



PRESS RELEASE

Capacity increase of sterile production to 100 million ampoules and vials at Aenova's Gronau site

- **Aenova starts up the new RABS filling line for ampoules from 1 ml to 5ml.**
- **This is supplemented by fully automatic optical inspection and a new packaging line.**
- **This will enable the Gronau site to produce around 100 million ampoules and vials per year. This corresponds to a capacity increase for sterile liquids of around 7%.**

Gronau, 26. March 2021 - The production and filling of sterile products requires the highest level of safety and quality. Market demand for production capacity in the sterile field has also increased significantly in recent years and has been further boosted by the filling requirements of COVID19 vaccines. At its Gronau site, Aenova, a leading development service provider and contract manufacturer for the pharmaceutical and healthcare industries, has now significantly increased its ampoule capacities. With the new ampoule filling and closing line, the sixth sterile line at the Gronau site, a new fully automatic optical control line and a likewise new packaging line, a total of more than 100 million ampoules and vials can now be produced per year. Aenova's strategy is aimed at significantly expanding capacity and optimizing supply availability at several of the Group's sites.

In aseptic manufacturing, safety and hygiene are paramount for product purity and process reliability. The new plant in Gronau is a so-called RABS plant (Restricted Access Barrier System) for the filling of 1ml to 5 ml ampoules and offers high safety for products and personnel while at the same time providing high flexibility. In a RABS (Restricted Access Barrier System), the production area and the operating environment are physically



separated. The production area provides a highly clean working environment through a special machine housing, securely locked doors, and glove intervention.

The high-performance filling line is supplemented by a new fully automatic optical inspection line and an additional packaging line including labeling and bundling machine to meet capacity requirements throughout the process. In liquid sterile production, the inspection of containers is particularly time-consuming and resource intensive. The new optical inspection machine with camera technology primarily checks for particles and leakage, so-called black burners, head geometry and correct crimping, color and closure of the crimp cap, color of the solution, as well as code rings and OPC points (one point cut for an easy-to-handle predetermined breaking point on the ampoule). It features high speed and can control both aqueous and oil-based ampoules and vials. Throughput times can thus be significantly reduced while simultaneously increasing capacity by around 7%. With this machine network, Aenova will be able to produce over 100 million ampoules and vials per year in Gronau.

"Our site is a center of excellence for sterile production and conventional solids within the Aenova Group and can point to more than 100 years of experience in pharmaceutical production. This innovation is an important milestone in being able to meet customer needs even better," explains Dr. Emil Wolf, Managing Director at Aenova in Gronau.

These new facilities are also an essential component of Aenova's strategy to further develop the company's position as a scalable end-to-end contract service provider for pharmaceutical and healthcare companies. This includes capacity expansions in tablet production at the Tittmoning site for the production of very large volumes and at the Regensburg site for the production of highly potent active ingredients (up to OEB 5), as well as an additional line for aseptic filling at the Italian site in Latina. COVID19 vaccines can then also be filled there.

"These investments are a major step for Aenova to be able to serve our customers' requirements even more reliably with the highest quality and very good delivery reliability," explains Jan Kengelbach, CEO of the Aenova Group.



The new fully automatic optical inspection in liquid sterile production at Aenova in Gronau significantly increases controlled output. Operator starts the inspection process.
(Photo Aenova. Tanita Teichfischer).



With the new sterile filling line, a total of 100 million ampoules and vials can be produced per year at Aenova in Gronau; here the cleaning and depyrogenation area. (Photo Aenova. Tanita Teichfischer).

Aenova Group

Aenova Group is a leading global contract manufacturer and development service provider for the pharmaceutical and healthcare industries for human and animal health. Our services include end-to-end manufacturing and development of all dosage forms and potencies (from nutraceuticals to high potent APIs) at 15 sites in Europe and the USA. With our comprehensive know-how, many years of experience, innovative technologies and highest quality standards, we are a reliable, long-term partner for pharmaceutical and consumer



health care customers worldwide. Around 4,500 well-trained employees contribute to the success of the Group.

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