

Press release

Syntegon Technology

Kindeva Drug Delivery and Syntegon install first Versynta microBatch in North America

- New Versynta microBatch underlines Kindeva's market-leading injectable CDMO capabilities
- Fully automated, gloveless production cell sets new standards in microBatch filling
- Designed for regulatory compliance, maximum product yields and fast changeovers

Waiblingen, Germany/Minneapolis, USA, April 9, 2024. [Syntegon](#) today announced the sale of its newly developed [Versynta microBatch](#) production cell to its first U.S. customer. [Kindeva Drug Delivery](#) will use Versynta microBatch to further expand its suite of [aseptic fill-finish contract development and manufacturing \(CDMO\) capabilities](#) meeting the latest global pharmaceutical regulations and trends. Kindeva is a leading global CDMO that develops and manufactures products across a range of routes of administration including injectable, pulmonary, nasal, transdermal, and intradermal delivery.

Robotic competence on the smallest scale

"Syntegon's Versynta microBatch enables Kindeva to offer significant flexibility to our customers by rapidly adding clinical development and small-scale commercial GMP filling capacity, which complements our large-scale vial, syringe, and cartridge isolator filling lines. Syntegon's technology expertise is unquestionable, but it is their ability to partner that has really made this an ideal collaboration for Kindeva," said David Stevens, Kindeva Global Chief Commercial Officer. "Versynta microBatch provides agility, best-in-class automation, and sterility assurance that meets our patient safety and regulatory compliance objectives which we believe sets the standard for CDMOs."

The fully automated production cell is specifically designed for very small batches of highly potent and often highly costly drugs, for instance in the field of cell and gene therapy, where maximum product yields are key. Versynta microBatch fills between 120 and 500 syringes, cartridges, and vials made of glass or plastic per hour with virtually no product loss. Fast batch-to-batch changeovers ensure that efficiency remains high without compromising on flexibility.

Prepared for regulatory challenges

As Kindeva serves a global client base, compliance with local regulations of its target markets is paramount. For Europe, this includes the [new EU GMP Annex 1](#), which is setting new benchmarks in aseptic fill-finish operations. Syntegon developed Versynta microBatch with these requirements in mind: the gloveless isolator with integrated air treatment significantly reduces operator intervention and the risk of contamination. The 100 percent in-process control ensures high quality. Five integrated inline inspection systems provide special safety, while optional network cameras ensure continuous monitoring of production in the isolator via remote access.

"During my 35 years of working in the pharmaceutical packaging and processing business, it is rare to experience the partnership Syntegon and Kindeva enjoy. With our joint successes,

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their experience, and high level of technical capabilities, Kindeva is a perfect partner for our technology-leading Versynta microBatch,” said Kerry Fillmore, Managing Director of Syntegon Pharma Technology in North America.

Join the microBatch experience at Interphex

Visitors to Interphex can experience the potential of Versynta microBatch first-hand. Syntegon will offer an immersive experience covering small and micro batch filling as well as ready-to-use (RTU) trends.

Visit Syntegon and Kindeva at [Interphex](#), April 16-18, 2024, at booth 1719 and 1147, respectively.

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Images



Syntegon sells its new Versynta microBatch to the first U.S. customer: a leading global combination product CDMO, Kindeva Drug Delivery.



The fully automated Versynta microBatch production cell with gloveless isolator and integrated air treatment is the ideal solution for highly potent drugs for small patient groups.

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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. www.syntegon.com

About Kindeva Drug Delivery

[Kindeva Drug Delivery](#) is a global contract development and manufacturing organization focused on drug-device combination products. Kindeva develops and manufactures products across a broad range of drug-delivery formats, including pulmonary & nasal, injectable, and transdermal. Kindeva's service offerings span early-stage feasibility through commercial scale drug product fill-finish, container closure system manufacturing, and drug-device product assembly. Kindeva serves a global client base from its state-of-the-art manufacturing, research, and development facilities located across the U.S. and U.K.