

# PolyPeptide Group fulfill FDA requirements

Strict climate control in weighing room is elegantly performed by a Munters ML Plus system.

The PolyPeptide Group works within all major peptide technologies and handles peptide production from small-scale (multi-10 mg) non-GMP batches to multi-10 kg (and larger) GMP manufacturing needs. The Group has more than 50 years experience worldwide within the field of peptide development and manufacturing project.

In the PolyPeptides facility in Malmö, Sweden, large scale GMP manufacturing for both SPPS (Solid Phase Peptide Synthesis) and LPPS (Liquid Phase Peptide Synthesis) projects takes place. The facility has successfully undergone approval inspections by the US FDA – all for cGMP manufacture.

Several Munters dehumidifiers have for many years been creating optimal climate conditions in various applications.

To fulfill the requirements from the US FDA a Munters ML Plus system was installed in a small weighing room in the Quality Department.

Very strict controlled conditions, identical to the production climate were required: 20°C/25%RH around the year. With the positive experience from existing Munters installations, PolyPeptide asked Munters to design a unit that could meet the FDA requirements. A ML Plus 420 was configured, and the elegant way to combine modules for pre- and post treatment of the air, was very much appreciated by PolyPeptide.

Apart from the basic module for dehumidification, the unit consists of modules for pre heating and cooling, post cooling and humidification. The small foot print of the unit was advantageous, too, as the system was installed on the room above the weighing room - among other air handling units.

For hygienic reasons, the systems run as an open system. On warm humid days the dehumidification process secures the low relative humidity needed, while on cold winter days the humidifier prevents static electricity that would create problems during the extremely accurate and demanding weighing procedure. The working safety is also improved, preventing particles from preparations or samples infiltrating the air inhaled by the laboratory technician.



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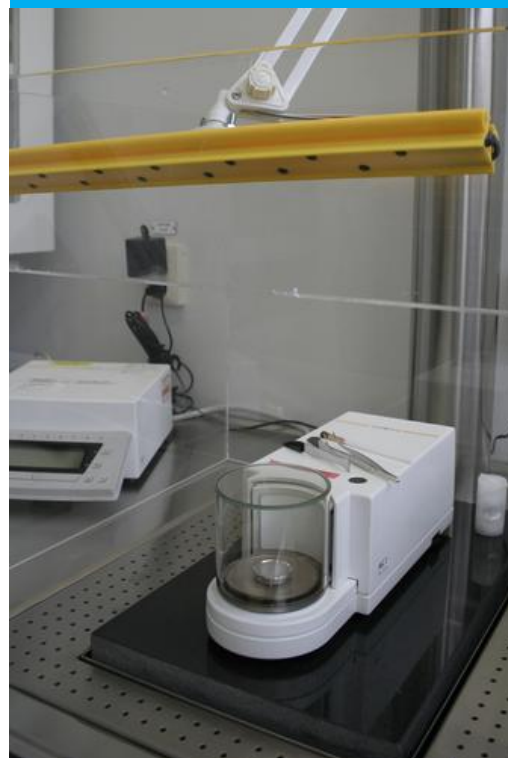
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## Weighing room



## Dehumidification ensures:

- Strict climate control
- Constant year round conditions
- Enables FDA approval
- Improved working safety
- Compact foot print
- Quality hygienic design
- Minimised energy consumption



# Munters