

CREATIVITY, RELIABILITY AND FLEXIBILITY. AS THE KEY TO FOLLOW PHARMA MARKET TRENDS AND BUILD FRUITFUL RELATIONSHIPS

A promising partnership around the project and design of R&D machines: Steriline and Ferring Pharmaceuticals case study

Como. February 17, 2020 - Steriline, a highly specialized manufacturer of complete lines for the aseptic processing of injectable drugs, started a new promising collaboration with **Ferring Pharmaceuticals**, a research-driven company, leader in reproductive medicine, maternal health and in specialty areas within gastroenterology, urology, endocrinology and orthopedics. Founded in 1950, Ferring Pharmaceuticals now employs more than 6,500 people worldwide, has its own operating subsidiaries in nearly 60 countries and markets its products in 110 countries. The company invests heavily in the process of creating new medicines through its research and development centers and research collaboration with scientific institutes as well as biotechnology and pharmaceutical companies throughout the world.

Steriline and Ferring International PharmaScience Center (IPC) in Copenhagen started their partnership in **June 2017**, with the technical assistance of **Jacobs Engineering Milan**, to satisfy the pharmaceutical company's R&D needs of a **small-scale customized Vial Capping & Decontamination Machine** for high potent freeze dried drugs processing, and a **small-scale External Washing Machine** for vials and cartridges.

Steriline developed the project of a flexible and small-scale solution, different from all those proposed by competitors, including a customized monobloc constituted by a **Vial Capping Machine (VCM50) & External Decontamination Machine (EDM-C)**, with the new application of a **transfer shuttle** for moving vials from the freeze drier to the capping machine, and a Robotic washing machine for vials & cartridges. The compact design of both machines was perfectly suitable to work under cRABS with common pressure control from EDM-C. Thanks to a continuous and open dialogue, the Steriline-Ferring-Jacobs team succeeded in finding solutions to all different challenges they faced, as for example through a joint study for the application of a PUSH/PUSH filter, providing a safer filter change procedure from the inside of the EDM-C due to space constraint. *«We experienced a good and open collaboration between three companies, Steriline, Jacobs Engineering and Ferring IPC – stated **Anders Magnusson, Senior Scientist & Project Manager, Pharmaceutical Development, Ferring IPC** – Together we found the way to develop good engineering solutions focused on functionality, flexibility and personal safety».*

Nevertheless, the bigger challenge came out when the proposed Standard Washing Machine (RA-V4) was still over dimensioned for Ferring batches size. Steriline insisted and proposed the prototype of a machine specifically studied as an alternative solution: a **miniature Robotic Washing Machine (RL-1)** capable of handling vials and cartridges loaded from trays. In fact, through open dialogue and ongoing guidance to the client, Steriline met Ferring expectations in regard to flexibility, price and delivery.

During the project lifecycle some problems occurred but even the RL-1 machine redesign was finally carried-out without any specific issue. The whole project implementation, from the kick-off meeting until the end of the Site Acceptance Test (SAT) took only 18 months: an exceptional timing considering

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all risks for designing, developing and evaluating prototypes for this kind of new customized machines. *«Developing novel equipment is known to be a challenging process. – affirmed **Helena Nicklasson, Vice President Global Product Development & Drug Delivery, Ferring IPC** – However, with the good collaboration of the three companies, the equipment is now in-use and I am confident that it will improve and increase the efficiency of our development process for new drug products».*

All this was made possible thanks to Steriline's accurate and widespread assistance and training service, so project teams showed an exceptionally striking cooperation attitude. *«The area of R&D is very challenging with clients asking for support when there are new drugs to be developed. – declared **Federico Fumagalli, Chief Commercial Officer at Steriline** – Then, we usually work on customizing our standard solutions or on developing the new ones according to the specific requirements. And this was exactly the case with Ferring».* Steriline has proven to be the perfect partner to design and plan together new solutions to satisfy all client's requirements, as happened for the specific case of miniature washing machine. When it became clear that a part of the project was being questioned, Steriline carried out the designing of a machine that would have solved the problem and perfectly fit with production and space requirements.

ABOUT STERILINE

Steriline is a well-established European manufacturer highly specialized in the production of complete lines for the aseptic processing of injectable products, supplying pharmaceutical companies worldwide.

Steriline was founded in 1989 in the Lake Como area (Italy) where its headquarters and manufacturing facilities are still based. With operations in over **50 countries** around the world, Steriline has a network of over 180 people, including direct employees and external partners in addition to 40 local sales representatives. Export represents more than 90% of Steriline's turnover with over 1,300 machines installed throughout **Asia, Europe, and the U.S.A.**

Steriline develops, manufactures and supplies a comprehensive range of solutions, including **both mechanical and robotic applications for the aseptic processing**. These applications are consistent with vials, ampoules, cartridges and syringes and can handle toxic or non-toxic products in both liquid and powder form. Steriline's **complete lines** include equipment spanning from washing machines, depyrogenating tunnels, filling and capping machines to external decontamination machines and barrier systems such as LAF, oRABS, cRABS and isolators.

For more information about **Steriline**: www.steriline.it or visit the Company profile on **LinkedIn**.

For more information about **Ferring Pharmaceuticals**: www.ferring.com/

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