



Ventilation and Air-Conditioning for Clean Rooms

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Clean rooms place the highest demands on ventilation and air-conditioning. This is comprehensible, as it is primarily in use in those industries dealing with pharmaceuticals, foodstuffs, semiconductors and electronics, in medicine or even aerospace engineering. Ultimately everywhere, where particles in the air could have grave consequences or where the quality of the product to be produced might be impaired.

Impeccable Hygiene and Comfortable Room Air

During the creation and maintenance of the desired room atmosphere, the room air technology is at a specific place. The prevention of germ transmission through the air is of the utmost priority. Thus, a faultlessly hygienic and comfortable room climate is essential. For the reduction or prevention of any entering airborne germs, the technical air handling units (AHUs) are vital. They take over the following basic functions:

- Filtering of air particles, dust and micro-organism
- Maintenance of the air pressure within the room (Δp) - rooms, which underlie greater hygienic requirements than the surrounding rooms, must be held in an overpressure range. Therefore, the AHU must pump more room air into the clean room than it extracts from it.
- Maintenance of the air humidity within the room (relative humidity) - the room air humidity can influence the effectiveness and shelf-life of medication during production. A certain atmospheric moisture is also essential, e.g., for pressure injecting of tablets.
- Maintaining the room temperature - The room temperature can, for example, directly or indirectly influence the production of pharmaceutical products. Indirect influence, for instance, can take place through contamination transmitted by employees.



AHUs by robatherm fulfill the highest level of hygienic requirements. This effectively prevents the entering and cultivation of micro-organism such as bacteria, fungi or algae in clean rooms.

Classification of Clean Rooms

Based on an ordinance of the European Commission, the ISPE Sterile Guide Grade defines for the pharmaceutical industry; four clean rooms are classified according to particle concentration, micro-organism concentration and particle size. The classes A and B define sterile areas compared to the classes C and D, which define micro-organism-reduced areas.

ISPE Sterile Baseline Guide	Environmental Classification			Grade 5	Grade 7	Grade 8	No Classified Control (with local monitoring)	No Classified Control
European Commissioning EU GMP, Annex 1, Vol. IV, Manufacture of Sterile Medicinal Products	Purity Class			A	B	C	D	not defined
	Idle State	Max. permissible number of particles pro m ³ (equal or greater)	0.5 µm	3.520	3.520	352.000	3.520.000	-
			5 µm	20 (ISO 4.8)	29	2.900	29.000	-
	Operating Status	Max. permissible number of particles pro m ³ (equal or greater)	0.5 µm	3.520	352.000	3.520.000	352.000	-
			5 µm	20	2.900	29.000	2.900	-
		maximum permissible number of viable organism [cfu/m ³]		< 1	< 10	< 100	< 200	-
FDA, Oct. 2004, Guidance for Industry Sterile Drug Products Produced by Aseptic Processing (Reference 9, Appendix 12)	Operating Status	Max. permissible number of particles pro m ³ (equal or greater)	0.5 µm	ISO 5 (Class 100)	ISO 7 (Class 10.000)	ISO 8 (Class 100.000)	not defined	See "ISPE Biopharm or Sterile Baseline Guide"
		Action level of viable organism in the air [cfu/m ³]		1	10	100	not defined	-

Threshold values are advised for the microbiological monitoring of clean area, which apply to the operating status. However, the given data presents the average values.

Advised Threshold Values for Microbiological Contamination				
Class	Air sample KBE/m ³	Settle Plates (Diameter 90 mm) KBE/4 hours	Contact Plates (Diameter 55 mm) KBE/Plate	Glove print 5 fingers KBE/Glove
Class A	< 1	< 1	< 1	< 1
Class B	10	5	5	5
Class C	100	50	25	-
Class D	200	100	50	-

Purity, Safety and Hygiene - Solutions by robatherm

The basic functions of air handling units is the provision of comfortable room climates, input of oxygen and removal of carbon dioxide. In clean rooms found in laboratories and hospitals, the AHUs by far, take over many more functions. Rooms must be protected from airborne contamination, micro-organism and pollutants discharged as well as providing room air in the desired temperature and humidity.

Air Purity



The air's purity is one of the utmost criteria demanded of AHUs in the pharmaceutical industry. A respectively high significance is given to the air filters that have the following duties: The filters protect people from infections as well as the AHUs and the channel network from contamination. Precise filter monitoring prevents the clogging of the filters and permeation of dust. It also reduces the operating costs, as the filters also reduce the pressure drop.

Test Ports



Aerosol test ports effectively support the impact of HEPA filter walls. Beyond that, they enable the monitoring and qualification of HEPA filter walls in a quick and easy manner.

Excellent Hygiene



Smooth stainless steel bottom without grooves or cavities

High levels of safety and hygiene as all components and materials are disinfectant proof, including Testing certification. The inner-housing is galvanized, powder-coated or of stainless steel

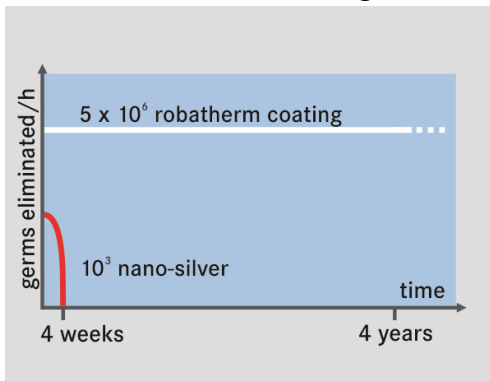
Routine maintenance and cleaning ensure a long life span of the AHU. The hygiene-friendly construction of the robatherm AHUs and good accessibility to all components make cleaning easy and thus, effectively contribute to the hygiene.

Free-Range Fans



Due to reduced input and output, free-range fans exhibit a high level of operating efficiency. The open construction also guarantees good cleanability and operating safety through the frequency controlled direct drive.

Antimicrobial Powder-Coating



Initially, commercial antibacterial coating in fact achieves recognizable results; the effectiveness however, usually declines just after weeks. In contrast, the robatherm powder-coating proves its effectiveness even after several years. In addition, it is - in comparison to antibacterial substances - also effective against algae, yeasts and molds. The housing's antimicrobial powder-coating inhibits the growth of multi-resistant germs. The high level of effectiveness and sustainable effect have been tested and confirmed during a long-term study.

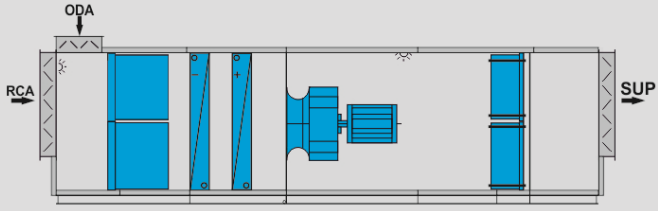
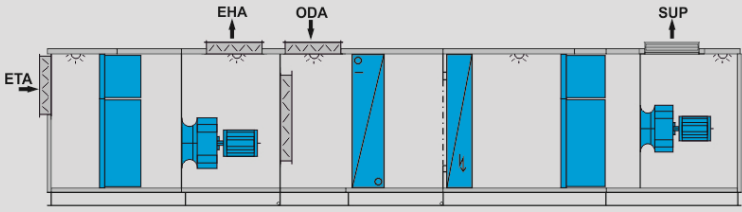
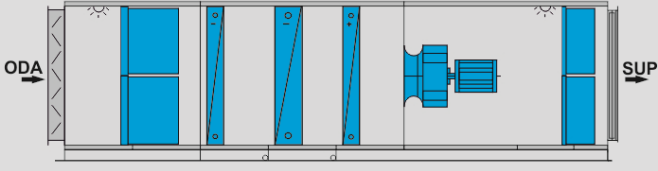
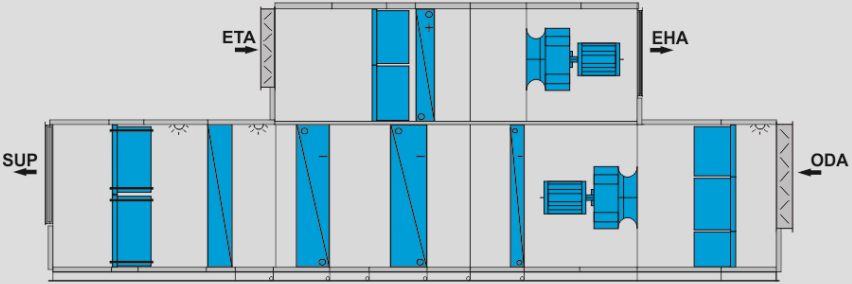
Certified Hygiene Features



The excellent hygienic characteristics of AHUs by robatherm have been tested and certified by the TÜV Nord (technical inspection agency). Combined with routine maintenance, robatherm guarantees that their AHUs provide hygienically impeccable room air. In addition, the customized AHU-Solutions save on operating expenditures and makes efficient operations possible.

Exemplary Unit Concepts for Clean Rooms

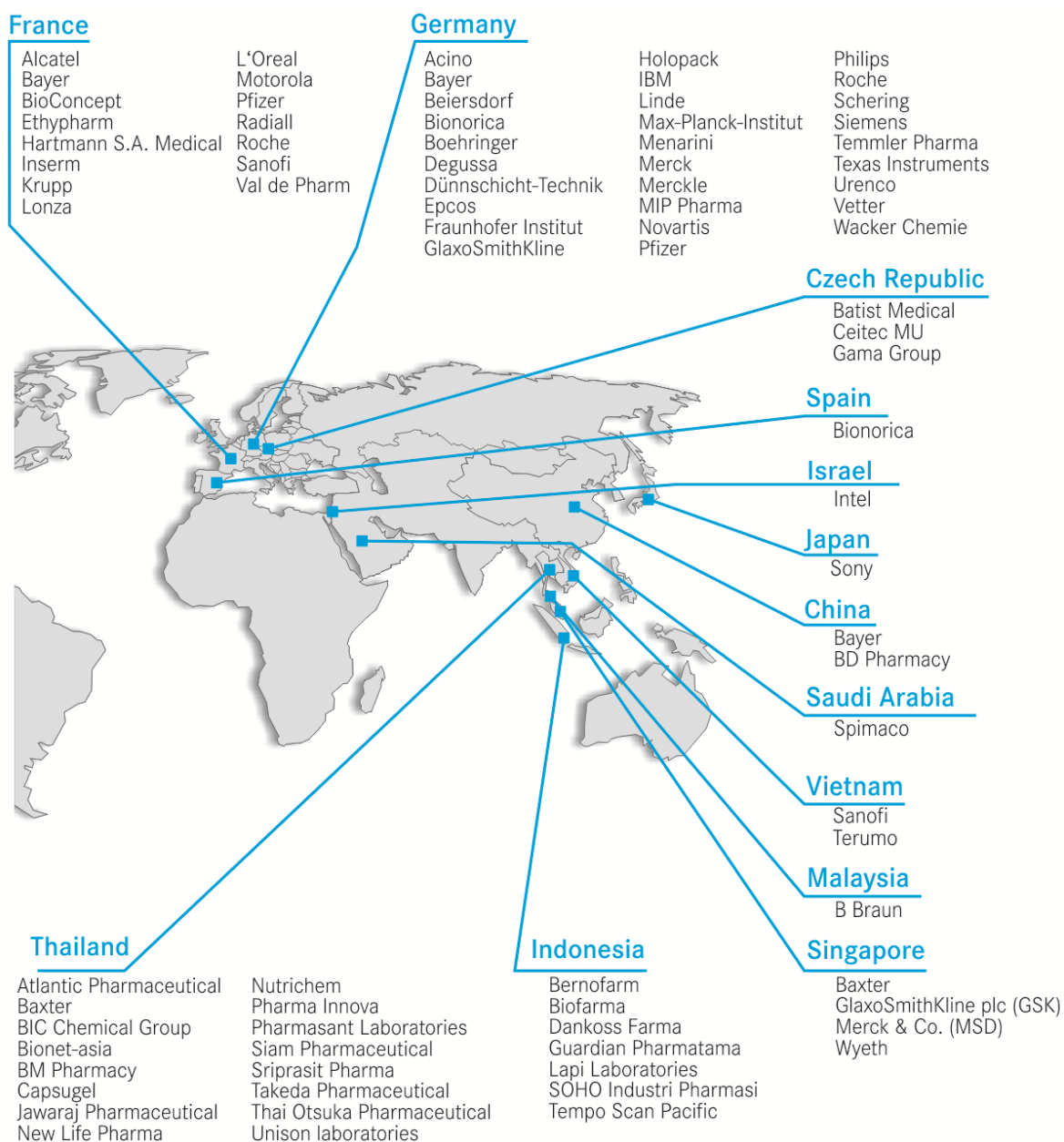
Sophisticated concepts by robatherm guarantee optimal functional safety and energy efficiency.

Unit Concept 1	 <p>Recirculating air/Outdoor air unit with HEPA-Filter</p>
Unit Concept 2	 <p>Combined supply and exhaust air unit</p>
Unit Concept 3	 <p>Outdoor air unit with free-range auxiliary heating and pre-cooling</p>
Unit Concept 4	 <p>Outdoor air unit with pre-cooling, HEPA-Filter and heat recovery from the exhaust air</p>

Always an Excellent Reference

Quality as a Foundation for Long-Term Trust

A trusting and long-term business relationship is based on qualitative, premium products and reliable service commitments. That's the reason why numerous, renowned companies have turned to robatherm for AHUs.



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