

UPDATE *Medical Systems*



More space for the Small Batch Production of Plastics

We are expanding the production area for Small Batch Production of plastics in Wackersdorf

We are increasing the capacity of our Small Batch Production in the Technical Competence Center (TCC) Wackersdorf. To this purpose, already existing production area has been converted into clean room space, and a new building with additional clean room and office space has been completed. We are reacting with the expansion of production space in keeping with the growing number of projects that require smaller numbers of units or for which a smaller number of complete products are already required prior to large batch production for development, approval, and industrialization.

We had already invested a double-digit sum in the millions in the expansion of Small Batch Production in Wackersdorf in 2018. In the context of the plastic and glass competence of the company, 900 square meters of additional area was at that time created for the development and industrialization of glass products like syringes and carpules.

A double-digit sum in the millions is once again being invested to adapt the capacity of Small Batch Production in the plastics segment to the growing number of projects. Produced here are, for example, patch pumps for administering medication, drug containers for injection without needles, point-of-care tests, infusion sets for X-ray contrast

agents, syringes, and much more. To this purpose, existing production space was converted into a 500 square meter clean room of the ISO 14644-1 classes 8 and 7. This clean room is already in operation. In a second step, an extension building is now being built, which, in addition to 245 square meters of office space, also provides 1,200 square meters of additional clean room area. Up to now, Small Batch Production had a total of 1,800 square meters of production area for the plastics segment in the ISO classes 7 and 8, as well as rooms of the GMP classes C and D for pharmaceutical glass production. Following the conversion, with 2,200 square meters, more than double the clean room area of ISO classes 7 and 8 are available for plastic production. The total production area of Small Batch Production now amounts to 2,900 square meters.

Through the manufacture of medical devices, such as, for example, patch pumps with internally devel-

oped micro pumps, in Small Batch Production, we open up a new business area as an Original Equipment Manufacturer (OEM). The classification of the company in the commercial register is therefore being supplemented by the point "Manufacture of medical and dental apparatuses and materials."

The expansion of production capacity in Small Batch Production is required due to the growing number of development projects for pharmaceutical and medical technology products. Prior to batch production, these products are subjected to a protracted development and approval process, for which small numbers of units are often required as samples. Small Batch Production thereby ensures the required product quality, as well as complete batch documentation at the level of subsequent large batch production. The experiences can also be transferred directly to subsequent production on a large scale when establishing large batch production.



From left to right: Holger Heining (Head of Small Batch Production, Gerresheimer Regensburg GmbH, Wackersdorf) and Michael Wiglenda (Global Senior Director Technical Competence Center & Moldmaking, Gerresheimer Regensburg GmbH, Wackersdorf) in front of the new building