

GMP compliance with help from Munters air treatment systems

At Xellia Pharmaceuticals Munters create a strictly controlled and GMP compliant climate

Xellia Pharmaceuticals is a leading producer of active pharmaceutical ingredients (APIs), specialized in fermented antibiotics. Xellia has its own production facilities in Denmark, Norway, Hungary and China and their APIs are available in bulk or Sterilized Finished Dosage Forms (FDF's)

370 employees are working at the premises in Copenhagen, Denmark and the production runs 24/7.

Already for many years Munters has been the trusted supplier of dehumidification systems for tableting and lab applications. Thanks to the positive experience from the previous installations Munters was contacted when Xellia's clean rooms for weighing of powder products recently had to be updated.

As all Xellia's facilities are cGMP compliant their ClassB cleanrooms need a strict control of both temperature and humidity and Munters was asked to design the optimal climate solution for these rooms.

The selected MLPlus and MXPlus systems are designed to fit into environments with high demands as to foot prints, energy efficiency and hygiene. Standard modules for pre- and post cooling can be added according to the actual specifications and all fit on a common base frame with cleaning friendly surfaces and elegant design.

At Xellia the units were designed fit into the existing AC system and to maintain conditions in the clean room at 20°C/ max. 20%RH.

In the systems incorporated pre cooler module the process air is cooled and dehumidified to 13°C/9.4g/kg and led to the dehumidifier that reduces water content to less than 2.5g/kg.

The temperature increase created by the dehumidification process is lowered by a post cooler from 40°C to 20°C and the air is led to the ducting system. HEPA filtration secures the correct and high cleanness of the air supplied to the clean rooms.

The air for reactivation of the rotor is filtered by a EU5 filter and the wet and warm air from the dehumidification process is exhausted outdoor.

By choosing a Munters Plus system the customer is enjoying the benefit of having only one supplier for both dehumidification, pre- and postcooling/heating, filtration and humidification. The system is compact thus flexible in the design and composition of modules needed.

At Xellia Pharmaceuticals the climate control solution from Munters does not only secure the strict demands for the clean room classification but also solves a practical problem. Without dehumidification the weighing process in the clean room could be seriously disturbed by outdoor weather conditions causing the production to be interrupted or postponed. Now the climate in the clean room is completely unaffected by outdoor variations in temperature and humidity and production can be precisely planned.

Being very satisfied with the Munters climate solution, Xellia Pharmaceuticals has appointed Munters as supplier for the next clean room refurbishment.

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GMP Compliant Clean Room



Benefits:

- Constant and strictly controlled climate around the year
- Enables GMP compliance
- Compact system solution with add-ons
- Only one supplier
- Small foot print