

Cellana XL1



Automated Filling Line for production scale-up

The Cellana XL1 addresses the needs of scaling-up the aseptic filling of novel pharmaceutical and biotech products, including cell and gene therapy products, their intermediate products, and other advanced therapies.





SKAN Group technology

As a member of SKAN, we combined our 20-year expertise and SKAN's stateof-the-art isolator technology to bring you this integrated isolated Filling Line.

Automated

The AT-Closed Vial[®] Technology XL1 Filling Line is fully automated. Filling up to 10 AT-Nest[™] of AT-Closed Vial[®] (depending on vial size) without any manual manipulation.

100% IPC of weight

Each AT-Closed Vial[®] is automatically weighed before and after filling, allowing the highest filling accuracy (100% IPC). This is reinforced by the selfdose calibration made by the XL1.

Embrace the future

SKAN isolators are the perfect solution for your aseptic processes, combining increased levels of contamination control and quick ROI, thanks to SKAN's most advanced technologies, and reduced operational and facilities costs.

Ensuring cGMP compliance

The SKAN Cellana isolator creates an ISO 5/Grade A environment with unidirectional airflows and the integrated automated skanfog H_2O_2 decontamination system.

The AT-Closed Vial[®] Technology XL1 Filling Line is an automated filling line for the AT-Closed Vial[®], which reduces contamination risks with its unique ready-to-fill AT-Closed Vial[®] technology.

The XL1 has 100% IPC of weight, meaning each AT-Closed Vial[®] is weighed before and after filling, providing you with the highest level of filling accuracy.

Modular and adaptable to your needs, the Cellana isolator is 21 CFR Part 11 compliant.

With both technologies combined together, the AT-Closed Vial[®] Technology Cellana XL1 filling system ensures safe and efficient aseptic processing.



Enabling Quick, safe and easy fill & finish

The automated XL1 Filling Line allows for quick and hassle-free filling, not requiring any manual manipulation during the process.



The ready-to-fill AT-Closed Vial[®], organized in AT-Nest[™], and other consumable materials are introduced into the main chamber via a rapid decontamination airlock, while the bulk product is aseptically connected to the main chamber of the isolator thanks to the use of the AT-Port[™] system, integrated on the isolator wall. Such configuration allows the bulk product to be homogenized and cooled.

The robot picks up an AT-Nest[™] from the shelf, then picks from it an individual AT-Closed Vial[®] and loads it onto the processing wheel where it will be weighed (empty), filled, laser re-sealed, weighed (filled) and capped. The processed vials are then placed back into the AT-Nest[™] to finalize the fill and finish process.

When all vials from the AT-Nest[™] have been filled, the robot takes another AT-Nest[™] from the shelf and resumes the filling operation.

Offering the best of our joined expertise

SKAN technologies

Combining Aseptic Technologies' most innovative Filling Line and the AT-Closed Vial[®] together with SKAN's specific Cell & Gene isolator, the Cellana XL1 allows aseptic processes to take place quickly and safely within the highest sterility conditions.

The SKAN Cellana isolators offer everything you need to control and operate your ATMP processes. Advanced lab equipment can be integrated directly into the Cellana isolator, creating a complete process solution within a fully compliant manufacturing platform.



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

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

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