News

STERILINE & BESS PRO TOGETHER FOR A NEW POWDER FILLING LINE: WHEN THE IDEAL SOLUTION COMES FROM DEEP SPECIALIZATION AND LONG EXPERIENCE

A turnkey solution to radically improve production volumes provided in only 10 months despite COVID-19 pandemic.

Steriline, a highly specialized manufacturer of complete lines for the aseptic processing of injectable drugs, recently successfully delivered a new line to **bess pro gmbh**, a Berlin located company part of the **bess group**, manufacturing and distributing high-quality devices and medical products 'Made in Germany'.

bess pro works on a range of packaging and R&D processes, including sterilization, sterile packaging, secondary packaging and also on innovations and further developments of products in the fields of head & neck surgery, pneumology and gastroenterology, working on about 1,000 different types of medical devices and pharmaceutical products with **very small batch sizes**.

The request for Steriline included then the substitution of manual and laboratory machines with **more performing and reliable automatic solutions** with an **extremely small footprint**. They specifically needed a new complete line including a new **Powder Filling, Stoppering and Capping Machine** (**PVFCM50**) under **Laminar Flow** but also a **Rotary Washing Machine** (**RA-V4**) and a **Depyrogenation Tunnel** (**ST0**).

Steriline provided a **turnkey line, fully operating** and ready to perform at full capacity, including training and validation assistance in approximatively 10 months, from the order to the line installation, starting with technical discussions, pre-testing, and trials until the order placement phase.

One of the major challenges was the design of the **PVFCM50** under **Laminar Flow Hood**, taking into consideration the newest filling process requirements: in line transport and small width, reduced volume to be monitored and sterilized, and the need for operators to reach any point of the machine by gloves.

After the final agreed layout, the continuous monitoring of the viable and non-viable particles is provided, together with a 100% IPC (In Process Control) of the weight and a check weighing system with feedback to the powder filling station. The stoppering process is performed by a vacuum assisted Pick & Place system while the capping by a particle less rotary blade system. A sensor detects stopper and cap presence and consequently the machine rejects all un-stoppered vials as well as those with nonconforming product weight. Steriline PVFM can handle to 200ml vials with minimal format changes and production speeds up to 200 vials/min, according to vial size and filling volume.

Furthermore, a highly accurate dosing process was needed to handle and dose powder extremely gently for vials' filling. Steriline projected and designed then a **special Auger Filling Head** equipped with a customized screw shape added to the PVFCM50 to protect product integrity. In this way, the extraordinary accuracy requested for the specific filling process could be achieved not compromising at all the very sensitive product handled.

The Powder Filling Machine was also equipped with a 100% check weight system. Several trials were performed, practically testing filling vials with several different Auger Filling Heads dimensions, and hundreds of samples were produced to understand product stability. In the end, unexpected results showed that the new Auger Dosing Head was definitely even accurate than expected.

«*Steriline distinguished itself already during the supplier's selection by fast and binding communication and never let us down in this respect, during the further course of the project.* – affirmed **Martin Gördes, Chief Technical Officer at bess pro gmbh** – *Special customer-oriented solutions, such as a special receptacle for the powder hopper to integrate specialized upstream manufacturing processes of the drug substance, were implemented excellently*».

Thanks to this solution, small batch sizes production is now possible, while always keeping low average consumption and purchase costs. The entire line cycle can now run automatically, without any human interfering. Furthermore, the process has been demonstrated as secure according to GMP and the output, in terms of production, has been significantly increased.

«*The area of R&D is very challenging with clients asking for support when there are new drugs to develop* – commented **Mirko Ebeling, Managing Director at Ebetech GmbH**, Steriline Sales and Service Organisation for German territory – *We usually work to customize our standard solutions or to develop new ones following specific requirements and this was exactly the case with bess pro*».

«*The collaboration with the Steriline project team was incredibly motivating, always responsive and solution oriented* – concluded **Martin Gördes** – *and it is therefore hardly surprising that this project was completed without any significant delay despite the pandemic*».

In this regard, Steriline provided two alternative solutions for Factory Acceptance Test (FAT) virtual procedure, always available in live streaming mode or also recorded and released later for client revision and acceptance. Despite all this, after the lockdown and pandemic's first wave in Italy, bess pro technical team felt confident in performing FAT tests in person, not virtually, for one week in Como.