

# Pioneering production cell for the pharmaceutical and biotech industry.

Vetter and Syntegon join forces to develop Versynta microBatch



**What happens when two equal partners take on a new challenge? In the case of Vetter and Syntegon, the answer is “Versynta microBatch”. The fully automated, gloveless, Annex 1-compliant production cell for the aseptic filling of very small batches opens up new perspectives for both companies and underlines their respective pharmaceutical and technological innovative strength.**

As a leading Contract Development and Manufacturing Organization (CMDO), Vetter always focuses on the needs of its customers in the pharmaceutical and biotech industry and integrates global market trends into the development of new processes. The pharmaceutical market is changing. Looking to the future, the range of products needed is expanding – from large production volumes for indications with high sales figures to high-value products in small quantities for the individual treatment of rare diseases. This leads to an increasing need for small batch sizes, which in turn requires high flexibility and productivity, i.e. frequent batch changeovers as well as efficient and resource-saving processes. In addition, API (active pharmaceutical ingredient) losses must be kept to a minimum.

## **A suitable partner as a critical success factor**

As early as 2019, Vetter recognized the need for a new solution that was not yet available on the market. “When it comes to small batches, flexible, fully automated production cells are a sensible and sought-after addition to our existing portfolio,” was the conclusion of one of the first joint discussions between Vetter and Syntegon. Arno Schroff, Director Site and Plant Development at Vetter, and the interdisciplinary team paid particular attention to the future requirements of Annex 1, which was being revised at the time.

### **A. Versynta microBatch Infeed**

The gloveless isolator with integrated air treatment significantly reduces the risk of contamination as there is no need for manual intervention.

**B.** The fully automated Versynta microBatch production cell from Syntegon fills between 120 and 500 containers per hour with virtually no product loss.

### **C. Versynta microBatch Outfeed**

“Especially from a regulatory point of view, the available equipment solutions did not sufficiently meet our high requirements. It became clear to us that we needed to create something completely new, together with a system and engineering partner,” Schroff explains. “We quickly decided on Syntegon, as we enjoy a good working relationship and have been working together on joint developments for many years. In fact, finding the right partner was one of the critical success factors for us.” Klaus Ullherr, Senior Product Manager at Syntegon, who was also involved in the project from the very beginning, confirms: “We had, of course, already considered the possibilities of gloveless micro batch filling. However, we needed a partner from the pharmaceutical manufacturing industry who could contribute their experience in aseptic filling and in dealing with customer and regulatory requirements. Tackling such a far-sighted development was only possible together.”

### Specific (regulatory) requirements

The first brief specification from Vetter already contained many details and set the course for the joint development work. “We had examined future market requirements and the regulatory framework intensively – not only with regard to the then ongoing revision of Annex 1, but also with regard to the increasingly stricter requirements in the pharmaceutical industry globally,” Arno Schroff confirms. “Our established Vetter CleanRoom Technology (V-CRT®) provided the impulse for a set-up process and viable monitoring that is fully automated thanks to the gloveless concept. Furthermore, the primary packaging materials should not come into contact with H2O2 due to the high sensitivity of many biopharmaceuticals.”

“The biggest challenge was to design the production cell based on isolator technology without glove ports,” Klaus Ullherr explains. But it has proven to be successful: the gloveless isolator with integrated air treatment significantly reduces the risk of contamination and eliminates the need for manual intervention by the operators. The gloveless infeed of sterilized equipment and packaging after the H2O2 decontamination cycle was an important criterion for Vetter right from the start. The isolator that Syntegon typically integrates into many filling systems and lines is new territory for Vetter in this form. “Only gloveless, automated handling and monitoring makes it possible for Vetter to operate in a class C cleanroom environment,” Schroff explains.

### Small, smaller, microBatch

With a length of 3.5 meters, a width of approximately 2 meters, and a height of 3 meters, the machine can be easily integrated into existing production environments. The isolator cell itself measures only 1.6 by 1.5 meters. It houses the tub opener, the filling station, and the combined stopper placement and crimping station. The integrated air handling system minimizes the need for interfaces to the building and technical ceiling installations.

Thanks to the laminar flow optimized design, the air flow reaches and flows around the containers unhindered (“first air supply”). Optional cameras ensure continuous remote monitoring of production in the isolator.

Low-loss filling was another important aspect of the conceptual design, which is particularly important for customers with small, costly batches. Versynta microBatch achieves this through 100% in-process control (IPC) and short product paths. The production cell fills and closes between 120 and 500 glass or plastic containers such as vials, syringes, and cartridges per hour.

### An award-winning development partnership

In October 2023, the time had finally come: Syntegon presented the Versynta microBatch prototype live at CPHI Barcelona – and announced the sale of the first machine to Vetter. However, the production cell had already attracted attention beforehand. The development partnership won the PDA Drug Delivery Award in the “Partnership Innovation” category in 2021, followed by the German Packaging Award for Syntegon just a year later. “The technical implementation project is underway. We are currently defining and implementing further specifications and requirements. The machine will be used at our production site in Ravensburg,” Schroff says.

For Arno Schroff and Klaus Ullherr, one thing is certain: “Ever smaller batch sizes are and will remain a trend. They will be needed in the future to advance not only orphan drugs and high-value products but also personalized medicine with even lower output,” says Schroff. “Versynta microBatch is a big step in the right direction; more will follow,” Ullherr adds. The partners see themselves well prepared for future developments or regulatory changes in the pharmaceutical industry – and intend to continue to identify joint innovation potential.



At the first live demonstration at CPHI Barcelona 2023, Versynta microBatch quickly attracted visitors' attention.

## About Syntegon

Processing and packaging for a better life – this is what 5,800 Syntegon employees work for every day. Be it with individual machines, systems, or services, Syntegon helps its customers in the global pharmaceutical and food industries to improve people's lives. The company, which is headquartered in Waiblingen, Germany, looks back on more than 160 years of experience and achieved annual sales of 1.4 billion EUR in 2022. In the pharma sector, the company's intelligent solutions enable the safe and high-quality production, processing, filling, inspection, and packaging of liquid and solid pharmaceuticals. In the food industry, Syntegon's flexible and reliable technologies produce and pack confectionery, dry food, frozen food, and dairy products.

With 1,100 service experts and a comprehensive service portfolio throughout the entire machine lifecycle from spare parts management to digital line optimization, Syntegon lays the foundation for smooth production processes for all customers. More than 35 sites in almost 20 countries keep a firm eye on Syntegon's impact on the environment and society. Syntegon is a leader in the development of sustainable packaging solutions, reduces the energy consumption of its machines and pursues ambitious goals to lower its emissions.

## About Vetter

Vetter is a leading Contract Development and Manufacturing Organization (CDMO) with headquarters in Ravensburg, Germany, and production facilities in Germany, Austria, and the US. As a global player, the pharmaceutical service provider is also present with its own sales locations in the Asia-Pacific markets of Japan, China, South Korea and Singapore. Around the world, small and large renowned pharma and biotech companies rely on the decades of experience, high quality, modern technologies, reliability, and commitment of more than 6,300 employees. In close partnership with its customers, the Vetter team supplies patients all over the world with medicines, many of which are vital. The CDMO provides support from drug product development through clinical and commercial filling to a wide range of assembly and packaging services for vials, syringes, and cartridges. With innovative solutions, Vetter develops prefilled drug-delivery systems together with its customers to continuously improve patient safety, comfort, and compliance.

The company is an industry pioneer in sustainability and a socially and ethically responsible corporate citizen. The CDMO is a member of the UN Global Compact and Science Based Target initiative (SBTi) and received platinum status in the renowned EcoVadis ranking. Multiple awards such as the CDMO Leadership Awards, Frost & Sullivan Customer Value Leadership award or the recognition as Best Managed Company emphasize Vetter's commitment to sustainable business. Founded in Ravensburg in 1950, the company remains family-owned to this day.

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