

GSK provides contract manufacturing facilities with both Biopharmaceuticals and traditional Small Molecule API capabilities. Production can be accommodated in either a dedicated plant or in general-purpose, flexible multi-stream facilities. Our capabilities range from large-scale, highly automated manufacturing to smaller-scale specialist production requiring greater 'hands on' attention. Our manufacturing facilities have state-of-the-art control systems and are highly contained. Our API capabilities provide development and supply of Phase 1, 2, and 3 clinical trial materials for new compounds as well as launch and commercial material.

We have extensive expertise in physical properties characterization, and a long history of supplying actives for steroids, manufacture of which involves complex, multi-stage synthesis. Our Development Laboratory provides process and analytical technical support for Technical Development group priorities, ensuring that annual validation programs are complete. The lab provides analytical technical support / troubleshooting for established and new products, giving

analytical support for regulatory questions and participating in analytical technical transfers. Our Physical Properties Laboratory is a dedicated, modern laboratory with all of the instruments necessary for assessing suitability of API for drug product formulation.

GSK is at the forefront of process optimization with the application of methodologies that include Process Analytical Technology (PAT) and Quality by Design (QbD). Our manufacturing has support from comprehensive corporate resources, including Chemistry and Pharmaceutical Development.

GSK API facilities have an excellent compliance track record with strong FDA and EPA/HAS audit compliance.

Molecule to Market — Extending Your Capabilities






Manufacturing Capabilities

Small Molecule API

- High Containment
- Excellent regulatory compliance record
- EPA Integrated Pollution Prevention and Control (IPPC) licenced
- Comprehensive laboratory facilities
- Highly qualified and experienced staff
- Seamless two-way knowledge transfer
- Process analytical technology
 - Reaction monitoring (solution spectroscopies IR, NIR, UV)
 - Crystallisation monitoring (in slurry: Lasentech, Turbidity)
 - Distillation monitoring (Solution Spectroscopies in the vessel, Mass Spec and NIR for distillate lines)
 - Isolation and drying monitoring (Mass Spec and NIR for Vent Gas)

Equipment

- 14 Production buildings
- 32 Production modules
- 300,000+ Litres capacity
- 110+ reactors (30 - 16,000 Litres)
- Multiple glass-lined vessels, Hastelloy vessels, Stainless vessels
- 4 Hydrogenation vessels
- Large range of isolation and drying equipment - 23 isolation devices (Filter dryers and centrifuges, Boltz dryers, tray dryers)
- Solvent recovery systems
- Fully contained batching and off load via glove boxes and PTS systems

	Traditional Small Molecule	Large Molecule/Biopharm
API		
Ireland		
Singapore		
UK		
US		
GlaxoSmithKline Contract Manufacturing		

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