



Automated Filling Line for commercial production

The Crystal™ L1 Filling Line enables the scaling-up strategies of biopharmaceutical companies globally. This automated equipment is designed to perform filling of stability batches, clinical batches and mid-size production.



Compliance

Fully compliant with cGMP requirements and CFR 21 part 11, the Crystal™ L1 Filling Line is able to process the complete range of the ready-to-fill AT-Closed Vial® from 1ml to 50ml.

Automation

This automated Filling Line can fill up to 500 AT-Closed Vial® per hour, filling an entire AT-Nest™ without any manual intervention.

Adaptability

The Crystal™ L1 can be combined either with active Restricted-Access Barrier System (RABS), or with a SKAN Cellana isolator.

Using a six-axes robot for the operations, the format part are reduced to the minimum and change over time from batch to batch is very short.

SKAN Group technology

As a member of SKAN, we put together our 20-year expertise and SKAN's state-of-the-art isolator technology to bring you the integrated isolated Filling Line Cellana L1.

RABS

Minimal footprint

The Crystal™ L1, when combined with an active Restricted-Access Barrier System (RABS), provides the enclosed controlled environment for aseptic filling process with a minimal footprint.

- To be installed in a Grade B environment
- Reduced footprint
- CFR 21 Part 11 compliant
- AT-Port™ for fluid transfer
- Active Laminar Air Flow (LAF) or mousehole for material transfer
- Installed and qualified in one week

Relying on the Aseptic Technologies single-use materials and the AT-Closed Vial® of various formats, the Crystal™ L1 in RABS provides flexibility in cGMP fill & finish operations, while saving space in the manufacturing site.



Cellana L1

Highest sterility assurance

Combining Aseptic Technologies Filling Line and SKAN isolator, the Cellana L1 allows aseptic processes to take place quickly and safely within the highest sterility conditions.

- To be installed in a Grade C or D environment
- Integrated automated skanfog H₂O₂ decontamination system
- CFR 21 Part 11 compliant
- AT-Port™ for fluid transfer
- SARA (SAfe and RAPid decontamination airlock) for material transfer

The Aseptic Technologies L1 Filling Line is an automated filling line for AT-Closed Vial® with high filling accuracy, which reduces contamination risks with its unique AT-Closed Vial® technology.

Combined with the L1 technology, the Cellana L1 filling system ensures the safety and efficiency of aseptic processes.



Enabling

Quick, safe and easy fill & finish

The bulk product container, remaining outside of the RABS or isolator, is connected to the operating area with the AT-Port™ System, the aseptic liquid connector. Through the selected material transfer system of the equipment, the nested ready-to-fill AT-Closed Vial®, and other single-use material, are introduced to the critical area, where prepared for operation.

The operator positions the AT-Nest™ and prepares the fluid path, rendered possible with the AT-Filling Kit™. Activated from the HMI, the clean 6 axis robot then initiates the closed vial filling process.

Commanded from the Human Machine Interface (HMI), the aseptic filling line is calibrated to achieve high dosing accuracy.

The high-class cleanroom 6-axis robotic arm then begins the closed vial filling process, consisting of 3 steps: each AT-Closed Vial® is first filled through the stopper with a special non-coring needle, then laser re-sealed and capped by snap-fit. Each operation is performed with a dedicated tool on the robot head.

Once the AT-Nest™ is fully processed, the operator extracts it from the critical area via the exit material transfer system.

Our quality engagements

Validation Master Plan

A full Validation Master Plan with all tests related to the AT-Closed Vial® technology is supplied.

Aseptic Technologies certifications

- ISO 9001:2015: Quality management systems
- ISO 15378:2017: Primary packaging materials for medicinal products

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