SYNTEGON
PROCESSING & PACKAGING

Equipment and upgrade services for Annex 1 and RABS.

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WHICH SOLUTIONS DO YOU OFFER FOR THE PHARMACEUTICAL INDUSTRY?

Syntegon is one of the leading providers of packaging solutions and process technology for the pharmaceutical industry. We offer our customers seamless solutions from a single source – from formulation, processing, sterilization, fill-finish, barrier systems and inspection for liquid pharmaceuticals to processing, capsule filling, tablet pressing and coating for oral solid dosage (OSD) forms. Our comprehensive service portfolio covers the entire machine lifecycle including modernizations and upgrades, spare parts management, digital line optimizations, and carbon footprint analyses for more sustainable operations.

MORE SPECIFICALLY, WHAT SOLUTIONS DO YOU OFFER FOR INJECTABLE DRUGS?

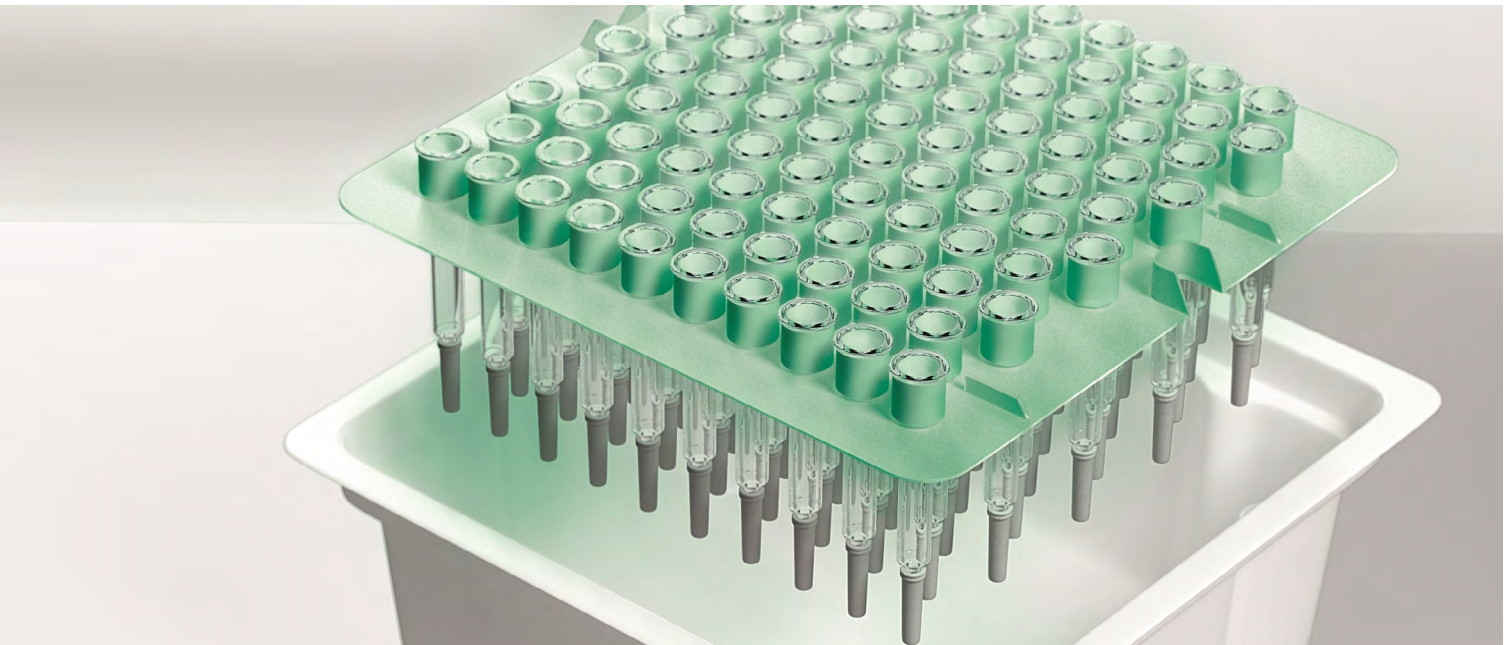
Syntegon provides solutions for all therapeutic areas. We supply single machines as well as complete lines to our pharmaceutical clients. These range from high-speed equipment, for example for anti-obesity drugs or diabetes treatment, to small and micro batch fill-finish solutions, for instance for oncology drugs. Depending on customer requirements, we can offer full line solutions including isolators or restricted access barrier systems (RABS), a large variety of filling systems, and even combi platforms to fill more than one pack style. While the fill-finish process is at the heart of injectable drug production, our large portfolio also covers the upstream and downstream processes: formulation, processing, de-nesting, rod insertion and labelling, inspection, and sterilization.

WHAT ARE THE TRENDS IN YOUR CUSTOMERS‘ DEMANDS IN THE INJECTABLE MARKET IN TERMS OF PACKAGING TYPE?

Ready-to-use (RTU) containers are definitely the most important packaging trend in the pharmaceutical industry. They are the preferred choice for small batch production, and their number is growing steadily. Pharmaceutical manufacturers benefit from simpler processing procedures, greater flexibility, and a reduced total cost of ownership. Numerous steps, such as cleaning, siliconization of pre-filled syringes, and sterilization of components, are outsourced to the packaging suppliers. They have the expertise and make sure that all processes are qualified and validated according to current global requirements and that containers are delivered with an endotoxin, germ, and particle concentration, which is below the required thresholds. In the best-case scenario, primary packaging and machine manufacturers work closely together to develop new solutions – just like we at Syntegon have been doing for many years.

WHAT ARE THE TRENDS IN TERMS OF EQUIPMENT SOLUTIONS?

In the past, the focus was mainly on large batch production for blockbusters and traditional drugs. High-speed bulk lines are still important, for example for the trending anti-obesity drugs. However, more and more pharmaceutical companies are now investing in the development and commercialization of small-volume medicines, which have very different production and filling requirements. The increasing prevalence of advanced therapy medicinal products (ATMPs), such as cell and gene therapies and bioengineered tissue products, shows that the industry is specializing steadily.



These drugs are not manufactured on huge lines. Instead, the focus is on small and even micro batch production.

WHICH IMPACT HAS THE STRENGTHENING OF REGULATIONS SUCH AS ANNEX 1 HAD ON YOUR CUSTOMERS' DEMAND?

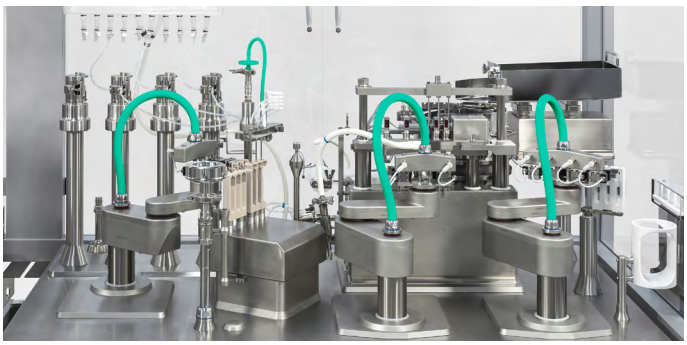
The primary objective of Annex 1 is to achieve the highest possible product quality by preventing product contamination. One rationale in this regard is the separation of the aseptic process area from the operator environment. For the first time, the document clearly recommends the use of appropriate barrier technologies, i.e. isolators and RABS. Pharmaceutical manufacturers will require at least RABS for the approval of new products. Hence, the demand for new machines with isolator technology and upgrades of existing equipment with RABS has increased considerably. Syntegon offers both solutions: Annex 1 ready equipment and a comprehensive portfolio of RABS upgrade services with an extensive choice of options, including peripheral topics such as viable monitoring, new stopper infeed solutions, or glove integrity testing devices.

DOES THIS DEVELOPMENT IMPLY INNOVATIONS IN THE EQUIPMENT YOU OFFER?

It definitely does. For example, the second chapter of Annex 1 highlights automation and robotic systems as "appropriate technologies". They reduce gloves and human intervention in barrier systems to an absolute minimum. New equipment developments will have to take this into account. But apart from technological demands, the ever-stricter regulations are leading to a shift in the relationship between pharmaceutical manufacturers and equipment suppliers. Drug producers need a partner who is familiar with all regulations and can proactively suggest new technological solutions. We know the market very well and listen closely to our customers. This enables us to develop innovations that comply with current and upcoming regulations from the start.

WHAT IS THE LATEST EQUIPMENT YOU HAVE LAUNCHED FOR INJECTABLE DRUGS?

Our new fully automated, gloveless production cell Versyta microBatch, which we developed together with the CDMO Vetter, is the ideal solution for new, highly effective drugs for small patient groups. It fills between 120 and 500 syringes, cartridges, and vials made of glass or plastic per hour with virtually no product loss. The 100 percent in-process control provides high quality, while five integrated inline inspection systems ensure continuous process monitoring and safety. Of course, Annex 1 was also taken into account during development. For example, the gloveless isolator with integrated air management significantly reduces the risk of contamination. Optional network cameras facilitate continuous remote production monitoring in the isolator. Moreover, the machine can be set up fully automatically with the robot, including the sorting devices.



The next innovation is our new, patented Settle Plate Changer for automated viable monitoring in the aseptic filling process. It is available both with the purchase of a new machine and as a retrofit for existing equipment, from Syntegon as well as from third-party suppliers. Settle plates may be exposed to cleanroom air for a maximum of four hours and must then be replaced to ensure consistent sampling. With our new robotic handling unit, this step can now be performed automatically. Machines only need to be stopped once a day, which results in noticeably higher machine availability of up to 300 hours per year. The Settle Plate Changer reduces manual operator intervention in the process zone by 80 percent and thereby minimizes the risk of contamination to a minimum.

About Syntegon.

Syntegon Technology is a leading global process and packaging technology provider. Formerly the packaging division of the Bosch Group, the company, headquartered in Waiblingen (Germany), has been offering complete solutions for the pharmaceutical and food industries for over 50 years. More than 6,100 employees at 30 locations in more than 15 countries generated a total revenue of 1.3 billion euros in 2019. The portfolio of intelligent and sustainable technologies includes stand-alone machines, as well as complete systems and services. Fields of application in the pharmaceutical industry are the production, processing, filling, inspection and packaging of liquid and solid pharmaceuticals (e.g. syringes and capsules). In the food industry, the portfolio includes process technology for confectionery as well as packaging solutions for dry foods (e.g. bars, bakery products and coffee), frozen foods and dairy products.

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