



umicore
Precious Metals Chemistry

Umicore APIs

High Potency Active Pharmaceutical Ingredients



Pt-API Production Room, Buenos Aires

Your partner for high potency APIs

**UMICORE'S EXPERTISE IN THE PRODUCTION OF HIGH POTENCY DRUG
SUBSTANCES SPANS MORE THAN 20 YEARS.**

Umicore Precious Metals Chemistry is one of the world's leading producers of platinum APIs for anti-cancer treatment. Located in Buenos Aires, Argentina, and managed under European standards and values. Our manufacturing site offers excellent conditions for competitive production of hAPIs, as well as unique and innovative options to develop launch strategies for new molecules. These can span from metal based APIs to molecules synthesized through complex organic chemistry.

QUALITY APPROVED AROUND THE GLOBE

Umicore's hAPI facility produces for global markets according to the latest cGMP regulations and ICH guidelines. It has been inspected and endorsed by a variety of regulatory agencies, including the U.S. FDA, Japanese PMDA and the European Medicines Agency.

CUSTOMIZED REGULATORY SUPPORT

Our regulatory affairs group offers professional services to the research and non-research based pharmaceutical industry. This includes, but is not limited to, filing and maintenance of DMFs, ASMFs, CEPs and documentation in paper or eCTD format, supporting the clinical development of innovative drug substances, for example with the preparation of CMC sections.

Depending on the respective region, we also engage external regulatory consultants to ensure a professional filing.



“The partnership with our customers is based on trust, quality, experience, and reliability – solid qualities for solid business.”



OEB 5 R&D Lab, Hanau

Contract development and manufacturing

In addition to our range of oncology APIs, Umicore offers contract development and manufacturing services for generics and new chemical entities (NCE).

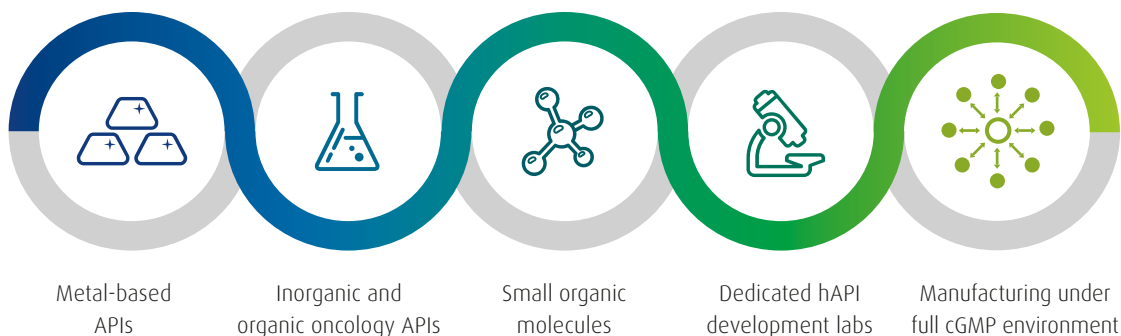
Our brand new dedicated R&D center in Hanau-Wolfgang, Germany, is equipped with the latest high containment technology to allow a safe handling of toxic materials up to occupational exposure band (OEB) 5.

Following successful development, manufacturing processes and quality control methods are transferred to our GMP site in Buenos Aires, Argentina.

Umicore's API locations in Germany and Argentina provide our clients with an attractive combination of a highly professional development environment and, at the same time, maximum cost efficiency for drug substance production under full cGMP.

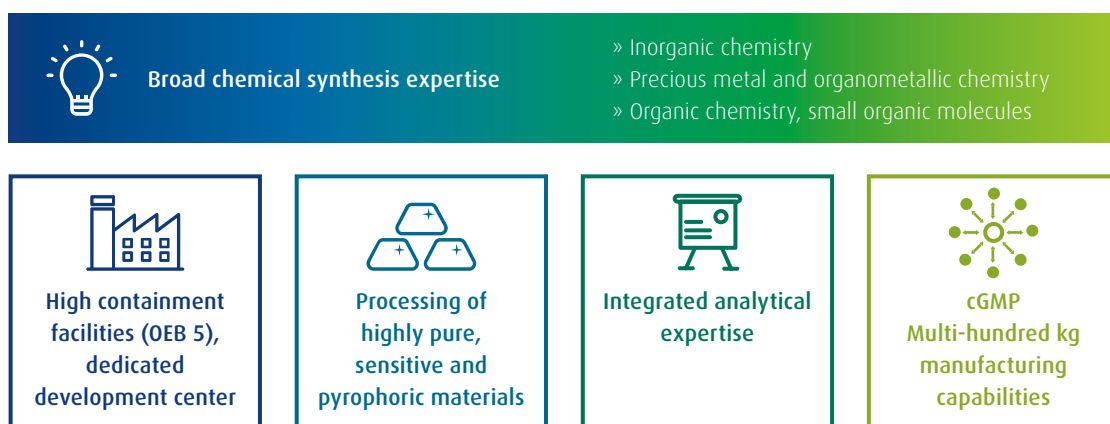
Our quality control teams in Argentina and Germany not only apply the latest analytical techniques and methodologies, but they also offer services beyond standard analytics, either using our in-house capabilities or in cooperation with qualified third-party laboratories.

EXCLUSIVE DEVELOPMENT AND MANUFACTURING

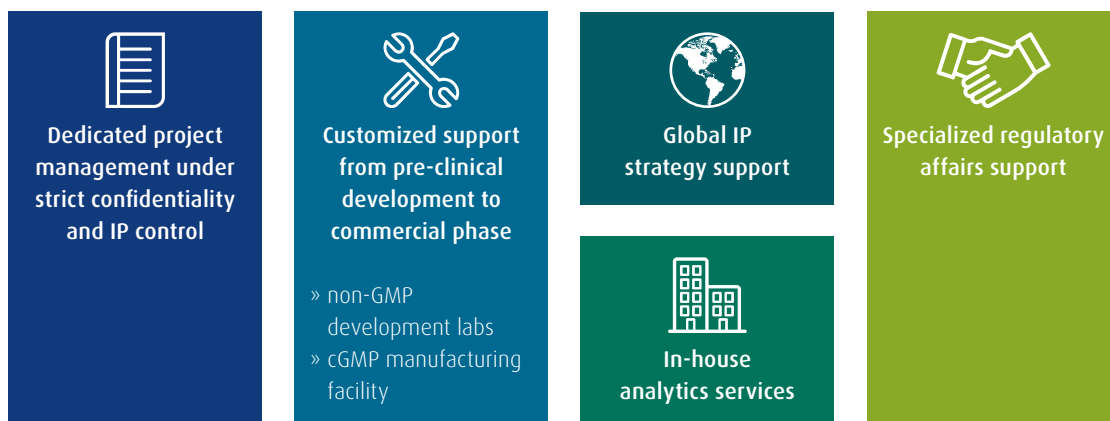


CONTRACT DEVELOPMENT AND MANUFACTURING CAPABILITIES

FOR PRODUCTION OF NEW HIGH POTENCY APIs



EXCLUSIVE SERVICES



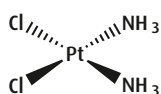
Metal based hAPIs – our competitive edge

As a market leader in precious metals, Umicore is vertically integrated into all steps of platinum API production, starting from a highly professional metals management and sourcing of metal to the world's most advanced metal recycling capabilities. This unique setup ensures a long-term, competitive cost structure to the benefit of our clients. Umicore also offers unique refining of platinum from expired vials or other waste streams from final dosage production.

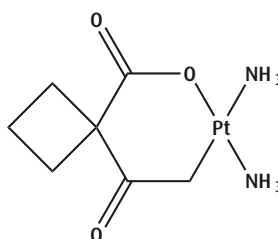
We have won the trust of our customers and they have made us a major player in the platinum API market over the last decades.

To further answer our customer needs, based on our experience in R&D, production and marketing of highly potent molecules, we have started to expand our portfolio into products with similar requirements.

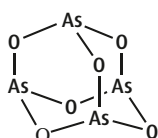
OUR GENERICS



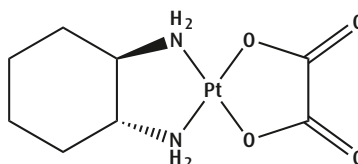
Cisplatin



Carboplatin



Arsenic trioxide



Oxaliplatin

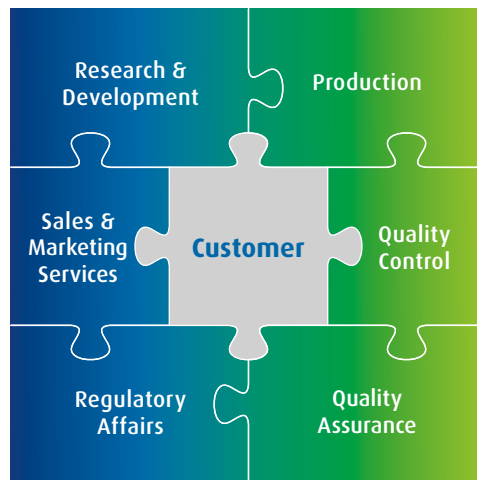
Team

We value our clients and long-term relationships

At Umicore, our values are transparent: Teamwork, respect, innovation and commitment, as well as trust and reliability reflect our basic business principles. Contact us to see for yourself.

UMICORE – YOUR PARTNER THROUGHOUT YOUR PRODUCT LIFECYCLE

- » Dedicated project management
- » Route scouting
- » Process development, optimization and scale-up
- » Clinical and commercial batch manufacturing
- » Analytic development
- » IP review
- » Preparation, submission and maintenance of regulatory documentation
- » Worldwide logistics solutions



Innovation

Commitment

Communication

work

Respect

Openness

For inquiries and
additional information
please contact us.

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