# A SCHOTT In The Arm

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***Schott built its pharmaceutical packaging facility with twice the footprint necessary for existing operations. When advances in biotechnology created a demand for syringes, the company had room to install a state-of-the-art production line.***

Extra space is a luxury not afforded by most plants. As companies look to diversity their product ranges, new equipment is squeezed onto ever shrinking plant floors.

But if space wasn't an issue, it would be theoretically possible to expand operations as market conditions created demand for certain products. This is exactly what happened at Schott's pharmaceutical packaging plant in Lebanon, PA.

**Glass House**

Built in 2004, the facility replaced Schott's smaller plant in nearby Cleona and carried on with the production of pharmaceutical vials, dental cartridges, and ampoules. Glass forming equipment supplies molded glass containers to a controlled area where products are packaged to customer specifications.

"We built the plant as a way to hold onto our employee base and we knew that we wanted to go into other product areas," explains Renard Jackson, Vice President of Schott North America and General Manager of Schott Pharmaceutical Packaging. But at the time, it wasn't known if existing product lines would be expanded or if new products would be added.

Only about 50 percent of the plant floor was in use until recently, when advances in protein and mammalian cell research led to an increase in the use of injectable drugs, and opened the door for Schott to fill the demand created by this shift in pharmaceutical delivery methods.

The decision was made to install a ready-to-fill syringe line at a cost of $14 million, with a capacity of 100 million syringes annually or approximately one-third of the current U.S. market. The line would need to be accompanied by a ISO 7 (Class 10,000) clean room and water treatment system capable of purifying and maintaining the sterile water-for-injection (WFI) used to wash the syringes. Instead of building the infrastructure to support one syringe line, Schott again looked to the future and installed systems capable of supporting four syringe lines, enough to exceed total U.S. demand by about 20 percent.

Schott was able to draw on experience from its facility in St. Gallen, Switzerland, where a similar syringe line was installed 8 years earlier. This internal experience combined with help from reputable engineering contractors helped Schott get the line up and running on time, on budget and without any unexpected regulatory roadblocks.

**Water Treatment**

An 1,800 square foot room houses the pumps, tanks, pipes, compressor, heat exchanger and monitoring equipment used to convert council water into sterile WFI through a process known as vapor compression distillation. Municipal water is brought in using redundant centrifugal pumps and sent through a carbon filter to remove the chlorine. Chlorine is removed not only because it is an unwanted impurity, but also because it could degrade the stainless steel tanks and pipes.

The distillation process begins when the filtered water enters the large still where it is heated and converted to steam. Steam then passes into a compressor where it becomes pressurized, increasing the temperature and allowing for latent heat transfer. When the steam is passed through the heat exchanger inside the still, the steam condenses and transfers its heat back into the system — the energy is

recovered.

The condensed water flows out of the system as WFI-grade distillate, where it is tested for conductivity in order to verify the purity level of the water. If the purity level is not reached, the water automatically flows to drain. A heating system keeps the WFI between 175 and 185 degrees F while dual circulation pumps keep the water moving in order to keep it in a sterile state. The constant circulation also removes the need to clean the holding tank. If temperature or conductivity falls out of spec, the automated monitoring system immediately alerts the operator. The system is capable of producing 1,200 gallons per hour of distillate.

## Under Pressure

Keeping particulates out of the products is a huge focus that affects the entire plant. Sterilization is used to kill bacteria, but it won't necessarily remove particles. Dirt and fibers can easily blow into the plant or be carried in on shoes or clothing. For this reason, a pressure gradient is maintained across the plant, causing air to flow from the most clean areas to the less clean areas and eventually outside.

While a controlled area already existed within the plant, the syringe line required an even higher level of air quality. The result is a clean room where access requires workers to pass through two gowning stations. Clothing and shoes are replaced with smocks, crocs, and goggles.

On the inside of the cleanroom the modular Bausch & Strobel syringe line is shrouded by a clear plastic curtain that keeps the air immediately surrounding the line at the highest air quality and pressure within the plant, meaning that air will flow away from the line and out of the room, and any chance of particulates blowing into the room is removed. Pressures across the plant are monitored and if the pressure gradient changes so that air is flowing back into the clean rooms, a shut down procedure is initiated and line cleaning takes place.

## Walk The Line

The Schott plant in St. Gallen, Switzerland forms the syringe glass barrels and delivers them to the Lebanon facility in Rondo trays holding about 20 units each. The goal now is to get the syringes cleaned, sprayed with silicone, capped, packaged and sterilized — ready for biotech companies to fill.

The first of the line's three major components simply removes the syringes from the Rondo trays and feeds them into the clean room and onto the wash line, where they are sprayed inside and out with WFI and then dried vigorously with compressed air.

As the syringes come off of the wash line they are fed into nests and tubs and covered with a  protective Tyvek sealing foil. A tub sealing system uses heat to seal the foil onto four tubs at a time. Each tub is then sealed in a labeled bag. This is where the automation ends, and line workers pass the packaged tub through an air lock into a storage area.

**Quality Control**

The porous material used to package the syringes allows them to be sterilized after packaging using an ethylene oxide sterilization process. But before and after sterilization, quality control procedures are undergone to ensure the product meets manufacturing requirements.

Samples are taken at regular intervals during production runs and after sterilization to verify that all quality attributes are acceptable, and the product is ready to ship. In the event that a customer has any questions on material or product quality, recording processes allow for full traceability of the product and materials used during production.

In the end, a forward-thinking approach to plant infrastructure puts Schott in a position in which expansion is more of a relief than a headache. And proactive planning is not by itself the recipe for success: Big aspirations—made apparent by the ability to expand operations well above 100 percent of market demand—also play a part.

By monitoring the marketplace and being flexible with its product portfolio, the company is able to take advantage of growth opportunities as they present themselves, even in a less than favorable economic climate.