Reference: Qualification of cleanrooms in sterile production for EVER Pharma Jena GmbH

EVER Pharma Jena GmbH is part of the EVER Pharma Group headquartered in Austria. The Group‘s focus is on research, development, manufacturing and marketing of products in the fields of neurology and specialising in injectables (such as oncology, intensive care, hormone therapy, pain therapy). Injectable drugs are manufactured at the site in Jena.

The goal

In order to increase production capacities, EVER Pharma Jena GmbH invested in a new aseptic production facility in Jena Lobeda in 2017. With a project volume of >100 million euros, this site will ensure a maximum filling capacity of around 130 million units per year. The filling areas are divided into four sterile production areas spread over three floors.

The total cleanroom area is 1,600 m² operated in GMP classes A to D, which must be qualified in accordance with the applicable DIN EN ISO 14644 series of standards and the EU GMP Guideline (Annex 1 and Annex 15).

Services of Testo Industrial Services

- Development of customized measurement procedures adapted to the structural conditions, taking into account the applicable standards
- Initial cleanroom qualification of the sterile productions areas (classes A to D) with corresponding airlock areas, sample train and weighing area as well as the surrounding CNC (Controlled Not-Classified) area
- Control and planning of the measurement campaigns with execution of the equipment, adapted to the course of the project
- Parallel planning of the upcoming routine measurements in already finalized areas
- Qualification measurements of equipment with clean room character, such as: Neck insulators, dehydrogenation tunnel or flanging machines

Your advantage: Our competence

- Detailed coordination of the requirements and definition of the procedure during the bidding phase by our GMP experts
- Flexible resource planning based on project progress
- Dedicated GxP Services team on site, minimizing coordination efforts
- Adaptation of the documentation structure to the customer‘s individual standard
- Handover of the documentation directly after completion of the measurements
- Flexible use of high quality equipment adapted

„We were very satisfied with the cooperation with Testo Industrial Services on our new building. During the project phase, as it happens, some changes and challenges arose, which Testo Industrial Services always managed very flexibly and, as it were, „on the fly“ with us. It was a close cooperation that worked very well – and that with such a high measurement effort in our new large cleanroom area. Meanwhile, we are already working together on a strategy to ensure the requalification of the rooms, so we are happy to continue the cooperation.“

Michael Böhme
Engineer Qualification (clean rooms), Ever Pharma Jena

► **Learn more at:** www.testotis.co.uk/reference-ever-pharma

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