



Active Pharmaceutical Ingredients Development Services

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. We are constantly developing the technical and analytical skills of our people to ensure that we are capable of meeting the demands of our customers.

From route selection and optimisation through to GMP manufacture Aesica's team of experienced Ph.D chemists have the skills and expertise to deliver all your process development and scale up requirements.

We focus on providing a safe, robust, scalable, cost effective process for your API.

In support of development and scale up we provide full analytical services including method development, optimisation and validation. Our regulatory team are experienced in the preparation and submission of DMF and CMC documentation and can offer support throughout the development process.

We hold UK Home Office licenses for the possession of schedule 1 substances and manufacture of schedule 2-4 controlled drugs and our facilities offer containment for safe-handling of highly potent compounds up to Safebridge® Category 3 (minimum OEL $0.1\mu\text{g}/\text{m}^3$) to the highest standards of c-GMP.

Our commercial scale capabilities offer complimentary facilities for seamless process scale up from kilo lab to pilot plant and full scale commercial manufacture. We have an excellent track record in safety and regulatory compliance; our facilities fulfil cGMP standards and are regularly audited by customers and regulatory authorities including the MHRA and FDA.

Development Laboratory

- Route selection & optimisation
- Process research & development
- Technology transfer
- Development of highly potent APIs and controlled substances
- DOE statistical experimental design
- QbD approach to critical parameter evaluation
- Safety studies using RC1 reaction calorimeter & DSC
- Parallel reaction capabilities
- Experienced team of chemists (90% PhD)
- Facilities for handling potent & controlled drugs
- Scale up of new routes as proof of concept

continued overleaf...



To discover how we can support your needs

Contact **Andrew Henderson Ph.D,**
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Analytical Development

- Automated HPLC & GC
- GCMS, LCMS & GC headspace analysis
- Particle size by laser diffraction
- IR & UV
- Photostability cabinet for stress stability studies
- In-house stability sample storage & analysis in compliance with ICH
- Analytical validation & technical transfers completed in compliance with ICH
- Reference materials supplied with CoA
- All equipment qualified & certified
- All operations to cGMP
- Develop protocol
- Facilities integrated into development lab

Kilo Lab

- Process scale up & demonstration to pilot plant & commercial scale
- cGMP kilo lab facilities
- Up to 50L reactor vessels
- Hastelloy filter drier technology
- Ability to handle multi-stage complex processes
- Facilities for handling potent & controlled drugs
- Walk-in hoods
- -20°C to 150°C reaction temperature capability
- Distillation & drying facilities
- Process validation
- Preclinical & early clinical phase supply

