

Aspen's sterile facilities and capabilities located in Gqeberha, South Africa

Aspen's facility at Gqeberha (formerly known as Port Elizabeth), has had niche sterile capabilities since the late 2000s when an investment was made, in conjunction with an anchor tenant, into eyedrops. The original sterile site, which we refer to as SVP 1 can also produce a wide range of standard injections filled into vials and ampoules. In 2013, we acquired our French-based facilities at Notre Dame de Bondeville, which added to our capabilities. This site has the capacity to produce millions of pre-filled syringes and blow-fill seal technologies, an investment made with our own anaesthetics products in mind.



Aspen's flagship manufacturing site in Gqeberha, South Africa

We saw the value in the manufacturing and commercialisation of sterile medicines and this vision has evolved over the past 7 years. In order to compete effectively in sterile manufacturing, we made additional investments in our global scale and capabilities to manufacture niche products with a high degree of complexity while remaining committed to quality at an affordable price. We have made excellent progress in reaching our goals with strategic capital projects at our South African, French and German sites drawing to a close in CY 2023.

The Gqeberha facility now provides significant sterile capabilities on the African continent. The recent capital investments in excess of R3 billion were made to allow for the production of our own Anaesthetics products, which is a significant step in the evolution of this site. The new sterile facility, which we call SVP 2 and which includes a high-potency suite, has numerous capabilities from less complex, non-specialty production type vials, ampoules and cartridges to complex sterile emulsions and lyophilisation capabilities. For insight into these complex items, we have two lyophilisers and lyophilisation is a process whereby medicines start out in liquid form and are freeze dried to extend the stability and shelf life of the medicine.

Included within SVP 2 is the contained filling line which represents the new capability in Gqeberha, which was constructed with our own product in mind and which gained interest during the current pandemic for the manufacturing of COVID-19 vaccines. Click [here](#) to view a video clip of the high-potency suite demonstrating the production of vaccines and [here](#) for a version that includes narration. Importantly, both SVP 1 and SVP 2 are compliant with leading international regulatory agency requirements enabling Aspen to produce for both domestic and export markets.

The difference between ampoules, vials and pre-filled syringes.

Ampoules and pre-filled syringes are typically single dose and often used in developed markets. Vials can be single or multidose, in other words you can provide more than one dose of medicine per vial, which can be cost effective.

Lyophilisation of COVID-19 vaccines

Studies are being conducted into the lyophilisation of COVID-19 vaccines, with these results still to be released. Other vaccines and medicines are lyophilised which can provide stability to the medicine, thereby increasing its shelf life.

Production capability at Aspen's sterile facility in Gqeberha

The Gqeberha sterile facility SVP 1 currently produces eye drops and other non-specialty injectable medicines. Once SVP 2 is fully operational, the joint SVP site will be able to produce Aspen's anaesthetics products as well as vaccines and other third party products. Our lyophilisation capabilities ensure that we are capable of finishing and filling medicines across a wide range of therapies and potentially complex molecules. We have excess capacity available for third-party manufacturing and additional Aspen products.

Supplying vaccines to South Africa and Africa

The two lyophilisers mentioned were installed with, among others therapies, vaccine production in mind. The COVID-19 vaccines are not lyophilised but other vaccines are lyophilised and we would hope to be able to manufacture these at this site in future. We have built world-class sterile facilities at our manufacturing site in Gqeberha and would be pleased if any medicine produced at this site were to be used in South Africa and in Africa.

Understanding the vaccine manufacturing process

Generally speaking, and not specific to any vaccine, when Aspen produces any new sterile product, we begin with dry production runs that confirm capability of the new equipment as installed and commissioned to ensure that it is working correctly and efficiently. We then conduct a placebo or trial run, which may have no active substance in the medicine container. We then follow this with further trial run/s, which include the active substance. A validation process takes place thereafter, where we would produce at least three batches and submit the data from these batches to the regulatory authorities for review. Provided that all validation batches are safe, correctly made and are the same as the original product being transferred in, we can then submit the site for registration as a supplier of the product to the healthcare authorities.

Manufacturing vaccines can take a long time and it is a complex production process. Vaccines are tested at each stage of production and quality control testing is done by various regulatory authorities on the finished product around the world. As vaccines are a biological process, manufacturing requires a high level of expertise which we have developed at Aspen over a number of years. Aspen's vaccine capabilities are in formulation and filling, freeze drying and packaging.

About Aspen

Headquartered in Durban, South Africa, Aspen is a leading global specialty and branded multinational pharmaceutical company in both emerging and developed markets.

Aspen improves the health of patients in more than 150 countries through its high quality, affordable and effective healthcare solutions. The Group's key business segments are Manufacturing and Commercial Pharmaceuticals comprising Regional Brands and Sterile Focus Brands that include Anaesthetics and Thrombosis products.

Aspen employs approximately 9 100 people and has 69 established business operations in over 50 countries. The Group operates 23 manufacturing facilities across 15 sites and holds international manufacturing approvals from some of the most stringent global regulatory agencies. Its manufacturing capabilities are scalable to demand and cover a wide variety of product-types including steriles, oral solid dose, liquids, semi-solids, biologicals and active pharmaceutical ingredients. For more information visit www.aspenpharma.com