



V.A.R.I. produces millions of 20 mm valves for pharma aerosols a year in ISO class 7 cleanrooms.

# Decisive Cleanroom Competence

**TURN-KEY  
INSTALLATION BY  
ENGEL GUARANTEES  
PRECISION,  
EFFICIENCY AND  
PEACE OF MIND**

**W**hen it relocated to larger premises with a new cleanroom for injection moulding operations, Oggiono, Italy-based pharmaceutical valve manufacturer V.A.R.I. opted to switch to a turn-key Engel injection moulding package.

V.A.R.I. is a leading global manufacturer of valves and actuators for pharmaceutical aerosol products. The manufacturing process is highly complex — in terms of

both moulding and assembly. Every new type of medication recipe requires a new valve design, so the process must be flexible yet highly precise. The fact that the valves are only 20 mm in size means that a special gripper had to be designed for automated handling. Given the heavy regulation required for pharma inhaler devices, the entire moulding and assembly process must take place in an ISO 7 cleanroom. And the fact that several million valves are produced each year, the

production lines must be capable of mass production while maintaining strict accuracy tolerances.

V.A.R.I. operates a modern production site covering 6,000 m<sup>2</sup> — including 1,500 m<sup>2</sup> devoted to cleanrooms, a laboratory of 300 m<sup>2</sup>, and 900 m<sup>2</sup> of office space. The new factory was built from scratch in 2009 and is equipped with “ultramodern” positive-pressure HEPA filtered cleanrooms with fully electric Engel e-motion injection moulding machines with a clamping force of 100 tonnes, each with a HEPA laminar flow box above the clamping unit. All servoelectric drives are fanless and entirely encapsulated, as is the injection unit. The completeness, size, functionality and dosing capacity of all the valves produced can be checked directly on the assembly lines. The valves are also laser-coded for full traceability.

When the factory was built, Engel outbid rival injection moulding machine suppliers to provide a turn-key installation service — they delivered the presses, the automation systems, the laminar flow boxes and the mould change system as well as all the necessary documentation for the cleanroom equipment (with the EverQ certificates) in line with good manufacturing practices (GMP).

**Design**

Every time a new recipe is developed, the valves must be adapted to suit the new pharmaceutical mix. V.A.R.I. has its own laboratory and engineering departments to cope with these requirements.

**Manufacturing**

V.A.R.I.'s cleanroom for injection moulding production is the heart of its production operations. Five Engel e-motion fully electric injection moulding machines were commissioned here in late 2010. According to Giovanni Corti, V.A.R.I.'s Oggiono plant manager: "Fully electric machines ensure extremely clean operation and at the same time a high level of precision, and we need this for automated assembly downstream."

Engel claim their machines achieve highly



sensitive mould protection thanks to a combination of a fully electric drive system, highly accurate position measurements with absolute encoders, high precision linear guide rails for accurate movements and Engel's autoprotect software.

All machine movements are controlled by servoelectric drives, from injection and metering through to the mould and the ejector. This ensures a high degree of efficiency, with virtually no energy consumption while the machine is idle. The servodrives have a central energy supply where braking energy is recovered as electric energy and fed directly back into the power grid. Parallel motion of all drives reduces the dry cycle and cycle times, thus additionally improving efficiency.

**Outbidding competing suppliers**

Although V.A.R.I. was already using Engel machines at V.A.R.I.'s former site, they reckon it was not merely a matter of course to continue working with them for the new installations. Quotations from several machine manufacturers were examined and talks were held, with Corti paying attention to one thing in particular: the manufacturer's cleanroom competence. "As plastics processors we ourselves have only limited experience in the pharmaceutical field," Corti points out. "We have to trust, absolutely, in the machine manufacturer's experience and know-how." Corti appreciated the proximity of Engel's Italian

**Engel provided a turn-key service — including the presses, automation, laminar flow boxes, the mould change system as well as all the necessary documentation for the cleanroom equipment in line with good manufacturing practices (GMP).**

subsidiary in Vimercate, just half an hour's drive from Oggiono, as well as the expertise from Engel's dedicated medical business unit, headed up by Christoph Lhota in Austria. The staff of Engel Italia were just as familiar with the details of the project as Schwertberg. "Whenever I called with changes in the planning phase, everybody immediately knew what I was talking about," says Corti.

### Turn-key supplier, including EverQ certification

To avoid wasting time during the planning and commissioning stages, Engel was entrusted — as a turn-key supplier — with the delivery of the e-motion presses, the automation systems, the laminar flow boxes and the mould change system. The turn-key package also included the documentation for the cleanroom equipment (with the EverQ certificates) in line with good manufacturing practices (GMP). "Not every machine builder is capable of supplying the required documentation scope," comments Corti, "you really have to take a very close look at the offers at the bidding stage."

### A cleanroom in the cleanroom

At the new Oggiono factory the Engel e-motion machines are installed in an ISO 8 cleanroom. The clamping units on all of the e-motion presses are encapsulated and equipped with laminar flow boxes incorporating HEPA filters rated to Class ISO 7, just like the adjacent cleanroom where the valves are assembled. "The laminar flow boxes are totally custom built," emphasises Christoph Lhota, "we collaborated with our partner Max Petek Reinraumtechnik to come up with a custom solution here."

### Uniquely designed grippers

Each injection moulding machine is equipped with an Engel ERC 23 robot which takes care of part removal from the mould. The grippers were designed individually to meet the requirements of valve production, as a standard solution would not have been suitable for handling small parts with diameters of between 2 and 20 mm. After removing the parts, the grippers deposit them on a conveyor belt

When patients complain of allergies or asthma, sore throats, or runny noses, aerosols are increasingly the medication of choice. Sprayed into the mouth or nose, they typically act more quickly than other forms of administration. Modern applicators make use easy for the patient. The aerosol is stored in a handy aluminium container with a valve onto which the mouthpiece or nosepiece is placed. When the patient pushes the two parts together, a defined volume of the medication is expelled at each stroke. This simple principle is the result of a huge amount of engineering know-how, because the pharmaceuticals industry insists on the dosage remaining constant from the first to the last spray stroke. The plastic valves on the medication container are decisive in achieving this.



integrated into an ISO 7 enclosure. The conveyor belt transports the individual components through an air lock into the neighbouring intermediate storage. From this point on, the ISO 7 standards are complied with throughout.

### Cleanroom quality control

The intermediate storage fulfils several functions. This is where the quality control areas for the moulded parts are located and the individual components are packed for final transport to the assembly line in a third cleanroom near the other two. The valves are assembled in a fully automated process. The tolerance for the moulded parts is between 0.02 and 0.05 mm, a requirement which the fully electric ENGEL e-motion machines fulfil with ease. ■■

**The laminar flow boxes are totally custom built, emphasises head of Engel's Medical Plastics Business Unit, Christoph Lhota. We collaborated with our partner Max Petek Reinraumtechnik to come up with a custom solution here.**