## IMA Freeze Dry Drug Medication Packaging Manufacturing Dispensing Production Line.

The filling line for sale consists of the following components and can be used for liquid and lyophilized final drug product. The line was originally designed to be used with Botulinum Toxin but could be utilizied for filling of other potent compounds. The active API portions of the filling line are protected by an open RABS system to allow for worker protection. The filling line can fill vials from 2R to 6R size with minimal to no modification and could be modified to allow filling up to larger vial formats The system has never seen any product and was only commissioned but not validated and never used with Botulinum toxin active product.

## **Components**

The IMA Life Vega rotary washer used to wash the interior of vials for non-aseptic filling. The washer is capable of speeds up to 250 vials at a 2R vial per minute (VPM). All components in the system are designed to operate at the 250 vpm filling speed. The machine could be adapted for aseptic vial washing.

http://www.ima-pharma.com/Product/EN/Products-F575/Aseptic Processing and Freeze Drying-S633/Washing%2fBlowing%2fSterilizing-T634/Vial\_washing\_and\_decontamination\_technology-Q636/Rotary\_vial\_washers\_\_\_VEGA\_Series-M56.html



The air blade dryer is used to internally dry 2R vials post internal washing. Conveyors run between each of the individual components to allow for automated operations.

The Extrema F2000 Filling/stoppering machine allows for 2R vial filling up to 250 vials per minute in its current configuration. The unit is served by (6) lvek precision surgical pumps for accurate filling to 0.2 mL to 10 mL. The system also automatically stoppered the vials prior to Lyophilization. The automated filling line can be utilized for liquid only filling in its current configuration if Lyophilization is not needed.

http://www.ima-pharma.com/Product/EN/Products-F575/Aseptic Processing and Freeze Drying-S633/Aseptic Processing-T638/Liquid filling and stoppering-Q640/In line filling and stoppering machine XTREMA-M63.html



(2) IMA Lyophilizer Lyomax 17 sq. M Lyophilizers for use with potent product. EWac Lyo has redundant safety systems for Lyophilization of potent product including toxin/cytotoxins , and ADC.



Two independent compact loading systems are used to automatically load and unload vials from the 17 Sq. M. lyophilizers

http://www.ima-pharma.com/Product/EN/Products-F575/Aseptic\_Processing\_and\_Freeze\_Drying\_ S633/Freeze\_Drying\_Equipment-T646/Industrial\_freeze\_dryers\_ Q647/Industrial\_freeze\_dryers\_\_LYOMAX-M69.html

The ALU400 Capper is utilized to cap the vials post Lyophilization. The system is designed to operate at speeds up to 300 vpm in case the line would be utilized as a liquid filling line only.

http://www.ima-pharma.com/Product/EN/Products-F575/Aseptic\_Processing\_and\_Freeze\_Drying-S633/Aseptic\_Processing-T638/Alu\_capping-Q644/Rotary\_capping\_machines\_\_\_ALU\_Series-M68.html A Hydra 300 external washer rinse the outside of the vial neck down post lyophilzation to ensure no carry over from the Lyophilization process. This system is designed for operation up to 300 vpm.

http://www.ima-pharma.com/Product/EN/Products-F575/Aseptic Processing and Freeze Drying-S633/Washing%2fBlowing%2fSterilizing-T634/Vial washing and decontamination technology-Q636/Decontamination technology%3a external vial washers HYDRA 100 and HYDRA 300-M57.html

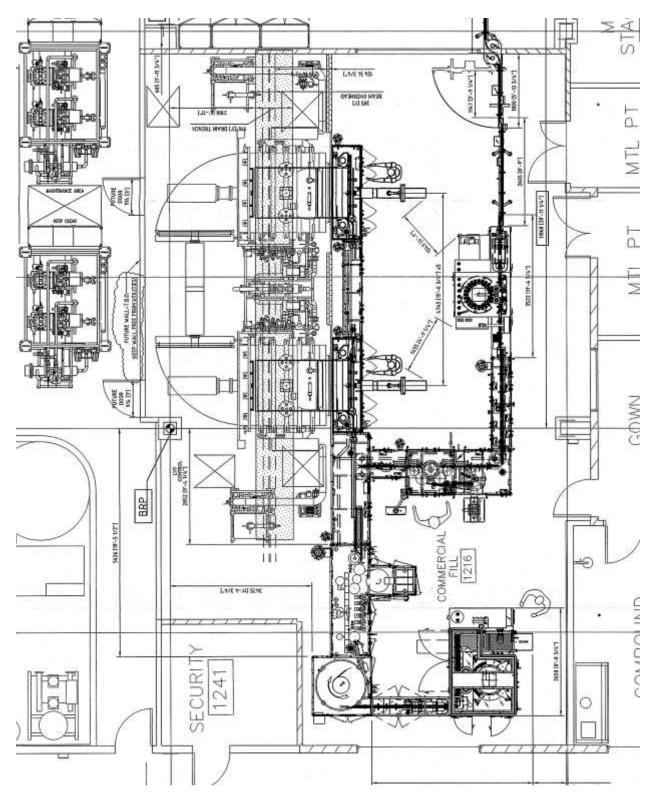


The filling line employs an open RABs (Restricted Area Barrier) system from the Extrema Filler to the Capper to allow use with potent products. This system utilizes negative pressure relative to the room environment to protect workers from the product being filled.

http://www.ima-pharma.com/Product/EN/Products-F575/Aseptic\_Processing\_and\_Freeze\_Drying-S633/Aseptic\_Processing-T638/Barrier\_technology-

<u>Q645/Barrier\_technology</u> <u>Open Active RABS and Open Passive RABS (Restricted Access Barrier</u> <u>System)-M242.html</u>





Complete commercial line layout

## Actual pictures















Original acquisition cost was slightly over 8M. Wait time to get similar line from IMA is over a year!

Line was just installed and never been in production. Located in FDA licensed/approved biotech facility. Available for full inspection. Will be professionally crated/disassembled prior to shipping at seller cost we will update information and provide actual pictures shortly. Video of line in test operation can be downloaded per request.