# Press release

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**New sterile laboratory for „Burg Apotheke“ in Königstein**

**Cleanroom monitoring with image documentation for safe preparation of sterile products**

**An intelligent monitoring system is required in the preparation of sterile products in order to minimise risks for employees and patients and to provide the producer with maximum legal security. For this reason, the “Burg Apotheke” has invested in an image-based weiss**technik® **monitoring system.**

Sterile products often have to be prepared specifically for patients. Due to their short shelf lives, they are often produced in pharmacies with their own cleanroom. In this respect, it is important to have a comprehensive overview of the production processes to exclude all sources of errors. As the producer of patient-specific infusion solutions, “Burg Apotheke” is committed to the highest requirements of cleanliness, quality and service. The ready-to-use products are prepared in its own laboratory in accordance with the regulations of ApBetrO (Apothekenbetriebsordnung – German pharmacy operation ordinance). In the field of parenteral drug production, the 2012 modification brings ApBetrO into line with the EU GMP regulations. The cleanroom necessary in this regard was extended and with an innovative monitoring system that records additional images as well as the usual process data.

**Cleanroom with integrated upgrade option**

As an established cleanroom specialist, Weiss Klimatechnik GmbH can refer more than 100 projects in the field of GMP conform cleanrooms. This experience gave us an instrumental advantage in the planning and implementation of the project, for example in regards to defining the measuring points and the avoidance of possible sources of errors. However, „Burg Apotheke“ special requirements call for individual challenges .

With a total area of 200 m2, 150 m2 qualified cleanroom area and 50 m2 non-qualified area for equipment and adjacent areas were to be installed. There had to be space for five clean workbenches and an isolator in the production area. In the first stage of the expansion, the GMP cleanroom was to be set up for production in the cleanliness classes euGMP A in C as per ApBetrO. If required, at a later date it can be converted to production in the cleanliness classes euGMP A in B and production in accordance with the German Medicinal Products Act (Arzneimittelgesetz). The vestibule necessary in this regard also had to be considered during the planning, as did the design of the personnel and material airlocks and the dimensions of the ventilation technology components.

**Planning and construction of the GMP cleanroom**

For structural reasons, the room was equipped with a compact air conditioning unit with its own integrated cold-water chiller. In this way, the aim of increasing the operational safety of the cleanroom system independent of external supply media was achieved. The system works in recirculation air mode with process-dependent outside air. Using additional filter fan units with H14 high-efficiency particulate air filters in the production room and a separately controllable preparation room. The necessary temperature and cleanroom class are generated in the sterile laboratory. An innovative monitoring system is installed to identify process deviations and contaminations as quickly as possible at the “point of use” and to prevent them in a lasting manner.

**Innovative monitoring system with image documentation**

The control and operating software is easy to use and provides reliable results. It monitors all relevant standard values. In this way, temperature (limit temperature 25 °C), humidity, room pressure and particle load are recorded. The EU GMP conform particle monitoring system measures particles sized 0.5 and 5 µm using an isokinetic sampling probe within the workbenches. Furthermore, the patent-pending monitoring function takes additional image documentation during the process.

Depending on its settings, the image is taken by the system at defined time intervals or on an event trigger and is time stamped. Combined with the further sensor data, it means that the production of each batch can be accurately tracked. It provides the manufacturer with uninterrupted tracking for every batch and therefore the highest legal security because with the new monitoring system it is possible for the first time to prove what the conditions were and what events occurred for any point in time. When completed, a total of six cameras are planned for the work stations.

**S!MPATI monitors processes**

The S!MPAC®control is the centre piece of the monitoring system. It has web visualisation and free interfaces to laboratory equipment, which could be used to connect scales, e-sign or a bar-code scanner for example. For „Burg Apotheke“, the new upgradable cleanroom with monitoring system provides optimal production conditions for the present and many additional options for the future.

**The Weiss Technik Companies**

Under the slogan “Test it. Heat it. Cool it.”, the Weiss Technik Companies offer solutions that are used around the world in research and development as well as in the production and quality assurance of numerous products. A strong distribution and service organisation with 22 companies at 40 locations in 15 countries ensures optimum customer support and guarantees a high degree of operational safety. The brand **weiss**technik® includes individual solutions for environmental simulation, clean rooms, climatic engineering, air dehumidification and containment solutions.

Weiss Klimatechnik provides reliable air-conditioning solutions wherever optimal climatic conditions for man and machine are required: in industrial production processes, clean rooms and measuring rooms, hospitals, mobile operation tents or in the information and telecommunication technology fields. As one of the leading providers of professional clean room and air-conditioning systems, we provide you with effective and energy saving solutions, and support you with our expertise from the planning to the implementation of your projects. The Weiss Technik companies are part of the Schunk Group, which is based in Heuchelheim, close to Giessen.

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