

COMPLETE SOLUTION FOR VIALS

More would be too much

Biomabs is highly satisfied with its mid-range vial filling line. High efficiency is not the machine's only attractive feature. The customer commends the line for its well-engineered process flow which is tailored to their specific application.



Infeed Washer / Sterilization Tunnel



Filling

The first processing step in the Biomabs vial line is cleaning. An infeed turntable transfers the vials to the INOVA WMR 1800 washer, which grasps the vials and flips them 180° in groups of four enabling them to be washed both inside from the bottom and outside. As the needles move with the rotary unit, they are inserted into the vials from the bottom at which time they inject recirculated water to remove any particulate matter that may be in the vials. The final steps in the washing process are air rinse, final WFI (Water for Injection) rinse, and blow drying.

The vials are then transferred to the sterilization tunnel. When they exit the tunnel, they are transferred to a turntable which is the beginning of the open RABS zone with laminar flow.

Versatility – the secret to success

The quad linear INOVA VFVM 10,000 filling and sealing machine has four rotary dosing pumps and dosing needles for filling the vials. The fully automatic quad 100% IPC unit detects the

tare weight of the vials and then checks the gross weight after filling. The functionality of the IPC goes beyond quality control. It is also used to correct drift in the rotary dosing pumps and optimize filling accuracy. Ionization is provided in the weighing zones to prevent build-up of electrostatic charge, which could otherwise falsify the weighing result. The line also has a unit to inject inert gas (nitrogen, etc.) into the vial headspace before and after filling just prior to sealing. This is done to protect the product from oxidizing.



Sealing on the INOVA VFVM 10,000 is performed by a quad unit which inserts the stoppers. The stoppers are fed to the sealing unit from a sorting bin and transferred to the vacuum gripper which secures the stoppers and pushes them into the vials. An optical check ensures that the stopper is present. Unsealed vials are rejected. The rotary INOVA VVM 2428 crimping machine receives the caps from a sorting unit. An optical check ensures that a crimped cap is present, and any rejects are removed from the process. All products that successfully pass the checks leave the line and are placed into trays. The filled and sealed vials are manually unloaded.

In a second operating mode during the sealing process, lyophilization stoppers are placed onto the vials but not fully inserted. A feed and discharge turntable located between the stopper placement and crimping unit provides the flexibility to integrate freeze drying into the process. The freeze-dried pharmaceuticals are returned to the line where they pass through the crimping machine and on to the discharge trays.

A moveable conveyor belt which allows the operator to easily move between the front and rear of the machine



Sorting / Stopper insertion / Discharge

in the customer's sterile room is one of the line's special features. It is only a minor design aspect, but it can make the operator's job a lot easier in day-to-day operation without the need to interrupt the production.

Simply good

Biomabs placed the order for this system along with the syringe line (shown on the preceding double-page spread), at the beginning of January 2010. Acceptance of the vial line took

place at Optima Group Pharma on October 22nd – 26th. The results of the FAT were very impressive. Efficiency exceeded 98% during the test runs. The customer, who is aware that this level of performance cannot be taken for granted in today's market, was highly satisfied.

Two operators deliver vials and stoppers to the line, which is designed to handle 2R, 4R, 15R and 20R size vials. Changeover takes about 30 minutes. The medium-range line has a maximum throughput of 12,000 vials/h. ●