

# Process R&D and Scale Up



# Process R&D and Scale Up Services

Key Organics' experienced Chemists have supported many Process R&D and scale up programs, from route scouting, synthesis of preclinical tox batches, scale up of key intermediates and synthesis of intermediates for GMP manufacture.

We have successfully worked with clients in Pharma, Biotech, Academia, Agrochemicals, Oil and Gas, Materials and Consumer Health industries and therefore have a very broad range of Synthetic Chemistry experience.

As many of our customers work to tight deadlines, we seek to optimise the efficiency of a scale up route by getting to the heart of the issues quickly.

Our chemists work closely with our in-house analytical team to ensure that final compounds meet or exceed the purity specification required by the customer. We can also provide SDS, BSE/TSE, GMO statements as needed by the client. We also consider green chemistry metrics and COG issues.

**Our new, state of the art facility at our Camelford site will enable us to help more customers with their development and scale up projects.**



## New Scale Up Lab Profile

- Six bespoke walk in Fume Hoods, fully flexible from benchtop to scale up chemistry
- Two bespoke walk in scrubbed and wash down Fume Hoods to enable chemistry that needs an extra level of safety and containment
- Two vented hoods fully accessible from all sides for general small-scale chemistry
- 100m<sup>2</sup> lab space
- 40m<sup>2</sup> office and storage space
- Designed to be fully flexible to allow our chemists to carry out chemistry from benchtop to 30 litre scale (in future, potential to house up to 100 litre vessels)
- Fully serviced high spec design



## Testimonial

Over four years and two different programs Key Organics have delivered for us right from the start. From initial engagement through to shipping and delivery it has been seamless. The expert chemists at Key Organics have delivered high quality material and data, rigorous process development and creative solutions to the inevitable problems that arise. Last-minute requests and the all too frequent changes in scope have been accommodated without fuss. While the chemistry has been exemplary the innovative solutions extend beyond the lab. A recent project would not have got internal approval without creativity, flexibility and input from their BD.

In one project I am particularly pleased about, the process development and scale up work, carried out by Key Organics, on a critical component from our crude discovery route enabled them to provide material we simply didn't have the internal capacity to deliver; this fed directly into the supply chain for our phase 1 program.

The first-class communication, discussions and the thorough and detailed reporting, which is essential when you're on the other side of the world, has made my life that much easier. My confidence in Key Organics is the same as if they were in my own lab down the hall and I will be using Key Organics again and would do so more if I were able."

**Dr Andrew Donohue,**  
Head of Chemistry,  
PolyActiva Pty. Ltd.



## Staff Profile



**Jon Ponting**

"I completed my undergraduate degree from Swansea University in 1991, joining Maybridge Chemicals in Apr 1992 working as a scale up chemist. I joined Key Organics in Nov 1994, undertaking a range of chemical and managerial roles. I have been involved with the design, construction and management of 2 kilo laboratories and have been responsible for all scale up chemistry within Key for nearly 30 years. I have successfully undertaken many FTE and custom projects for many customers covering a wide range of chemistry and often to a very high client specification."

## Our capabilities include:

Process Chemistry  
R&D to deliver  
robust routes

Scale up of  
intermediates and  
final compounds  
(Kg scale)

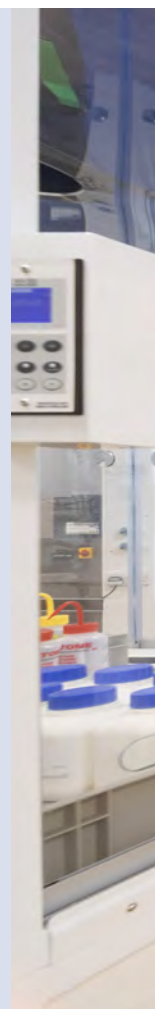
Synthesis of  
intermediates  
for GMP  
manufacture

Impurity and  
metabolite  
identification  
and synthesis

Full reaction  
profiling

### Our current suite of equipment features:

- Up to 30 litre vessels with temperature range of -20°C to +250°C
- Dedicated 10 litre vacuum jacketed vessel capable of -70°C via Huber 905 Unistat including precision and reproducible reaction dosing system
- Biotage 150 and Flash 75 large scale flash chromatography units capable of handling up to kg quantities of materials. Access to a wide range of separation media resulting in very low impurity contamination
- Biotage Isolera One and Isolera LS automated flash systems
- Teledyne ISCO ACCQPrep® HP150
- Buchi 220 pro rotary evaporator with up to 20 litre capacity offering excellent and efficient solvent removal with minimal fugitive losses maximising environmental protection
- 2" wiped-film still specifically for the distillation of heat sensitive materials
- 500ml to 2 litre vacuum jacketed vessels capable of full calorimetry and reaction profiling at -78°C to +150°C
- Hastelloy and stainless steel autoclaves up to 4 litres capable of undertaking high pressure (200 bar) and high temperature (+200°C) hydrogenation, ring reductions and carbonylations
- Advion Interchim Scientific ASAP® MS with Plate Express
- Biotage microwave
- Anton Parr sealed tube reactor



# Sustainability

We always aim to lower running costs, for example installing/using heat pump systems and solar panels which helps lower our carbon footprint. We aim to apply the principles of Green Chemistry where applicable as outlined by Warner et al: Anastas, P. T.; Warner, J. C. *Green Chemistry: Theory and Practice*, Oxford University Press: New York, 1998, p.30

# Quality

We have an internal QMS system including verified equipment servicing and calibration, goods in/out SOP/QC and separate storage for different projects/clients.

# Compound Storage and Stability Testing

Using our storage space and facilities, Key Organics can store your powder and liquid samples, format them on demand as required and distribute them to your site locations around the world. This service eliminates the need to have an organized compound repository on site while keeping your compounds easily accessible. Our storage conditions range from storage at ambient temperature to a refrigerated environment. We can also perform regular QC checks to monitor compound integrity during storage and provide valuable stability data.



# Quality control

Our Process Development and Scale up Service is supported by Key Organics analytical services. Compounds can be QC checked by any combination of LC-MS, NMR, GC or KF to ensure they meet the required purity and to confirm the correct structure.

Our dedicated team of experienced and highly qualified staff can provide the following services:

- Compound identification and structure elucidation
- Compound purity screening
- Impurity identification and isolation
- Reaction profiling
- Compound purification
- HPLC and GC method development and/or optimisation

Our analytical department is equipped with the following instrumentation:

- NMR: Bruker 400MHz AVIII NMR equipped with a 1H/13C multinuclear probe capable of performing routine 1D experiments plus variable temperature experiments
- LC/LCMS: Agilent 1260 LC multiple wavelength UV/Vis detector, ELSD, 6130 Single Quadrupole MS, Agilent 1260 LC infinity II with IQ MS and Agilent 1100 HPLC
- Gas Chromatography: Agilent 7890 GC, with flame ionisation detector
- DSC 25 - TA Instruments



# Key Organics Facts:

Who are we?

An international CRO based in the UK with over 38 years expertise in synthetic organic chemistry.

## Our customers:

We work with clients in Pharma, Biotech, Academia, Agrochemicals, Oil and Gas, Materials and Consumer Health industries.

## Our Services:

We offer a wide-range of bespoke chemistry solutions, from the custom synthesis of a single compound to multiple, long-term FTE projects.



- Collaborative R&D
- FTE Services
- Custom Synthesis
- Process R&D/Scale up
- Analytical Chemistry
- Consultancy

## Flexibility:

We work closely with our customers through the entire process – especially as project milestones often change and resources must be adjusted along the way.

## Why work with us?

With established fragment libraries, an extensive BIONET product portfolio and a proven track record in synthetic organic chemistry, Key Organics is able to support your discovery and development chemistry needs. Our Project Managers and Scientists are highly experienced at managing complexity. We utilise ELN, Reaxys, DataWarrior and other software tools to facilitate projects and information exchange.

## Partners

We work closely and confidentially with various partners who offer complimentary expertise, these include Reach Separations (chiral chromatography) OEA Labs (Elemental analysis, metal analysis) and DNA labs (5 Batch analysis).



**Key Organics Ltd.,**

Highfield Road Industrial Estate,  
Camelford, Cornwall PL32 9RA, UK

---

**T: +44 (0)1840 212137**

**E: [enquiries@keyorganics.net](mailto:enquiries@keyorganics.net)**

---



**[www.keyorganics.net](http://www.keyorganics.net)**