



Why GlaxoSmithKline?

At GlaxoSmithKline, our mission is to improve the quality of human life by enabling people to do more, feel better and live longer. We do this by developing innovative medicines and products which help millions of people worldwide.

Our Global Manufacturing and Supply (GMS) in-house organisation supplies patients and customers with quality pharmaceutical products. With over five years experience as long-term contract manufacturers, GSK provide customers with state of the art facilities designed for high volume, high quality manufacture.

At GSK Ulverston, we manufacture and supply world class bulk oral and sterile cephalosporin antibiotics. As part of the GSK network, we can provide flexible support and technical excellence to aid the customer throughout all stages of the manufacturing process; from preclinical development to scale up and commercial manufacture.

We engage with global product dose form sites to create an end-to-end supply chain process. And offer quality supplier management services.

Our customer service at Ulverston includes a fully compliant warehouse, an excellent record in delivering the product to downstream customers and product and analytical development services.

The capabilities of GSK as a whole are aligned to deliver a successful and world-class contract manufacturing experience.





Our Site

Building 11



Sterile manufacture and sterility assurance are two of the most important aspects of the Ulverston site.

Building 11 manufactures our key sterile products – Ceftazidime and Cefuroxime sodium. The building is split

so that both product streams can operate independently. Both process streams consist of a string of dedicated plant items which can be steam sterilised in place (SIP).

GSK Ulverston has made significant investments in installing state of the art sterile isolator technology. This technology makes us one of only a few sites in the world who can offer bulk sterile offload.

The site has gained significant experience in sterile manufacture and sterility assurance with products made successfully on site for the past 40 years.

Most recently the site has supplied the manufacture of phase III clinical trial material for a third party customer.

Building 12



Building 12 at Ulverston specialises in the manufacture of bulk oral API. Cefuroxime Axetil is produced using large scale spray drying technology to create precise particle sizes and reduce microbiological contamination. A specialised wax encapsulation process is

used to manufacture Axetil suspension, improving the tolerance of the product as a paediatric formulation.

Intermediates



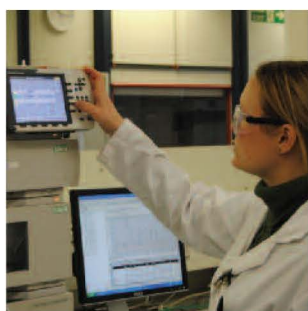
Our Intermediate plants on site perform a series of chemical conversions to convert purchased raw materials into the desired input for Building 11.

Building 14 also includes a second crop process which recovers non-sterile ceftazidime pentahydrate from Building 11 liquors.

Intermediates include a mixture of manual and computer sequence assisted plant, with all equipment dedicated for each process stage. The processes typically involve the use of flammable solvents, low reaction temperatures and water reactive materials.

Environmentally, the plants have carbon absorption units to minimise the release of solvent vapours into the atmosphere.

Support Services



At the Ulverston site, we have both Technical and Quality Assurance support labs which help to ensure the safety of our products, our patients and our environment. The labs are in place to make sure any change is assessed and controlled. In the labs, we can run scaled

down versions of the processes carried out on site, also giving us the capability to do development work before rolling out to full scale production.

Our Quality Assurance labs are set up for routine analysis. As part of our extensive quality control system, they are aligned to test purchased or manufactured compounds, i.e. raw materials, intermediates or final products. The main QA lab deals with daily testing, while a shift team supports production on a 24hr basis, providing real time testing. Our Microbiology labs use specialised analytical techniques to ensure the biological quality of our antibiotics.

At GSK Ulverston, we also have Technical labs dealing with non-routine assessments, as well as working in conjunction with Quality Assurance. Technical carry out chemical and analytical investigations which can improve and create new methods of testing and manufacturing – for example, 2nd generation chemistry development to improve our existing processes. Technical also support Quality Assurance when approving new raw materials and suppliers.

This close relationship between our labs enables us to monitor and control our products throughout their lifecycle thus guaranteeing quality.

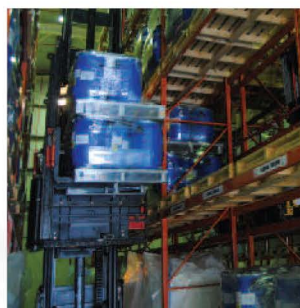
Solvent Recovery



Sustainability is an area which GSK Ulverston takes pride in. Solvent Recovery is another important feature of the site which both supports the manufacturing process and contributes to the sites sustainability. By collecting all waste streams produced by the

processes on site, we are able to recover 70% of solvents for reuse in manufacturing. At present, we have seven recovery processes with capacity for two more. Solvent Recovery also treats effluent to be within the consent limits of the environmental agency.

Supply and logistics



Supply and Logistics deal with a variety of activities on site. By planning ahead (by up to 5 years), we ensure that we have an adequate supply of materials on site for all our manufacturing needs. This includes the storage of material for forward cover to

minimise the risk of major disruption to supply in the event of a problem with production.

Our warehouses are a key asset to the site. They operate seven days a week to organise the flow of material passing from suppliers, to/from production and the dispatch of goods to our customers – primarily Barnard Castle and Verona.

Safety of the storage of our materials is also key to the design of the warehouses. Temperature controlled areas secure materials affected by heat, while our stock holding policies segregate reactive materials, with SAP being used to ensure compliant storage.

SAP is also used to trigger the movement of materials to and from production, recording manufacture and the creation of documentation for production.