

STERILINE UNVEILS NEW ROBOTIC VIAL FILLING MACHINE AT CPHI MILAN 2024

Como, Italy -2^{nd} September 2024 - Steriline, a leading Italian manufacturer of highly specialised production equipment for the pharmaceutical industry, will be showcasing its latest innovation at CPHI Milan ($8^{th} - 10^{th}$ October). The new **Robotic Vial Filling & Capping Machine** (RVFCM11-S) will be displayed at the Steriline stand at CPHI (A42, Hall 18). This cutting-edge machine is poised to attract pharmaceutical professionals and companies eager to enhance production efficiency and maintain compliance with stringent industry standards.

RVFCM11-S: Enhancing Sterility and Efficiency

The RVFCM11-S is an advanced robotic solution specifically designed for the primary packaging of cell and gene therapies. With an exceptionally compact footprint of 2.25m by 1.65m, the machine operates with nested 2R, 6R, 8R and 10R vials and can also be configured to fill Pre-filled Syringes (PFS) and cartridges. Equipped with a single filling head connected to an aseptic peristaltic pump, a single stoppering head, and a single capping head, the RVFCM11-S utilises two Stäubli Stericlean Robots for the discrete handling of primary containers with zero glass-to-glass contact. The machine features a double-wall isolator that minimises the risk of contamination and is integrated in the structure of the machine.

The process begins with a manual de-bagger and a de-lidder station, followed by the loading of empty vial trays into the filling zone via a conveyor belt. The vials are then removed discretely by the use of magnetic levitation, presenting each vial to the robot arm. They then proceed to the filling station, where an integrated check-weigh system (aligned with Steriline's zero-loss philosophy) ensures precise filling. Once filled, the vials are moved to the capping station.

In a seamless movement, the second robot arm handles capping and places the vials back into the nest. The capping process is monitored and controlled by machine vision, ensuring each filled vial is accurately sealed.

Production Capacity and Storage Compliance

The RVFCM11-S boasts a production capacity of **15 nested vials, syringes or cartridges per minute**. Additionally, its design includes **software-based tracking features to ensure that temperature-sensitive products do not exceed the time limit in the solution**, preserving their pharmacological efficacy.

Meeting the Needs of Cell and Gene Therapies

"Our new RVFCM11-S addresses the specific challenges associated with the production of cell and gene therapies, where sustainability is often determined by product loss," said James Rorke, Vice President of Operations at Steriline North America. "The entire supply chain can now benefit from a solution that ensures minimal loss, a high degree of sterility assurance, and compliance with Annex 1 requirements."



Federico Fumagalli, Commercial Director at Steriline, added, "Steriline remains committed to developing innovative pharmaceutical packaging solutions. Our aim is **to advance the industry by providing more efficient systems** that optimise the production process for the greater good."

ABOUT STERILINE

Steriline is a well-established European manufacturer, highly specialised 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 300 people, including direct employees and external partners, in addition to 40 local sales representatives. Exports represent more than 90% of Steriline's turnover, with over 2,000 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 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 ranging from washing machines, depyrogenation 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's profile on Linked in

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