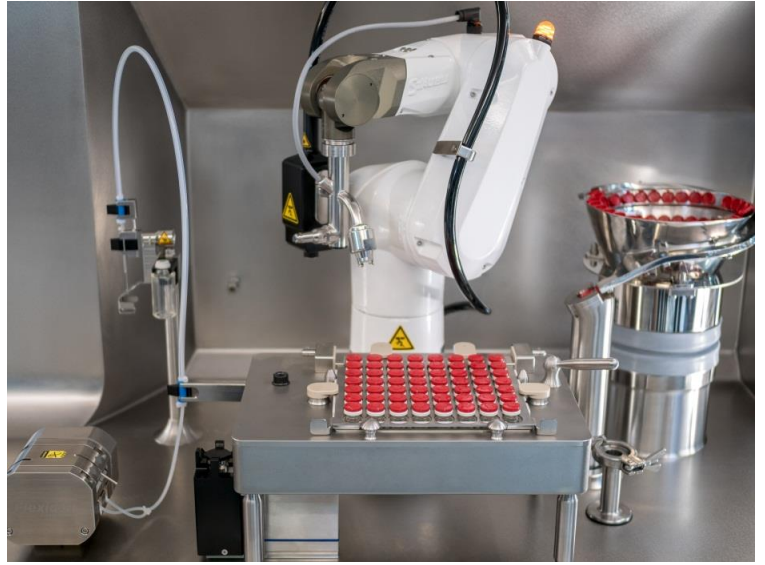


Crystal® L1 Robot Line

The *Crystal*® L1 Robot Line is an automated equipment designed to perform filling of stability batches, clinical batches and mid-size commercial production.



Process

Filling

- Ready-to-fill AT-Closed Vials® are organized in nests, manually positioned and locked.
- Filling performed by the robot, by means of a specially designed needle that pierces the stopper and dispenses the liquid inside the vial.

Laser re-sealing

- The robot places the needle on its support, and activates its laser tool.
- The puncture trace is re-sealed by a laser shot on the stopper surface.

Capping

- Using its third tool, the robot performs capping inside the barrier, by simple snap-fit of a plastic cap.

Compliance

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

Crystal[®] L1 Robot Line: Specification

Applications	Aseptic filling of liquid parenterals, including cell and gene therapy products
Output (2ml vials)	up to 600 vials per hour.
Filling volume	0.1 ml to 50 ml.
Filling accuracy	Typically, 1% (over 1 ml, for water-like viscosity product).
Dimensions	mm: 1392 x 927 x 2475 (RABS arrangement). in: 55 x 36 x 97
Utilities	Electricity only. No water, no compressed air.
Product Path	All single-use.
Materials	AISI 316L for product contact parts. Compatible with classical sanitizing agents, H ₂ O ₂ decontamination.

Versions

- As part of Cellana-L by SKAN, in isolator with H₂O₂ decontamination;
- In active/passive RABS;
- Ready for integration

Entry/exit systems

- H₂O₂ decontaminated airlock.
- AT-Port™ System for drug product;
- RTP (Rapid Transfer Port);
- Mousehole;



Validation package

The Crystal[®] L1 Robot Line is delivered with a full Validation Master Plan of the AT-Closed Vial[®]. The table of content is available on our website in the chapter Compliance > Validation > AT-Closed Vial[®] Technology.