



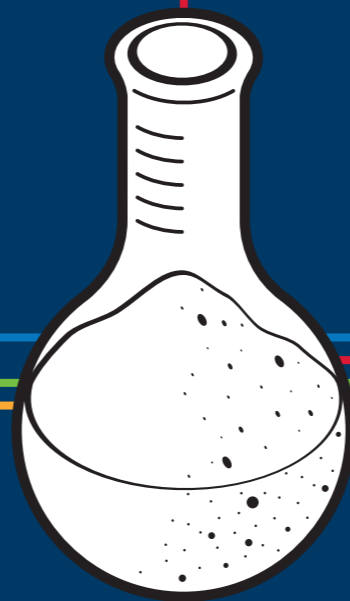
Active Pharmaceutical Ingredients





API Specialists

Development Lab
Kilo Lab
Pilot Plant
Analytical Development
Commercial Scale Plants
Potent Drug Capability



Explore the chemistry

Our business is growing.

We are expanding our operations around the world.

We are constantly introducing new products and capabilities.

It is our ambition to be the number one supplier of APIs and formulated products to the global pharmaceutical and biotechnology industries.

An ambition that we can only fulfil by working with like-minded customers who value the unique qualities and expertise that we have to offer.

If you'd like to discover if your business could benefit from working in partnership with us, contact us at info@aesica-pharma.com to arrange an informal discussion. We're sure your reaction will be a positive one.

Welcome to Aesica

From the day we founded Aesica in 2004, we have been committed to being fast, flexible, innovative and reliable. Qualities that are helping to make us one of the world's leading contract developers and manufacturers of pharmaceuticals.

Equally important to our growing success, but much harder to quantify, is our dedication to service and working in partnership to achieve outstanding results. We are constantly developing the technical and analytical skills of our people to ensure that we are capable of meeting the ever-changing demands of our customers.

Our state-of-the-art facilities enable delivery of a full API development and manufacturing service in a growing number of markets.

Most importantly, we are aware that customers want more than a supplier, which is why we work in partnership to provide a flexible, efficient and dependable service.

Welcome to Aesica.

API Specialists

Our technical expertise and customer service focus have helped make us the partner of choice for some of the big names in the pharmaceutical and biotechnology industries.

Our ability to work from laboratory through to commercial scale plants is matched by our comprehensive analytical services and reputation for working in close partnership with our customers to understand their specific needs and provide a tailor-made and responsive approach.

The result is a level of consistent quality that few can equal.

From development...

Our highly qualified team working in purpose-built facilities is key to being able to deliver all your process development and scale-up requirements.

Problem solving abilities are vital to the flexible approach to process development that we offer.

We produce a broad range of chemical synthetic compounds, including potent drugs and controlled substances, in quantities for use in pre-clinical and Phase I to III clinical trials.

We have the facilities to progress easily from grams created in the development lab.

...through scale-up...

Our dedicated Kilo Lab can handle multi-stage complex processes and is equipped with all the standard tools of an organic synthetic laboratory.

Our experienced team works to evaluate critical areas during scale-up to produce safe, robust and scalable processes.

We operate to cGMP standards and work in quantities from 10g to 5kg batches.

...to Pilot Plant...

Our dual facilities make the scale-up of a process easy.

We work in quantities from 10kg to 100kg batches.

Our facilities are suitable for the manufacture and isolation of controlled drugs.

We operate to cGMP standards.

And, as with all of our facilities, we are implementing an investment programme that will broaden our pilot scale capabilities.

...and thorough analysis...

Our full analytical service safeguards standards of product and manufacturing quality.

We offer method development and validation in compliance with ICH to support all your IND/CMC requirements.

Our in-house stability sample storage capability and analysis comply fully with ICH.

We only use fully qualified and certified equipment.

...to commercial scale production...

We have eight cGMP manufacturing plants dedicated to the commercial-scale production of APIs and GMP intermediates.

We operate at scales from kilograms to multi-tonne.

We produce both patented and generic drugs.

We produce potent drugs and controlled substances to commercial scale.

We have the approvals necessary to supply into the US and other major markets.

...and regulatory services.

Our experienced Regulatory Affairs Team has submitted DMFs to all significant regulatory authorities around the world.

We offer customer support through the ever-changing regulatory environment.

In expert hands

Our investment in and expansion of state-of-the-art plants, equipment, laboratories and support facilities play a critical part in our continuing growth and success.

We fully appreciate that an investment in hardware alone is no guarantee of continued prosperity.

We value experience.

We appreciate enthusiasm.

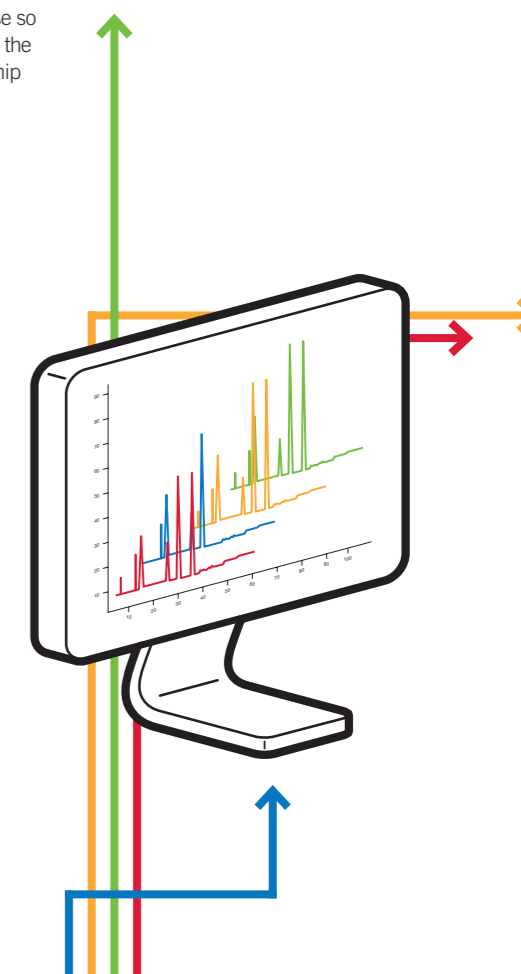
We encourage enquiry and innovation.

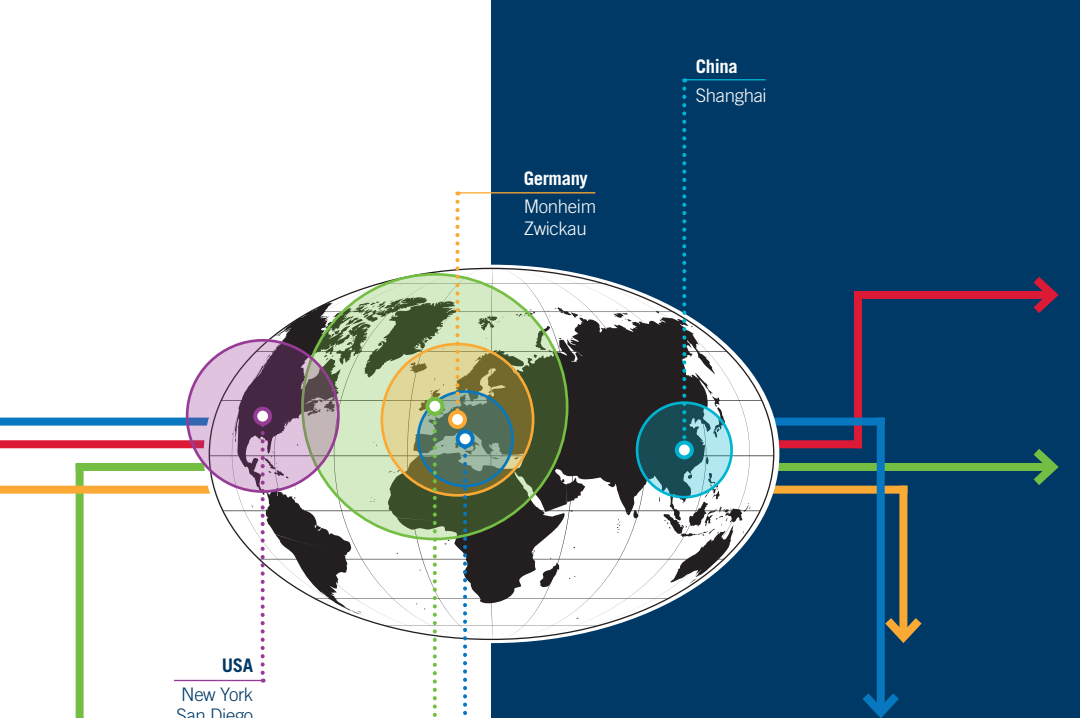
We demand excellence from our people.

All with the single aim of improving our expertise so that we can provide you with the level of service, the high-quality products and the reliable partnership that you seek.

The benefits of an Aesica partnership

- Working with a fast-growing UK company with an expanding international presence
- Working with a flexible, dynamic, innovative organisation
- Working with a full service manufacturer – from process development to commercial scale manufacture
- Working with a partner who can be trusted to deliver the highest standards in all areas: consultation, development, manufacture and delivery





USA
New York
San Diego

UK
Newcastle upon Tyne (HQ)
Cramlington
Queenborough
Nottingham

Italy
PianeZZa

Germany
Monheim
Zwickau

China
Shanghai

Aesica

To discuss how Aesica could deliver your contract pharmaceutical needs, **contact us today**

www.aesica-pharma.com

Our API services

Development Lab

- Process development
- Route optimisation
- Mettler RC1 calorimeter
- Short path distillation services
- Parallel reaction capability

Kilo Lab

- Multi-stage complex processes
- Reactions up to 50L scale
- Operates to cGMP standards
- Distillation, drying facilities & hydrogenation
- 5L Hastelloy filter drier
- Operates to cGMP standards
- GMP storage facility

Pilot Plant

- Walk-in drum booth with extraction
- Hastelloy filter drier with glovebox isolation technology
- Glass-lined reaction vessels up to 250 litre volume
- Ideal for 10kg to 100kg manufacture
- -20°C to 150°C reaction temperature capability
- Operates to cGMP standards
- Complemented by kilo laboratory operating at 50 litre scale

Analytical Development

- Automated HPLC & GC
- IR & UV; LC – MS
- GC headspace analysis
- Particle size by laser diffraction
- GCMS
- Preparative HPLC
- Photostability cabinet for stress stability studies
- ICH compliant in-house stability sample storage & analysis
- ICH compliant analytical validation & technical transfers completed according to defined protocols
- Reference materials supplied with CoA
- All equipment qualified & certified

Commercial Scale Plants

- 2 computer controlled multi-purpose plants working to cGMP standards
- 6 manufacturing units able to produce APIs and GMP intermediates working to cGMP standards
- Manufacturing in campaigns from 3kg to 800mt
- Home Office licence for controlled drug production
- Reactors from 1m³ to 10 m³
- Reaction temperature ranges from -15°C to 150°C
- Filter dryers from 0.35m² to 6m²
- Bespoke software solutions for complex inter-reaction chemistry
- Sophisticated isolation facilities for solids & liquids
- Clean room facilities for finished product handling
- Solvent recovery unit integrated within the manufacturing plant
- High vacuum (< 3 mbar) distillation & drying equipment
- Screw feeders for controlled solids charging to reactors
- Plant scale hydrogenation, hydrochloric acid gas & bromine technology
- Approvals to supply into US and other major markets
- MHRA certification & FDA approval
- ISO 14001 & ISO 9001 accreditation

Potent Drug Capability

- Handle high potent drug classes, up to SafeBridge Category 3
- Operates at scales of 1kg to 20kg
- 450L glass lined reaction vessels
- Preparative HPLC system for isomeric separation
- 270L Multi Purpose Processor (MPP)
- 50L Hastelloy filter dryers
- Manufacturing areas under negative pressure
- Inter-locked doors for personal and material entry/exit
- Product packaging in a HEPA filtered glovebox
- Raw material charges and product discharge utilising split butterfly valves and Contained Transfer Couplings (CTCs)

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