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**A new DPI device
for the generic
drugs market**

gerresheimer
innovating for a better life

MERXIN and Gerresheimer worked successfully together to realize the shortest possible time-to-market for the MERXIN MRX003 capsule DPI

Gerresheimer has assumed responsibility for the industrialization of a dry powder inhaler for the treatment of respiratory ailments for MERXIN (United Kingdom), a company that specializes in making inhaler devices. The inhaler is produced in our production site in Pfreimd (Germany) for worldwide distribution. Beyond the technically sophisticated industrialization of the product, the main challenge of the project was to coordinate an optimal development process aimed at ensuring the shortest possible time-to-market at lowest cost.

MERXIN MRX003 capsule dry powder inhaler is used for pulmonary delivery and in particular for the treatment of chronic, obstructive pulmonary diseases (COPD) and asthma. The API is aerosolized and distributed with the respiratory system to find its way deep into the lungs of the patient. The correct interplay of inhaler and formulation plays a decisive role in the success of the treatment.



Close cooperation for a fast pace of development

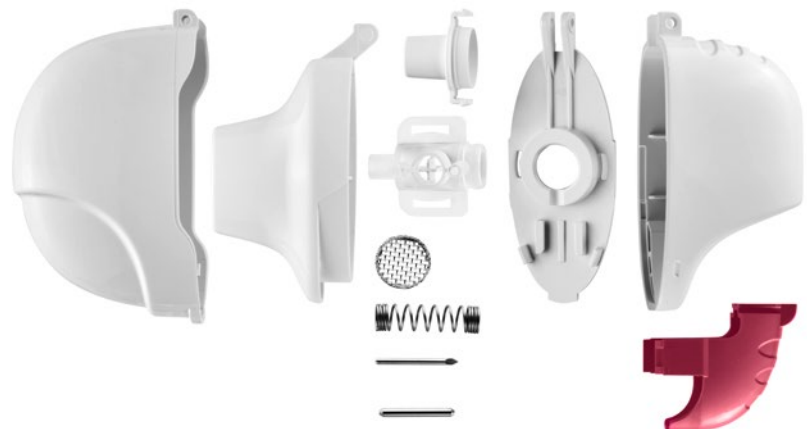
The interplay of device and industrialization drove the cooperation of the partners in the development project. MERXIN Ltd was founded in 2015 and specializes in making inhaler devices. MRX003 is a capsule dry powder inhaler available to pharmaceutical companies globally for the development of finished dosage forms under their own brand names.

The first product target for MRX003 was a generic version of an API. Because of the nature of the generic market, it was of essential to achieve the shortest possible time-to-launch. This was achieved through a close cooperation between the partners. Decades of expertise and know-how in inhaler design and production were combined between Gerresheimer and MERXIN. Jochen Wegerer (Program Manager, Gerresheimer Regensburg GmbH, Wackersdorf) was impressed by the cooperation: "The good teamwork within the project is noteworthy. Challenges were always discussed in a goal-oriented, creative, and open manner, so that approaches to solutions could be formulated and implemented within the shortest time possible."

Robust production processes for a low-cost product

The design of the manufacturing process of MRX003 had to deliver high product quality with the most stable, fully automated processes possible and to enable affordable production for the generic drugs market. "With the help of our DMF package, we were able to create, implement, and qualify the molds to be very robust," Richard Gradl (Mold Engineer, Gerresheimer Regensburg GmbH, Wackersdorf) explains. "The

stable component quality and high process capability of the molds ensure good conditions in the series production environment." Our risk management approach was based on procedures that were tailored to the special features of the project, from qualification and validation to long-term production security, as highlighted by Tobias Bernklau (Global Head of Quality Engineering, Gerresheimer Regensburg GmbH, Wackersdorf): "The focus is always on the user for all decisions. For critical areas and functions, we deliberately invest more effort than for less critical areas and functions."



The injection molded parts of MRX003 are produced in our production site in Pfreimd (Germany)



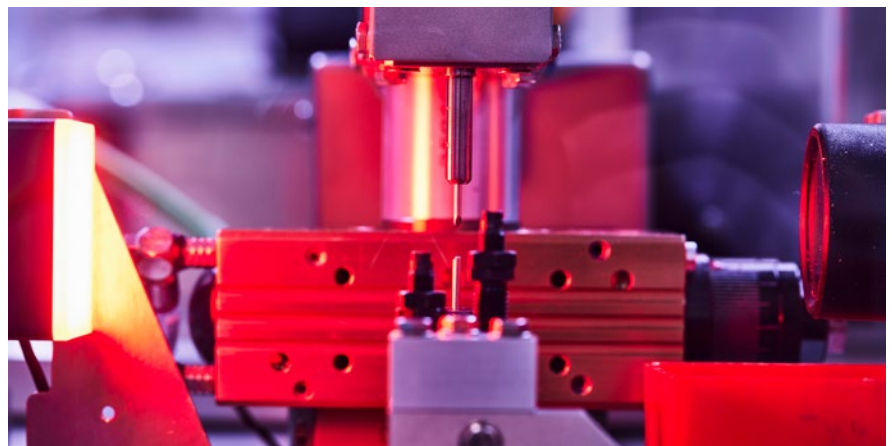
MRX003: the assembled device is inserted and sealed in a foil pouch.

MRX003: an inhaler with sophisticated components

The inhaler is assembled from a total of 12 parts, meaning seven injection molding parts of ABS or MABS (base element, capsule housing, hinge plate, button, mouthpiece, filter housing, sealing cap) as well as five stainless steel bought-in components (two lancets, spring, cylinder pin, and fine filter unit). A pouch is used for the packaging of the finished product. For the BICs, Gerresheimer selected suppliers who are capable of fulfilling sophisticated quality.

The injection molded parts are produced in Pfreimd in multi-cavity molds. Automated assembly takes place at three table stations. The first station is responsible for the base unit of the inhaler. The capsule housing is inserted into the base unit and the button is pre-mounted together with the lancets and spring. At the second station, the mouthpiece is assembled with the filter housing, into which the filter is sealed and shaped with great precision. Presence, correct orientation, and exact positioning are checked inline at both stations without gaps.

At the third station, all three modules are joined together, the correct discharge value of each inhaler is measured, and the sealing cap is finally



Checking the needle cut



A view of the fully automatic assembly line of MRX003

placed. The released products are then transported to a fully automated packaging system. In this system, a

foil is first printed with the necessary information and the inhaler is subsequently sealed into the printed foil.

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