

Newsletter 6 - November 2014

## MG2 and Hovione, low dosages and extreme precision

*MG2, Bolognese leader in the design and manufacture of capsule fillers and end-of-line solutions, employed its competences in order to develop inhalation drugs.*

### The protagonists of the story

Hovione has been working for more than 50 years on the global market, thanks to its four production facilities, FDA approved, located in the United States, China, Ireland and Portugal. The company, which pursues very high quality standards as for its products and services, is specialized in all drugs' development and production phases, with a special knowledge in the field of inhalation drugs. The partnership between Hovione and MG2 was born to improve the development of drugs into hard shell capsules to be used with inhalators, also thanks to the increasing market requests. The Portuguese company was in need of a solution for all development and approval phases of a very low dosage drug.

### MG2's solution

The product to handle featured particular physical and technological properties, such as limited flowability and marked tendency to stick to surfaces. Moreover, it was necessary to make different ranges of low dosages, up to a minimum of 5 mg, without compactation. To meet Hovione's requirements, the Bolognese company offered FlexaLAB, a capsule filler specifically designed for R&D laboratories, clinical trials, small batch outputs and special productions. For productions up to 3.000 cps/h, it is based on the same functioning principles as MG2 high speed machines. FlexaLAB can work either at continuous or intermittent motion, depending on the type of dosing unit installed. Thanks to the possibility to install more dosing units at the same time, it enables to make product combinations inside the same capsule, in order to guarantee the maximum flexibility required by Research & Development laboratories and small producers.

The FlexaLAB machine supplied to Hovione is equipped with the MultiNETT system for the 100% in-process net weight control. MultiNETT is the most advanced solution available on the market, as it guarantees the control of each dosed component, with a very high accuracy level which, as for low dosages, is usually reaches +/- 0,5 mg. The system is integrated in the specific unit for low dosages, optimized for powders to be inhaled, which cannot be compressed.

Gonçalo Andrade, Business Development Manager, said “Hovione has a proven track record in the field of inhalation product development. With our core API process development, particle engineering and manufacturing expertise, Hovione produces pulmonary delivery-friendly particles which can then be used to fill inhalation capsules. The acquisition of the MG2 FlexaLAB unit allows Hovione to support capsule filling activities in all stages of clinical development and even low volume commercial manufacturing of inhalation drug products. Customers can now partner with Hovione for a full service inhalation drug development manufacturing, all under one roof”.

### FlexaLAB for containment

A containment version of the FlexaLAB is also available. The containment system features a particular liftable isolator concept, which allows the machine to keep its peculiarity to change different dosing units. This result is obtained while ensuring proper production safety, for both the operator and the environment; in fact, the system allows the machine to satisfy the highest containment class, OEL5, guaranteeing a concentration of active substance - less than 1 µg per cubic metre. FlexaLAB containment version can be equipped with a Wet-in-Place system, which allows to fix powders when the production cycle ends, before opening the isolator. Through the same spray gun it is possible to use both liquids and compressed air. By adding some spray balls and other devices, FlexaLAB is configured for a complete Wash-In-Place system, to further automate the cleaning process. Other optional devices enable to customize the production outfeed to an external container or a continuous liner, as well as the connection to other devices, such as a deduster or a metal detector.

