> Boehringer Ingelheim microParts GmbH manufacturing facilities in Dortmund.

>> Dr Bastian Knabe (left) heads the Engineering Standards, Services and Innovations department. His colleague Dr Manuel Kemmler (right) is the Senior Project Manager.

“Getting down to business”

Several years ago, the pharmaceutical company Boehringer Ingelheim microParts GmbH achieved a technical innovation with its RESPIMAT® inhaler: It works without a propellant. The core element is a special micro-nozzle which atomizes the medication. Fraunhofer IPM was commissioned to develop an optical in-process inspection system to precisely control the quality of this microfluidic component during production.
Dr Bastian Knabe and Dr Manuel Kemmler, the persons responsible for the project at Boehringer Ingelheim microParts GmbH, have discussed this innovation with us in detail.

Boehringer Ingelheim microParts GmbH manufactures the RESPIMAT® product range in Dortmund. RESPIMAT® is a propellant-free pocket inhaler which has been available in a reusable format since 2019. With a production capacity of 45 million devices, the approximately 650 employees in Dortmund provide for the world market exclusively on behalf of Boehringer Ingelheim. The main working steps in production are the creation of the plastic parts via injection molding, the etching and separation of the nozzles, and the final assembly of the device including quality control.

How did you come to work with Fraunhofer IPM?
Kemmler: At the beginning of 2011, we opened a general inquiry with the Fraunhofer Vision Alliance regarding the direct quality control of a microfluidic component during production. Fraunhofer IPM offered a compelling solution.

How did you proceed?
Kemmler: Following the initial feasibility study on using autofluorescence to detect silicone, we really got down to business in the subsequent projects: We wanted to also be able to detect other component materials, various plastics, glass, and silicon. But there was nothing on the market for this. So Fraunhofer IPM developed systems for us that we now use to conduct quality controls in a three-shift cycle.
Knabe: Meanwhile, we have collaborated on many other projects together in a tremendous effort that spans our entire value chain. I think that Fraunhofer IPM knows our company in and out by now.

The RESPIMAT® inhaler: Boehringer Ingelheim microParts GmbH uses measurement systems from Fraunhofer IPM for automated quality assessment of key components.

What do you look for in a development partner?
Knabe: When we take complex problems that require customized solutions and add yet another element to them, that’s where we need Fraunhofer IPM. The regulations governing medical device manufacturing require that inspection systems be put through their paces. In order to prove this, we rely on scientific methods: hypotheses, experiments, series of tests, etc. When statistic methods must be applied as a matter of principle and your partners are also scientists, it’s easier to join forces and come up with the necessary tests relatively quickly. That’s where I see the greatest advantage to working together with Fraunhofer IPM.

What determines a project’s success?
Knabe: The most important thing is that our project partner is truly interested in the problems at hand and in finding a solution. A deep understanding and commitment to a given development project – particularly when it is so complex – is critical, as is a sense of responsibility for the final result. Only then can a project succeed.

Is there something in particular that makes your collaboration with Fraunhofer IPM special?
Kemmler: If you are looking for a special, customized solution for your existing customized solution, there are few partners who compare to Fraunhofer IPM, particularly when it comes to image capturing and processing.
Knabe: Since we work so closely with each other, we also come into contact with other industry sectors via measurement technology. We leave joint meetings with a lot of food for thought. That’s something unquantifiable that we can’t get anywhere else on such an outstanding level.

To what extent is it worth investing in measurement technology?
Kemmler: You might think that new products only catch on if they’re less expensive than what’s already available on the market, but that’s only true to a certain extent. In manufacturing medical products, quality plays a huge role. In general, a higher-quality product will cost more money.
Knabe: Amortization is an important variable, but not the only one. There are also projects that have been implemented without it. However, the projects that we’ve most recently conducted together with Fraunhofer IPM saw both amortization and an increase in quality.

What technological challenges do the pharmaceutical and medical technology industry face?
Knabe: I view sustainability as the most important topic. And I think it will continue to be very relevant in the industry moving forward. I also believe that the market will reward companies for improving sustainability. For instance, we have recently released a new version of our inhaler with precisely this vision in mind. The inhaler can now be reused, massively reducing its carbon footprint. Other manufacturers are becoming more concerned with hygiene. And this is another area where measurement technology comes into play: How can sterility be quickly verified using simple resources?
Kemmler: Another trend is that software is becoming increasingly important in measurement technology. These days, there’s more and more talk about artificial intelligence. The question is: How can such software be validated in a regulated environment? Until now, validating the functionality of software has always required the existence of a viewable source code. In the world of neural networks, however, this doesn’t exist. We have to find a different solution.

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