

## Experienced cGMP Manufacturing Provider SAFC Pharma™ – Gillingham

SAFC Pharma's Gillingham, UK production facility provides APIs development and manufacturing services that support Pre-clinical through Phase III trials.

Fully validated, this 55,000 sq.ft. cGMP manufacturing facility was specially designed for complex, multi-step custom synthesis of APIs and key intermediates. Experienced development and production chemists ensure seamless operations for customer programs in all areas of scale-up, optimization and production. The Gillingham facility hosts an on-site hazard evaluation laboratory and operates with comprehensive QC and QA procedures in place to help customers bring their products to market quickly and efficiently.



### Chemical Services

- Laboratory-scale production
- Scale-up expertise
- Process optimization
- Analytical reference standards and markers
- Analytical methodology development and validation
- Kilo scale to multi-ton manufacturing
- Process validation
- Stability studies programs
- Regulatory filing experience and support

### Capabilities

Gillingham's completely-segregated production train was designed to eliminate the potential for cross contamination and maximize efficiencies in every customer program. Process chemists operate in shifts around-the-clock to move projects through the plant in the most proficient manner. If required, on-site chemists coordinate with sister sites for projects that may be transitioning to other SAFC manufacturing facilities.

- Development through multi-ton manufacturing
- Reactor range: 50 L to 1,600 L
- Small quantity manufacturing in 3 fully-segregated HEPA filtered Class 100,000 (ISO 8) kilo labs
- Process chains to 1,600 L vessels
- Temperature range: 85 °C to 220 °C

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- HEPA filtered and segregated Class 100,000 (ISO 8) isolation equipment. Hastelloy® filter dryers, stainless steel centrifuge, agitated pan dryer

- Fully equipped hazard evaluation laboratory with Mettler RC1 (low temperature capability, Hastelloy pressure vessel for hydrogenations), and DSC and ARC equipment

- Ability to investigate desired reaction and potential thermal decomposition



#### Quality Control

Extensive focus on quality includes analytical development programs, quality control and quality assurance. Our experienced personnel can perform method development, analytical validations and verification to the most rigid specifications and ensure cGMP compliance of all released batches. Capabilities include:

- HPLC
- LC-MS with MS/MS capability
- 400 MHz multi-nuclear NMR
- GC-Headspace for residual solvents
- Stability studies capabilities



#### Site Technology Expertise: Hydrogenation

Gillingham is equipped with 2 L and 20 L hydrogenators (Hastelloy, 150 °C, 50 barg), allowing cGMP production to 20 L batch size.

Equipment has been engineered to give equivalence for heat and mass transfer ranges of 2 L, 20 L and 800 L. At this site, customers can expect a one-hour reaction performed at laboratory scale to take one hour at plant scale, with total control over the impurity profile.

The site is equipped with an efficient 800 L cGMP Biazzi hydrogenator. (Hastelloy, 150 °C, 50 Barg).

Key points:

- Extremely efficient mixing
- Mass transfer
- Highly efficient heat transfer due to large surface area
- Internal plates facilitate fast reaction times
- High level of process control
- Use of sequence control for high level of quality assurance



SAFC Pharma's Gillingham site can support customer projects with reliable API scale-up and manufacturing, bringing your product to market quickly and efficiently.