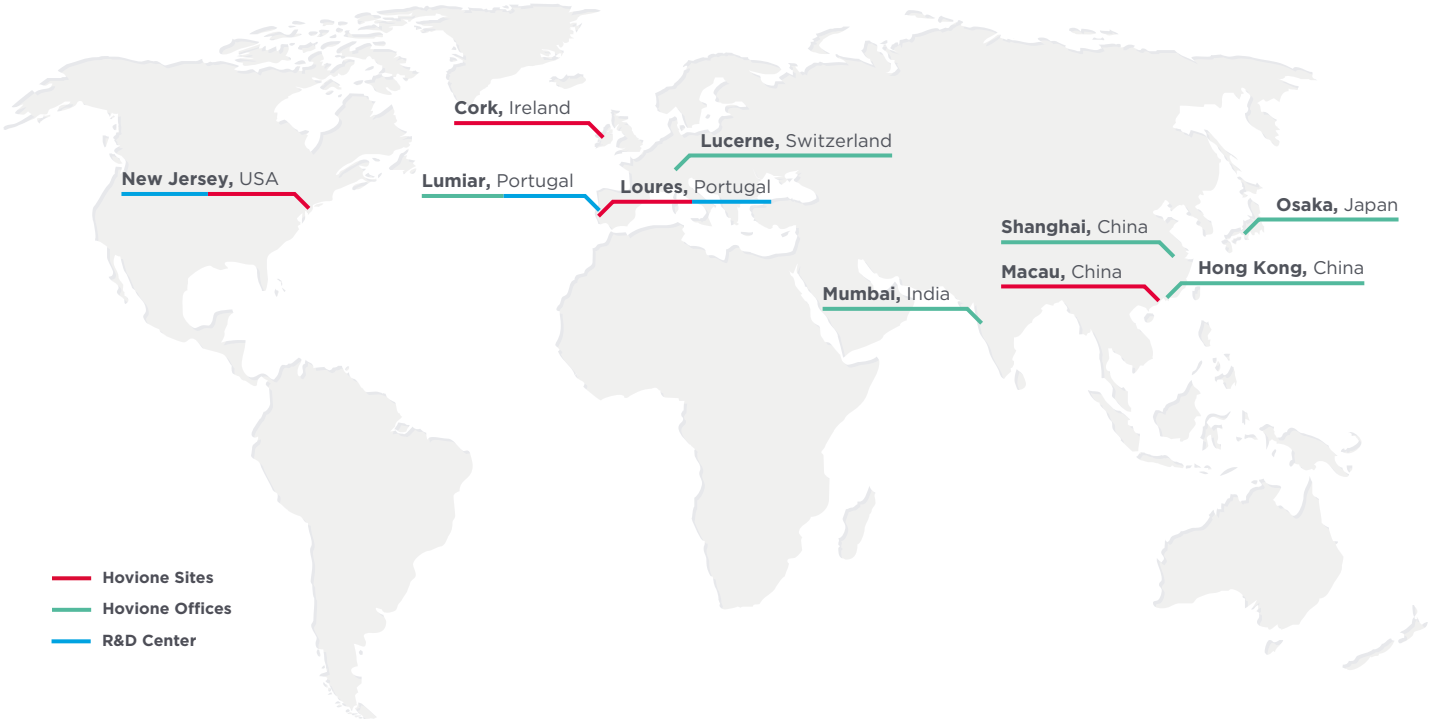
Drug substance contract manufacturing services

Hovione

In it for life

Extensive Manufacturing Capacity



Hovione Drug Substance manufacturing capacity spans over four FDA-inspected sites on three continents.

With over 1 000 m^3 of vessel capacity, we have the flexibility to accommodate our customers' products, whether they are low volume orphan drugs or the next large volume blockbusters:

- Hovione Cork, Ireland
- Hovione Loures, Portugal
- Hovione Macau, China
- Hovione New Jersey, USA

Expertise in key areas

Based on our experience in drug substance development and manufacturing, Hovione handles most types of chemistry with flair and has developed unmatched expertise and physical assets in some key areas such as Cryogenics, Hydrogenations and Fluorination. We also have been investing in capacity to handle highly potent compounds down to below 1.0 µg/m^3 OEL.

Cryogenics

Hovione has an abundance of experience and assets to carry out reactions at low temperatures in a GMP environment from process development to commercialization. All manufacturing sites have the capability to run reactions at temperatures as low as -150ºC, even in our largest 10 000 liter vessels.

Hydrogenations

Hovione has vast capabilities in developing hydrogenation processes using both heterogeneous and homogeneous catalysis and performs these reactions up to large commercial scale (100's MT per annum). Extensive capacity is available with vessels up to 6 000 liters and pressure ratings from 10 to 25 bar.

HPAPI

Hovione sites in Loures and New Jersey have drug substance manufacturing capacity to handle highly potent APIs down to 1.0 µg/m^3 OEL. At both sites, spray drying of highly potent compounds is also available. This combination is unique in the industry and offers our customers the ability to synthesize an HPAPI and seamlessly convert it to a spray-dried dispersion - all at the same site.

Environment for Pharmaceutical Companies

Hovione‘s clients are now routinely faced with the challenge of quickly scaling a technically exacting synthesis against a demanding timeline, while complying with ever more stringent regulatory requirements.

This is especially true in light of the unprecedented increase in the number of orphan and fast track drugs under development that have compressed timelines to regulatory approval. Hovione has adapted to this changing landscape and our technically experienced scientific teams are well positioned to advance your API efficiently through development. In addition, our expertise in advancing client compounds to commercial fruition has been routinely demonstrated, no matter what degree of complexity or technical challenges have been encountered.

What we do

Hovione focuses on developing processes and GMP compliant manufacturing of active pharmaceutical ingredients. With a greater than 50-year track record of demonstrated performance, our technical staff has the know-how required not only to develop robust, efficient processes, but also the ability to clearly prioritize the work flows throughout any phase of development for NCEs.

Doing the right things at the right time in the most efficient way is not easy. That is why Hovione developed the Excellent Development & Manufacturing (EDaM) guideline. EDaM not only incorporates decades of Hovione knowledge, but also embraces the latest in state-of-the-art methodologies such as Britest, Quality by Design and Lean 6 Sigma. This framework aligns Hovione to our customers’ projects, offering the best science - with the most reasonable cost - at the pace you need.

Working with us

Exceptional people

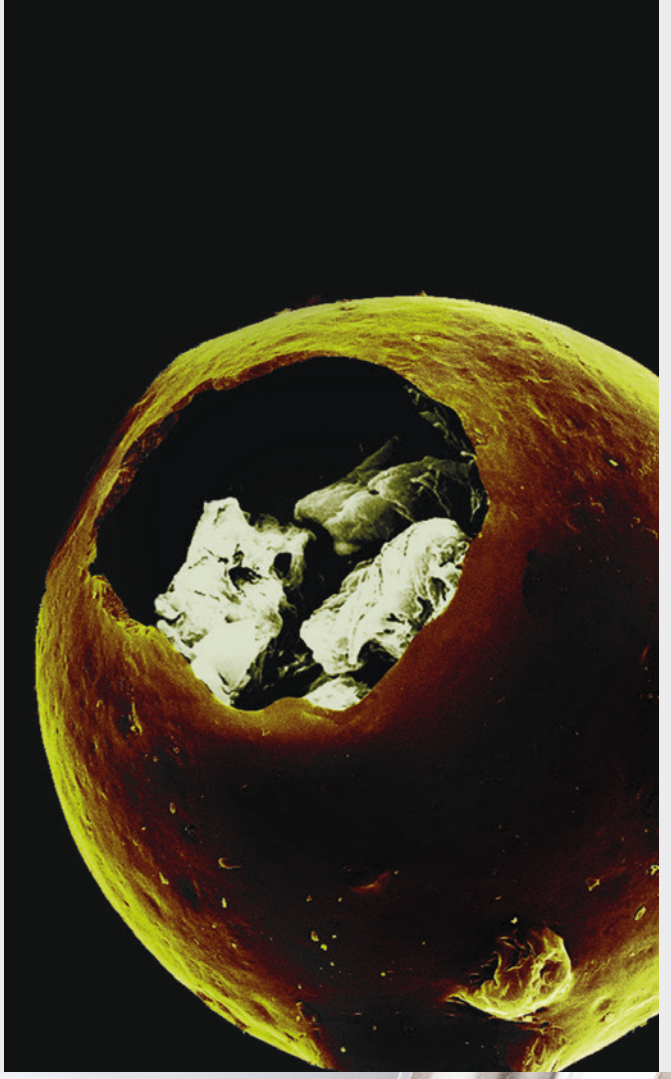
Hovione has a very experienced and highly qualified team with an average of 10 years in the industry. The passion and personal commitment team members bring to projects translate into better solutions that really matter for customers. Hovione fosters a culture of collaboration and partnership that team members embrace. This inspires the way in which relationships are built with customers and the way people take ownership of the projects they are involved in.

Rigorous project management

At Hovione, we develop a deep understanding of every customer's process, translate it into a well-structured proposal, then deliver on our promise through excellent project management and communication skills.

Trust is an essential ingredient in a business relationship built on good communication and transparency. At Hovione, we provide regular updates, report issues when they happen and collaboratively work to efficiently overcome them. In addition, Hovione customers have access to Navstream, a proprietary platform that allows customers to see in real time a comprehensive range of information about their projects, such as analytical test results, production status, and controlled documentation.

Integrated Offering



Particle Engineering

Hovione has built the most comprehensive set of technologies, including spray drying, hot melt extrusion and air jet milling, to help our customers in optimizing drug substance powder properties for formulation.

Whether the challenge is particle size reduction, density enhancement or solubility improvement, Hovione is your partner for particle engineering.

Drug product

Hovione's expertise used to develop complex API synthesis and world-leading particle engineering approaches is now also applied to inhalation and oral dosage form drug product manufacturing.

Hovione offers a fully integrated service for clinical and small commercial scale complex drug product development and manufacturing. Customers can benefit from compressed timelines and seamless project management by having all activities performed by the same partner at the same site.

Inhalation capabilites:

- Highly potent products handling
- Low dosage/High yield capsule filling
- MultiNett 100% net weight verification

Oral dosage capabilities:

- Roller Compaction
- Tableting
- Tablet Film Coating
- Highly potent products handling

Hovione

Certified B Corporation

Portugal
United States
Macau
Ireland
China
India
Japan

hello@hovione.com
www.hovione.com

In the United States,
call 1 609-918-2600

In Europe and the rest of the world,
call +351 21 982 9000

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