaceutical ingredients (APIs) for CDMO and generic markets, integrating chemical synthesis and biological processes while always embracing the highest international safety, quality, and environmental standards.

With one of the longest track records of the API industry, having deep development expertise and a broad set of advanced technologies, we are the partner of choice which enables our client's molecules to enter the market successfully.

Olon has a global network of **11 manufacturing sites and 7 R&D centers across the globe**. Thanks to our **2,300 employees, including 300 highly experienced and qualified R&D experts, we represent a highly innovative and reliable partner**.

At Olon, expertise and competent flexibility throughout the organization help build successful outcomes for our clients in custom chemical synthesis and microbial fermentation, while always maintaining the highest levels of safety, quality, and environmental compliance.

Olon Group

Footprint

11 facilities spanning over 3 continents, with strong capabilities in both chemical synthesis and microbial fermentation

Headquarter
Rodano (Italy)

11 facilities
9 EU + 1 US + 1 IN

Offices
Olon USA
Olon Mumbai India
Trading: Infa GmbH, P&R Shanghai

Investments

impresa champion 2023 | italy post

Innovation drives our business model.

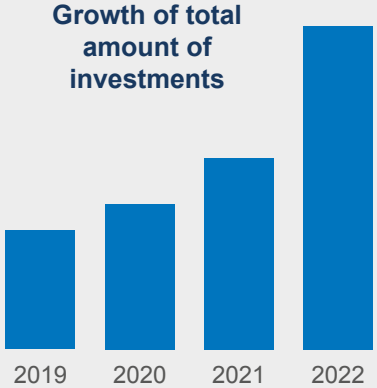
We've launched "**Innovation Initiatives**" to constantly develop technological platforms: a long-term programme in which the Group has invested substantial human and economic resources, in order **to explore new technologies or new applications for existing technologies**.

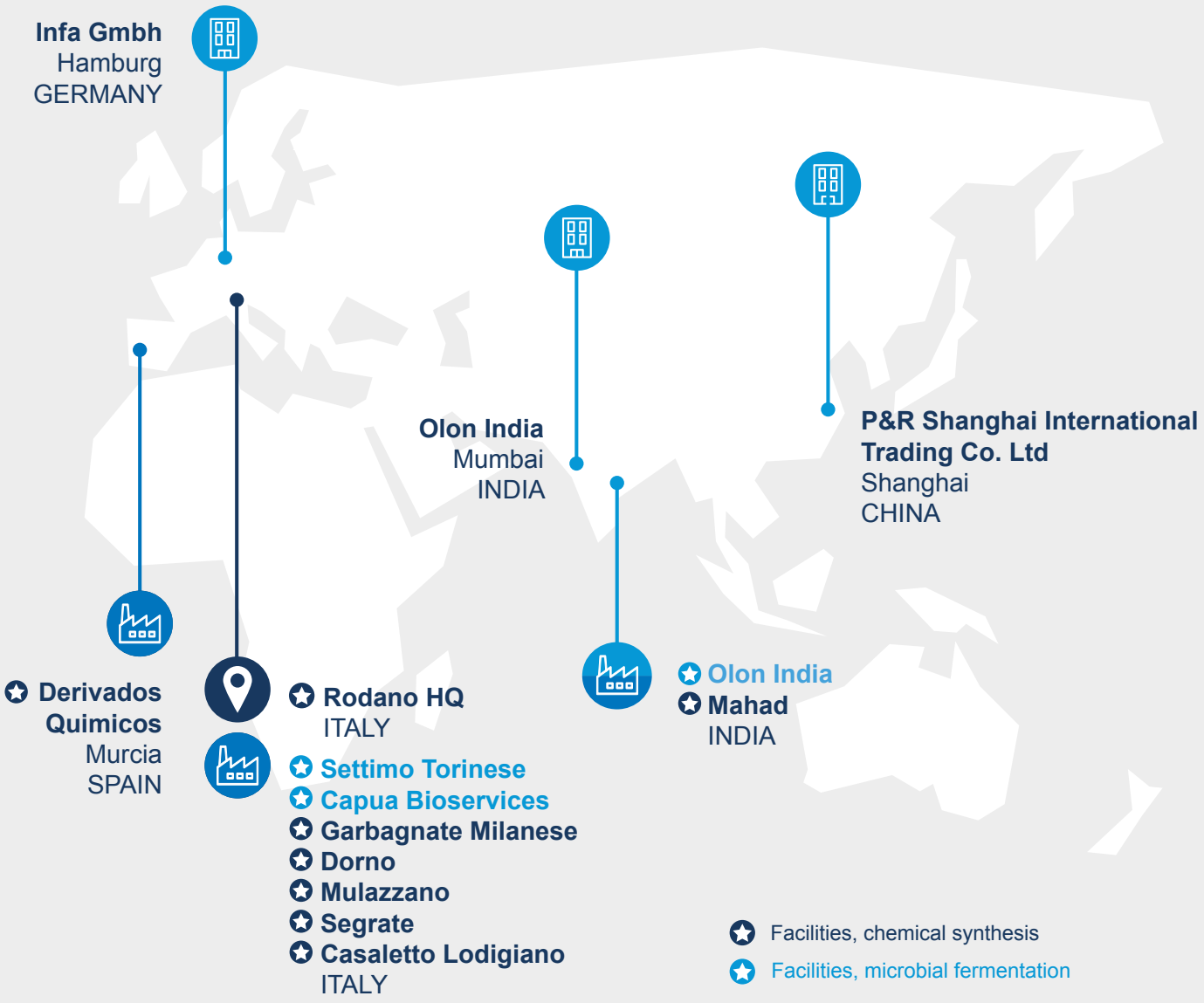
The **aim is to facilitate the production** of new pharmaceuticals **and improve the quality and sustainability** of the manufacturing process for those which we already produce.

We are **working on the cutting edge of R&D** both in terms of chemistry with flow chemistry, photochemistry and electrochemistry and in terms of biotechnologies.

+160%

Growth of total amount of investments





Olon at a glance

2.300 employees

300 highly experienced and qualified people in R&D team

610 Mio USD revenues (2021)

2.500 m³ reaction capacity

4.900 m³ fermentation capacity

300 APIs

11 Facilities

5 global offices

450 DMFs

Partnership with customer from R&D lab up to commercial manufacturing

Our level of manufacturing capacity, **custom on your needs and objectives**.

GMP

- IP
- Dossier
- Product Characterization
- Regulatory Strategy
- Documentation
- Filing
- Launch/Marketing
- Supply

0.1 – 1 kg
R&D
kiloLab

10 – 100 kg
Pilot plants

- Flexibility of batch size
- Responsiveness in adjusting process and technology
- Best validation timing

1 – 100 MT
Industrial production

Capabilities & Expertise

- R&D platforms, development and optimization of new processes
- Corporate Engineering
  - Wide expertise of construction of new production plant from green field
- Regulatory Affairs
- Safety studies
- Scale-up
- Analytical method development/transfer/validation
- Process validation

Next level technology

Combine well established and novel practices for **efficient and successful manufacturing**, ensuring **safe**, **fast and cost effective commercial process**.

Technologies

One of the widest range of leading-edge technologies chemistry and biotechnology expertise.

- High Potent Compound handling capabilities
- Filter driers, isolators and high-tech segregated areas
- Photochemical conversions
- Chromatographic purification
- High pressure hydrogenations
- Cryogenic reactions, Hydrogenation also for acidic substances, Fluorination
- Distillation column
- Biocatalytic transformation
- Controlled substances as psychotropic, lysergic acid intermediate
- Micronization
- Biotechnology expertise Gene Synthesis, Protein Expression & Production, Recombinant Peptides

Hazardous Chemistry

- Hydride Chemistry (Lithium Alluminium hydride and Borane complex up to hundreds of kg of active)
- Cyanation (hundreds of kgs of cyanide/batch)
- Fluorination with either Electrophilic or Nucleophilic fluorinating agent (not F_2)
- Large scale oxidations even in organic solvents (e.g.H_2O_2, HClO, Peracetic acid…)
- Bromination (up to 1,500 kg/batch)
- Carbonylation
- Organometallic reagent such as Lithium Reagents (up to hundreds of kg of active)
- Reaction with Sodium metal (up to 150 kg per production batch)
- Hydrazine/Hydroxylamine

Analytical capabilities

Our level of manufacturing capacity, customized on your needs and objectives.
We are one of the few able to implement in house Nitrosamine analysis.

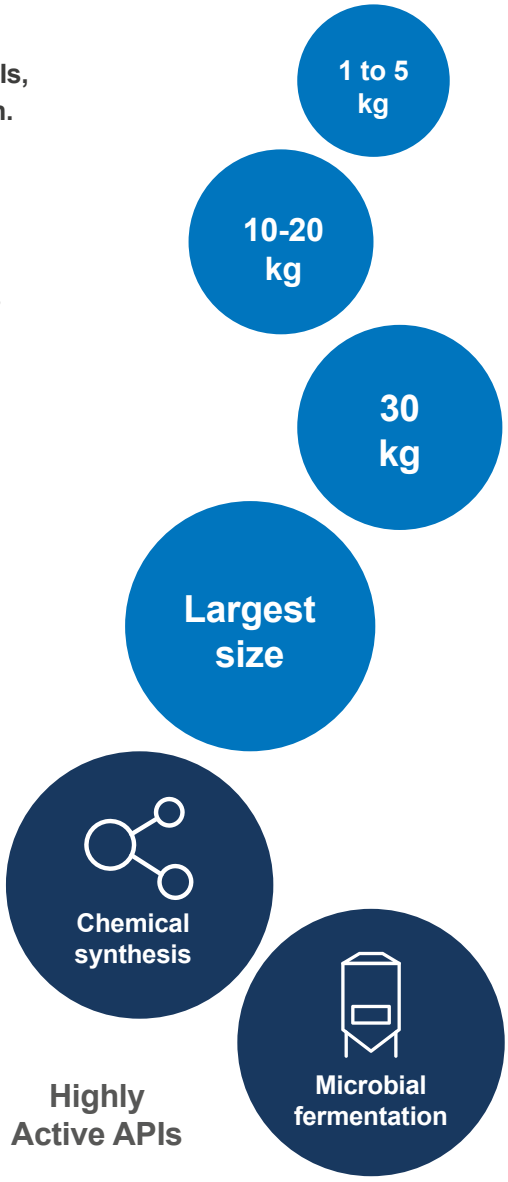
- **Atomic Spectroscopy**
- **UPLCs, HPLCs, prep-HPLCs, GC**
- **LC/MS, GC/MS**
- **NMR**
- **Molecular Spectroscopy**
- **Thermal Analysis**
- **X-ray**
- **Physical Testing**
  Particle size, microscopy, osmometry, dissolution, hygroscopicity, viscosity, surface tension
- **Isolation**
  Semai-prep chromatography
- **Stability**
  Reach-in and walk-in sized stability chambers, forced degradation, photostability

High containment production integrated plantform

We are building one of the most advanced and reliable HPAPI platform based on our unique expertise of the industry

Olon offers the capacity to develop and produce highly potent APIs, from very small to large scale, along the entire development chain.

We are rolling out a massive investment plan to expand internal expertise and capacity of high containment production. The Group offers **one of the most flexible and solid platforms in the global market, for the development and production of highly potent APIs and highly toxic intermediates**, with the capacity to develop and produce from very small to large scale, along the entire development chain. **It supports the customer at every stage of drug development**and during commercialization, which can range from a few grams to hundreds of kg per year.



Seamless service, highest expertise

We have developed a flexible manufacturing platform that supports the customer at every stage of drug development and also during commercialization, meeting API production needs, which can range from a few kg to hundreds of kg per year, depending on the disease.

“Innovation Initiatives” is a long-term vision that drives Company’s growth. A strategy of investments in processes, capabilities, and state-of-the-art technologies to offer one of the most complete and reliable end-to-end integrated developing and manufacturing platforms globally.

Olon, which in the past five years alone has more than doubled growth in strategic investments, is developing capabilities and expertise that make it **the partner of choice for pharmaceutical companies, owing to the support it is able to provide throughout all stages of the development process**. **This includes for new generation molecules, which are the focus of much of the research and development of the global pharmaceutical market**.

The general trend has been to steer the development of new therapies towards increasingly selective, and therefore increasingly potent, molecules, with the possibility of extending to all therapeutic areas and to oncology. Target therapies, i.e. drugs that are selective and therefore better tolerated by the patient, have an action that targets only the mechanism underlying development of the disease.

They are finding increasingly broad application in treating the world’s most widespread oncological diseases (primarily breast cancer), but also rheumatic and respiratory diseases and other major therapeutic categories with unmet needs. Improvements in treatment selectivity result in a demand for increasingly potent active pharmaceutical ingredients. To be produced, **these ingredients require highly specific technologies, systems and skills to meet the standard of containment procedures that can guarantee to our customers to avoid the contamination of operators and products**.

A new extremely high containment production line, OEB5, with reactors that allow us to produce highly potent APIs in large-scale product batches ranging from 30 to 150 kg. It enables us to serve the customer along all the stages of the scale up, in integration with our global sites. Starting with a few grams or macrolab in the GMP laboratory, we move on to batches of 1 or 2 kg, then several tens of kilograms, followed by the 30 to 150 kg range which we can produce with the new line, until reaching the largest quantities.

We are one of the few API suppliers to offer the range of specific integrated capabilities necessary to support the customer from the first clinical phase up to industrialization, regardless of the quantity of product needed and batch size required and regardless of the ongoing molecule development phase. From a few grams to hundreds of kilograms. **The expertise in high containment processes** is evident from the equipment we have at our disposal, but **even more so from the in-house know-how that we have developed in recent decades, among the most extensive in the global API manufacturing market**.

Recently we've kicked off the project to install a new high-containment production line in Olon India (Mahad) site, with advanced systems for containing and handling substances up to level OEB4 (up to 1µg/m3). The new lines will be suitable for producing medium-volume batches and will be able to respond to market requests flexibly, particularly in the CDMO field as well as for producing proprietary products.

We are one of the leading experts in highly potent APIs, whether cytotoxic or other kind of pharmacological action, in terms of full management of all aspects surrounding the plant: operator protection and training, policies and procedure, waste disposal and management of related issues. **Our knowledge in this area goes back a long way**: in the 1970s, our plants in Rodano and Settimo Torinese were two of the first sites worldwide to operate in containment, for the production of the first cytotoxic anticancer products on the market. Since then, Olon has continued to invest in the corporate culture of high containment and today it makes it available to its Partners.

Multiple integration

amoung global manufacturing network

- Integration along the development process and industrializatio (batch size scale up)
- Back integration along the supply chain (intermediates and finished API)
- Seamless integration among the lines of our sites aronud the world (US, Europe, India)

Olon Ricerca Bioscience
1,5 Mio of INVESTMENT
Development Process
Small Production

Rodano
16 Mio of INVESTMENT
Development Process up to Production
Small up to Massive Production

Mahad
0,5 Mio of INVESTMENT
Production Process
Small up to Massive Production

Small Production	Up To Oeb5*	Medium Production	Up To Oeb5	Massive Production	Up To Oeb5

(*Under Construction Oeb6)

Our operation model

Our strategy is to offer an extremely **high level of containment all along the API supply chain**, from R&D through development and launch all the way to sales.

We adhere to the principle of continuous process improvement.

We invest in the very latest, advanced facilities to guarantee product and operator containment, generating an improvement in the overall quality of the company and in the capacity to handle high-potency APIs.

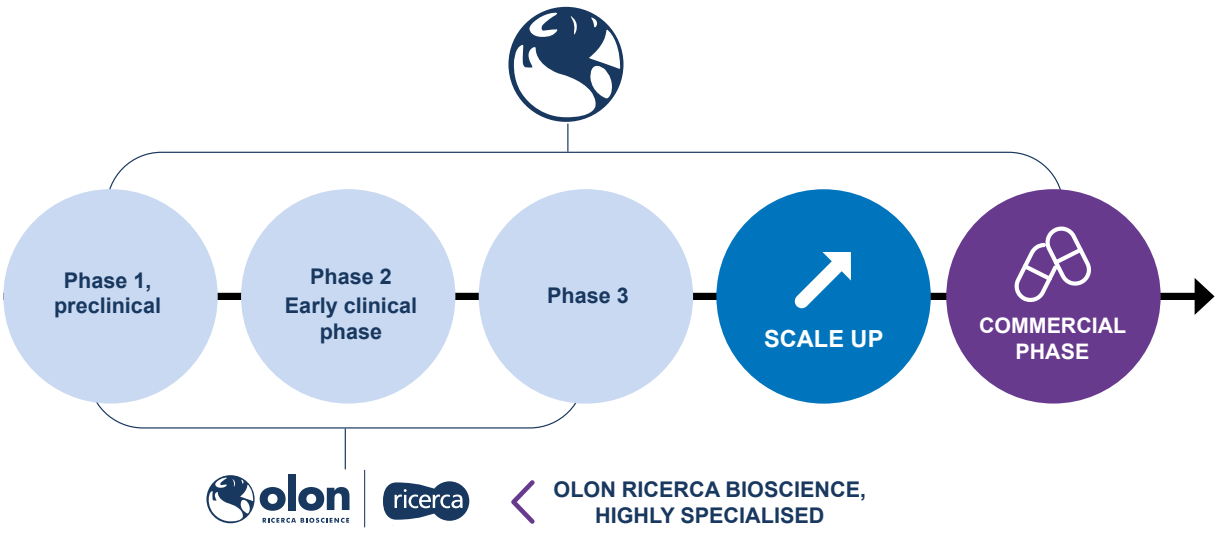
Our operation model

High-level expertise and know-how applied to specific processes, consolidated in the 11 Olon plants worldwide and 7 research centres, are connected, shared and extensively applied across the whole of the group's manufacturing network.

We provide multidisciplinary teams to work on our customers' projects in the areas of research and development, regulatory affairs and corporate engineering.

Seamless transition of the technology and scale-up.

Advanced control and in-depth understanding of out customers' processes from the outset, engaging the best in-house talent specialised in the specific process or technology, relocated to all the sites of the Group.



Global Regulatory Affairs
Dedicated end to end service

An i**ncreasing number of marketing authorization and clinical trial application** for drug obtain designations to accelerated and priority reviews. The need to streamline the pathway from development to commercialization path for these drug products has recently become of utmost importance.

So, for innovative pharmaceutical companies having API eligible to this **fast-track authorization procedure, it is getting more and more crucial for competitiveness** to identify an API supplier able to offer a smooth and quick regulatory process.

Olon Regulatory Affairs Department is a major asset of Olon Group and has seen significant development and diversification of its expertise in terms of regulatory frameworks and requirements of different geographic areas, including the most complex and demanding ones.

We hold in-depth knowledge of the worldwide regulatory processes, including Countries as China, Brazil and Japan ─ expertise gained from decades of consolidated, hands-on experience.

Our drivers are strategic consultancy, transparency, and **continuous feedback to our customers** for both generic and CDMO projects.

Olon **RA team comprises 35 highly qualified professionals** in Europe and Asia.

With as many as

300 APIs (large and small molecules)

500 DRUG MASTER FILES

80 CERTIFICATES OF SUSTAINABILITY

successfully submitted worldwide in support of our customers' marketing authorizations and clinical trials, with its diverse, in-depth knowledge of international regulatory frameworks, **Olon regulatory affairs service represents an excellence in the API industry.**

To reduce approval time, we work on some key factors such as the quality of regulatory documents. Based on our strong experience with several hundred APIs worldwide, we can reduce any possible negative impact on approval time.

The preparation of the CMC part (Module 3, Drug Substance and Drug Product) of the regulatory submissions is often a challenging step, particularly if your filing strategy takes you through the requirements of different Countries.

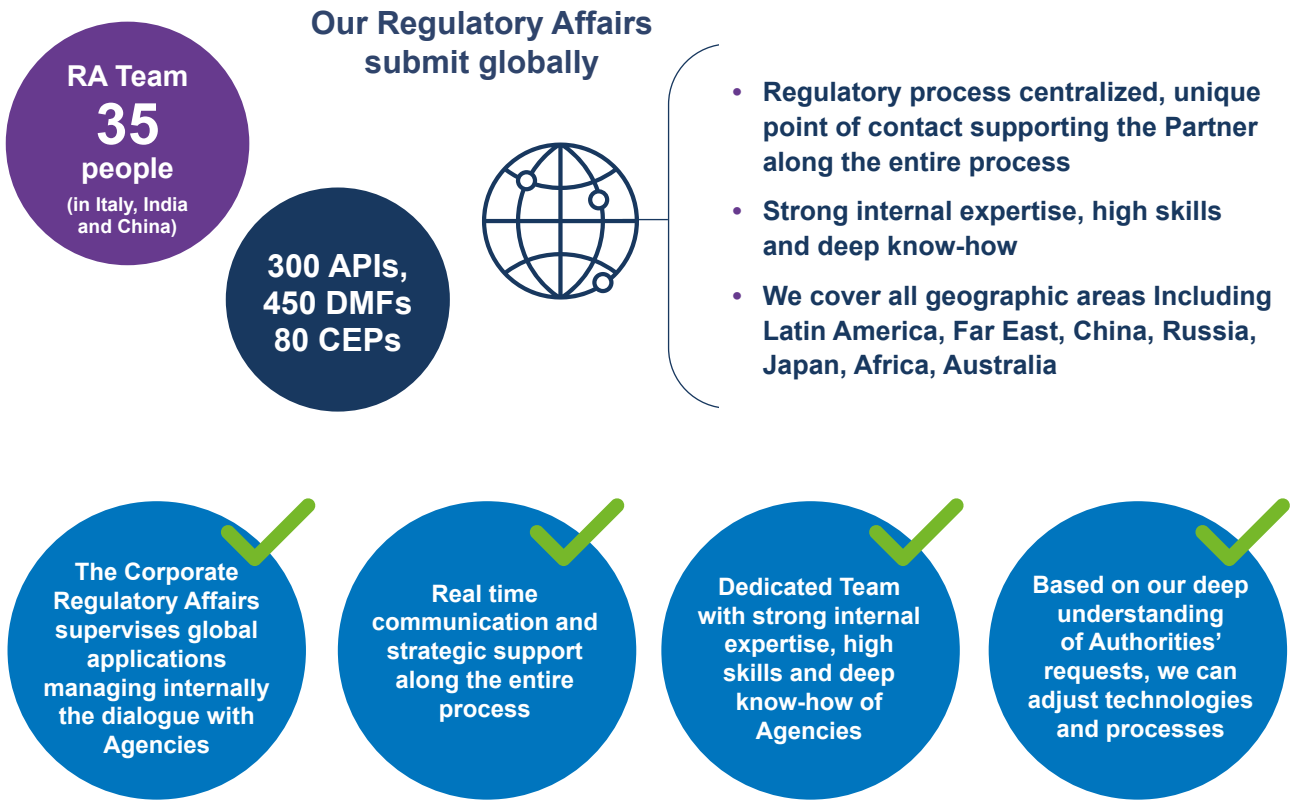
Our goal is to prepare **quickly and efficiently high-quality CMC** (Module 3, Drug Substance and Drug Product) **documents** for smooth filing, Health Authorities assessment and approval of our customers' marketing authorization and clinical trial applications.

Complexity management, speed, and flexibility: the key features that translates into reduced time to market and reduced costs for our clients.

With our in-house experience and expertise, we manage the entire regulatory process without outsourcing any stage of the service, including interactions with international regulatory authorities. We have utmost control and focus on the regulatory strategy according to our client's needs.

With a **deep knowledge of the worldwide regulatory requirements, we can fully support you** before, during, and after the planning, submission, and post-approval process, with proposals for **rapid solutions to meet the most complex challenges**.

We can reduce the risk of the request of CMC further information during the HA assessment giving a fundamental contribution to a cost-effective and sustainable regulatory process.



Quality

We are **constantly inspected** by the Regulatory bodies of all the Countries where we market our products.

Olon sites are inspected on regular basis **by the local Regulatory Agency, AIFA**.

Since November 1, 2017 the EU-FDA mutual recognition agreement (MRA) of GMP inspections, including Italy, has come into force: the MRA allows drug inspectors to rely upon information from drug inspections conducted within each other's borders.

FDA will continue to perform some inspections in foreign countries but FDA expects to perform fewer routine surveillance inspetions in countries like Italy, having a capable inspectorate.

- **Rodano**
- **Settimo Torinese**
- **Garbagnate Milanese**
- **Mulazzano**
- **Dorno**
- **Segrate**
- **Casaletto Lodigiano**
- **Capua Bioservices**
- **Derivados Quimicos**
- **Olon Ricerca Bioscience**
- **Olon API India**

Olon India
Mumbai
INDIA

P&R Shanghai International Trading Co. Ltd
Shanghai
CHINA

A safe partner

Olon offices based China and India count on a **local expertise and know how** to better control and supervise the supply chain through:

- **Regulatory audits**
- **Reliable supplier identification**
- **Continuous direct market monitoring**

Generic API supplier

With o**ne of the broadest track records of the industry, Olon portfolio is highly differentiated** and includes, among others, products produced by microbial fermentation, HPAPI, controlled substances, retinoic API.

Olon is a **leading international Generic API supplier**. We have in place a global business model that allows us to be a competitive and cost-effective API supplier to the Generics industry. We manufacture products via chemical as well as biological synthesis, relying on extended **internal technical expertise** while meeting the **highest standards of quality and reliability**. We have carried on since time a business continuity program to diversify our sources for all our key raw materials and reinforce the risk mitigation plan. Additionally, Olon's **facility footprint is truly global**, with bases in the United States, Europe, China, and India. This ultimately means that if there is a localized disruption in one area, operations can continue.

With a portfolio of 300 products including CDMO and Generic APIs, we offer one of the most extensive track records in the industry and we manage more than 500 Drug Master Files

Being an early adopter of the **most advanced technology and processes**, and handling the broadest range of analytical capabilities, we represent a partner enhancing competitiveness and time to market

Olon has diversified and backed investments across several lines and multiple facilities to be able to **manage various high-containment molecules at different scales** and guarantee flexibility on a significant scale.

Our pipeline of Generic APIs is reinforced in the **oncology area**, where we have solid expertise as one of the sector's top companies producing high-activity active substances, with the introduction of numerous oncology APIs, particularly those with selective high activity.

One of the widest track records in FIRST TO FILE in US MARKET and EARLY ENTERING in GLOBAL MARKETS

EARLY ADOPTER
of most advanced manufacturing technologies

EARLY PRODUCT LAUNCH
implementing Intellectual Property & Regulatory Affairs succesfull strategies

COMPETITIVENESS AND BEST TIME to enter in the market

FLEXIBILITY
to adapt multipurpose lines

SCALING UP
from small to largest volumes

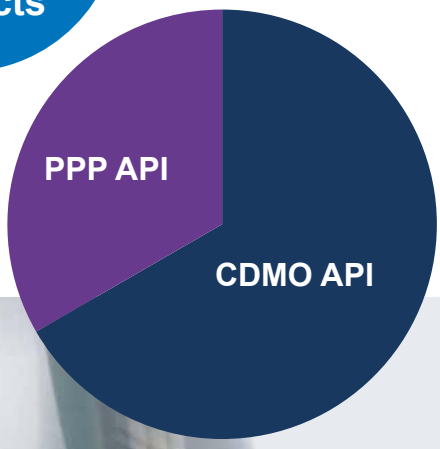
FOCUSED ON FLEXIBILITY AND SCALING UP

We use HIGHLY COMPLEX CHEMISTRY and BIOTECHNOLOGY, relying on broadest technical expertise

- One of the most extensive track record
- Highest quality standard
- Competitiveness and best time to market
- Early adopter of most advanced manufacturing technologies

One of the most extensive track record
300
products

Olon portfolio



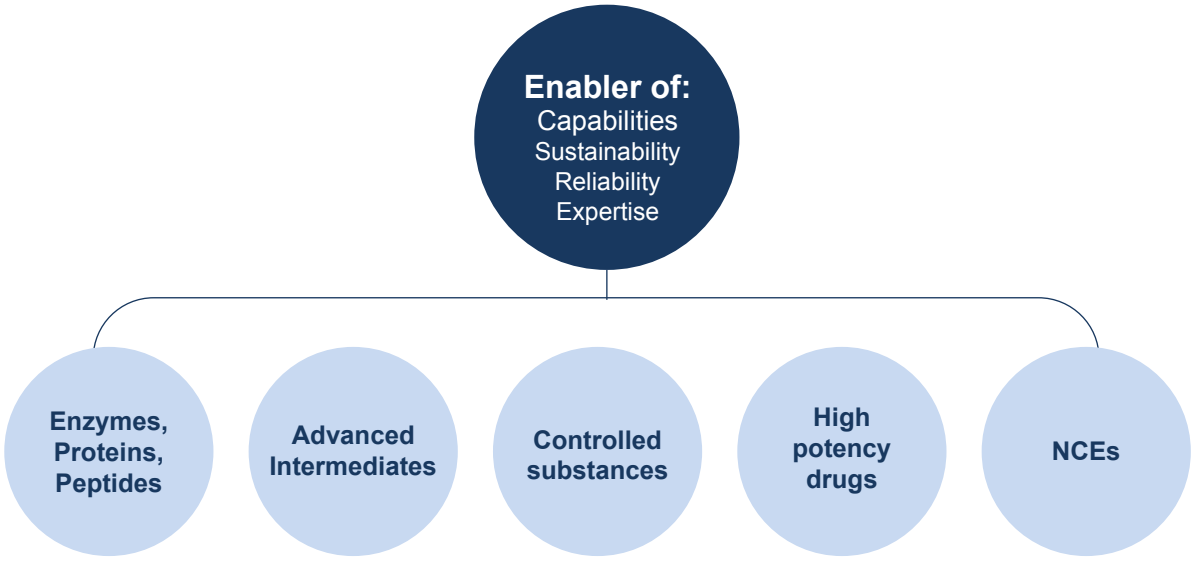
Custom Development and Manufacturing

2023 CDMO Leadership Awards

Through chemical synthesis, microbial biomanufacturing or a semi-synthesis approach, we offer, under GMP, **dedicated solutions** for the development and manufacturing of NCEs, advanced intermediates, building blocks, enzymes & proteins, peptides of rDNA origin and high potency drugs.

We guarantee customer support **from the R&D lab up to full-scale commercial manufacturing** and strong regulatory support. Our experience and global footprint allow us to follow the entire process in house, with a single point of contact for the customer and complete accountability.

During product development and technology transfer, **our partners are supported by a dedicated team**; it is made up of a **project management accountable**, which plans and tracks all activities, resolves any conflict of resources, solves critical issues, and communicates news and updates, and a **technical team**, which provides regular updates on the project status (Reports – TCs), communicates directly with the customer for technical topics, and supports the regulatory strategy.



Olon CDMO expertise, facts and figures

OLON BIOTECH

more than
30
ongoing projects

OLON SYNTHESIS

25
ongoing projects
1 UP TO 7 CHEMICAL STEPS
(API and intermediates)

OLON RICERCA BIOSCIENCE

11
API projects

One dedicated team

Project Manager
Planning and tracking all the activities, resolution of any conflict of resources, problem solving of criticalities, communication with the customer

Technical Team
Regular updates on project status (Reports – TCs), customer direct communication for technical topics

Olon Biotech

Olon is a global partner of CDMO services in the field of microbial fermentation.

We are an **industry leader** in applied biotechnology to industrialization and commercialization, **able to manage the strong complexity** implied in the tech transfer and in the scale up of biotech process.

Endorsed by a strong experience in developing the production process from pilot to commercial scale, our experience in fermentation embraces managing broad range of microorganisms as bacteria, yeast and fungi. We offer a strong expertise from small molecules to large molecules – peptides, enzymes, proteins and rely on a highly skilled team of operators. **Olon expertise gained over more than 50 years**, represents one of the most extensive know how of microbial fermentation in Europe.

We have **two Biotech Centers**, based in Settimo Torinese and Capua (Italy) that represent centers of **excellence in the microbial fermentation field**, meeting the **highest global quality standard**. Our Biotech Centers are multipurpose and able to manage the highest complexity; they are endowed with a unique flexibility and diverse capabilities thanks to the competencies gained by applying different manufacturing processes to different product and reach a total fermentation capacity of 4.900 m^3.

Olon is also developing **one of the market's most innovative technological platforms**, capable of offering high-quality peptides. We are one **of the few companies able to integrate expertise in the two areas of chemistry and biotechnology**, in both of which we have extensive experience, to offer seamless platforms combining two processes meeting the needs of our Partner.

ESG

We are constantly committed to **reduce the impact on the environment** where we operate and to promote a more sustainable API manufacturing approach.

We have very aspiring targets to **reduce consumption of water and energy**, to decrease wastes and carbon dioxide emission.

We **promote diversity&inclusion** and **people development**.

We conduct business with **ethical approach** and **we act with integrity**.

BRONZE 2022 ecovadis Sustainability Rating

ENVIRONMENTAL TARGETS

WATER
Target: 2025 vs 2018
-35%

CARBON DIOXIDE
Target: 2025 vs 2018
-33%

ENERGY
Target: 2025 vs 2018
-25%
(Specific per ton of product)

WASTE
Target: 2025 vs 2018
-40%

Sustainable Production

- **Continuous manufacturing processes**
- **Photochemistry, electrochemistry**
- **Biocatalysis**
- **Microbial fermentation**

Social Responsibility

- **Partnerships supporting the communities** where our sites are based
- **Public-private partnership** involving the African state's own government, aimed at **helping the local population suffering from sickle cell disease**

Supply Chain

- **Code of conduct and a declaration of sustainability requirements** that we submit to suppliers and business partners with which we collaborate globally

People

- **Initiatives and Programs for People development**
- **Diversity&Inclusion** – eg STEAMiamoci in partnership with Assolombarda
- Great attention to safety, with goal of **zero accidents**

Facilities

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FACILITIES

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Phone: +39 02 994421

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