

GSK provides contract manufacturing facilities for the production of Syringe, Vial, and Ampoule dose forms. Our sterile facilities offer flexible services for the formulation and filling of sterile liquids and lyophilized products. We also offer a sterile high-containment facility capable of producing both freeze-dried and liquid cytotoxic products.

Our facilities provide dedicated small-scale operations for development and clinical batches. Our sites also offer a complete process covering all aspects of cGMP commercial production from compounding, filling, and freeze-drying to the addition of final decontamination-in-place for high containment products.

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.

We can provide the technical expertise and capabilities to manage the development, launch and supply of new, in-licensed, and transferring products to over 100 global markets including US, Canada, EU, Japan, and International.

### **Sterile High Containment**

The sterile high-containment facility is a state of the art manufacturing operation suitable for freeze-dried and liquid cytotoxic products. The entire manufacturing process is carried out in a dedicated building that provides a total-containment environment. The multi-product facility can produce in excess of 6mm vials per year. Equipment includes a compounding suite integrated with isolator technology. Filling is at 200 UPM utilizing closed Restricted Access Barrier Technology (cRAB) with a fully contained loading/unloading system for freeze-drying. An Automated Vaporized Hydrogen Peroxide (VHP) cycle provides isolator sanitization.

**Molecule to Market — Extending Your Capabilities**











## Manufacturing Capabilities

- Lyophilization
- Syringes
- Vials
- Ampoules

## Supporting Technologies

- Filling vials from 0.5 - 100ml
- Aseptic filling of syringes from 0.1 - 20ml
- Filling ampoules of 0.5ml-10ml
- Isolator and Advanced RABS filling lines
- Isolator technology for dispensing
- Grade A continuity from Autoclave to filling machine
- Controlled thaw technology
- Disposable or stainless steel manufacturing and filling equipment

- Clean in place / Sterilize in place (CIP/SIP) systems
- Fully automatic packaging lines for vials, syringes and bespoke devices
- Controlled thaw technology for frozen bulk drug substance
- Homogenizer technology for production of emulsion products
- Automation managed by Supervisory Control and Data Acquisition (SCADA)
- Automatic continuous particle and microbiological monitoring systems
- Automated leak detection, crack detection and cosmetic / particulate inspection
- Fully automated packaging lines
- Freezer and Cold store capacity
- Cold / frozen supply chain and logistics expertise

					
	Cytotoxic/ Potent	Lyophilization	Syringes	Vials	Ampoules
<b>STERILES</b>					
France					
Italy					
UK					
<b>GlaxoSmithKline Contract Manufacturing</b>					

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