

## High tech turnkey for pharma Optima at Achema 2012



**Outstanding technical details on turnkey lines distinguish Optima's equipment for filling, closing and packaging of pharmaceutical products. Isolators, freeze dryers, flexible and compact machines as well as equipment for diagnostics are all included in the product range.**

A **complete Optima line for vials** encompasses all process steps from unpacking to tray loading of processed vials. Isolators and the freeze drying process are also components of the line. Numerous customized solutions have been integrated. A 100% IPC and the stopper re-setting process maximize product usage. The M+P isolator uses H<sub>2</sub>O<sub>2</sub> to sterilize the machine cabin. With the use of catalytic aeration, considerably shorter sterilization cycle times can be achieved. When in production the isolator operates at an ISO 5 environment. Never leaving laminar flow areas, vials are transferred via a turntable to one of 6 Klee freeze dryers to achieve the most flexible loading configurations. The same path is followed by conventionally stoppered vials. A combination crimp cap and coding machine and final tray loading complete the Optima equipment. Processes are monitored by numerous optical inspections, while the environment is continuously monitored for the presence of airborne particles and viable organisms. Outside of the isolator, a disposable product path provides an assured product path sterility and zero risk of cross contamination.

Interactive and 3D: The Optima **3D Box** at Achema offers visitors the opportunity to experience virtual reality and to “dive into“ filling and packing machines. A total of 5 projects have been prepared for the 3D Box.

First on the tour is a specially designed line for fully automatic high speed filling and stoppering of sensitive biopharmaceutical gels into ready-to-fill syringes. Even the entire HVAC for the customers' production rooms was designed and delivered by Optima. In the mid output range: Ionization, IPC, and nitrogen gassing for reducing the oxygen content and optical monitoring, are all integrated into another vials processing machine. Filling and packing of diagnostic products: A Kugler Linoline fills 12 cavities of a cartridge. Twelve servo driven peristaltic pumps dose 12 different liquids with 12 different volumes. A total of 13 weigh cells successively net weigh and gross weigh each filled cavity, so as to gain 100% IPC. Light sensitive products can be filled in complete darkness. These projects, as well as a Klee freeze drying unit and an automated loading and unloading system, will be presented to you in the 3D Box.

The real thing: Tangible machines at Achema include the **Inova SV125** in modular construction. This machine counts as being extremely compact and flexible. Equipped with isolator technology, the highest levels of sterility are achieved. The SV125 can be made to process both pre-sterilized nested syringes, as well as nested vials. Two or five filling stations can be integrated. A selection of filling systems, including rotary piston pumps, peristaltic pumps, mass-flow metering, and time-pressure filling can be used. The filler can be rounded out with tertiary equipment such as an automated de-bagger or Tyvek removal for full line automation.

The **Kugler Linoline** is a machine platform also specially suited to covering a large range of formats. The Linoline presented at Achema is capable of dosing small volumes (1 mL) right up to 1000mL. Typical bottle diameters range from 16mm up to a maximum of 95mm. Rotary piston pumps are used for dosing small volumes, while peristaltic pumps are used for volumes as of 50mL. The design allows for filling of 2-stage component products; allowances are made for the installation of additional weigh cells. Further features include pre-torquing, final torquing with an integrated torque monitoring system, vapor extraction at each filling station, and improved size parts for an even faster format change at the capping station.

**Klee** is showing its' **freeze dryer pilot** plant which was originally designed for performing freeze drying trials, with the capability of being reconfigured for production purposes. The design allows manual loading and unloading under an isolator. The freeze drying chamber can be VHP sterilized. A special device at the rear of the machine allows the stoppers on individual vials to be pressed in during the process to monitor progression of lyophilization at different stages during a test batch. The total usable area on the 3 shelves is 0.6m<sup>2</sup> and is set up for vials sized 2R to 200H. Batch sizes are between 2,429 and 207 vials.

The **M+P lab isolator** allows weighing and formulation of products to take place in a protected environment. The access doors are pneumatically sealed. Four integrated gloves give operators access to the pressure controlled zones. Adapter ports ensure compatibility to different port mechanisms.

The **Medicon ImmuCoat®** unit on display at Achema, will be fully functional. The modular and scaleable system consists of different units for fully automated coating of microtitre plates. The base station for 6 to 12 process modules which can be individually configured, will be on display with dosing and washing modules. These can also be complemented with different print and monitoring systems. Additionally, a fully climatized incubator / drying

module and final packing module are on display. The output is up to 1,200 plates per hour.

**Optima at Achema Frankfurt am Main, 18. - 22.06.2012: Hall 3.0, Booth A73**

**Optima information:**

Since its founding in 1922, continuous growth has accompanied this mid-sized family business. With over 1400 employees worldwide, Optima Group has consciously built customer focus by dividing the different business units according to their markets. Optima technologies are in demand worldwide, resulting in an export quotient of 80%. Highly reliable and innovative equipment for packaging single-serve solutions for coffee, packaging and palletising of paper hygiene products, turnkey systems for the pharmaceutical industry and flexible equipment for modern manufacture of wound care products are synonymous with the Optima name.

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