Air Handling Systems for Pharmaceutical Industries.

Highest Demands on Air Handling Technology.
AHU concepts specifically optimized to suit your application.

robatherm
the air handling company

Air Handling Systems for Pharmaceutical Industries

Impeccable Hygiene and Outstanding Room Conditions

Hygiene in the pharmaceutical sector is a self-evident prerequisite to the quality of pharmaceutical products. Avoiding pathogens transmitted through the air is top priority. A hygienically impeccable and comfortable room climate is essential during development or production processes in the pharmaceutical sector. Air handling systems are, therefore, indispensable for reducing or avoiding airborne pathogens.
AHUs in cleanrooms performs the following basic functions:

- Control airborne particles, dust and micro-organismen - Thru air filtration using high efficiency particulate air (HEPA) filters
- Maintain room pressure (delta p) – Areas that must remain cleaner than surrounding areas must be kept under a positive pressurization. Therefore the AHU must provide more air into the cleaner space than is mechanically removed from that same space.
- Maintain space moisture (relative humidity) – Humidity is controlled by cooling air to dew point temperatures or by using desiccant dehumidifiers. Humidity can affect the efficacy and stability of drugs and is sometimes important to effectively mould the tablets.
- Maintain space temperature – Temperature can affect production directly or indirectly by fostering the growth of microbial contaminants on workers.

Air handling units by robatherm are especially designed to minimize the introduction, generation and retention of particulate and microbial contaminations in pharmaceutical cleanrooms.

Classification of clean rooms

Cleanroom classifications are established by measurement of the number of particles 0.5 micron and larger that are contained in 1 m^3 or 1 ft^3 of sampled air.
Cleanrooms can be classified in accordance to the US and European Guideline, where Class 100 is equivalent to Grade A and B, Class 10,000 to Grade C and Class 100,000 to Grade D.

U.S. Federal Standard 209E					
Class Names		Class Limits			
		0.5 Micron		5 Micron	
English	SI	m^3	ft^3	m^3	ft^3
100	M 3.5	3,530	100	-	-
1,000	M 4.5	35,300	1,000	247	7
10,000	M 5.5	353,000	10,000	2,470	70
100,000	M 6.5	3,530,000	100,000	24,700	700

European Community Guidelines				
Grade Names	Class Limits at Rest[1]		Class Limits in Operation[2]	
	0.5 Micron	5 Micron	0.5 Micron	5 Micron
	m^3	m^3	m^3	m^3
A	3,500	0	3,530	0
B	35,000	0	350,000	2,000
C	350,000	2,000	3,500,000	20,000
D	3,500,000	20,000	Not defined	Not defined

[1] At Rest: State of cleanrooms is the condition where the production equipment is installed and operating but without any operating personnel.
[2] In Operation: State of cleanrooms is the condition where the installation is functioning in the defined operating mode with the specified number of personnel working.

All pharmaceutical facilities belong to one or other class of cleanroom. The following table gives the requirements according to the application.

Requirements according to the application		
Application	US-Class	European Grade
Tabletting facilities	100,000	D
Topical and oral liquids	10,000	C
Injectables class	100	A and B

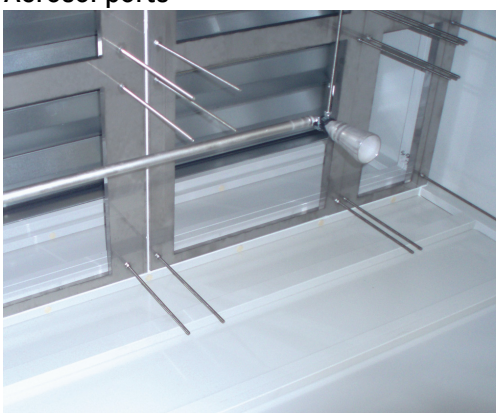
Solutions made by robatherm for cleanliness, safety and hygiene

The main tasks of air handling systems include supplying a sufficient amount of oxygen, removing carbon dioxide and maintaining a comfortable room climate that is unobjectionable from the viewpoint of climate-physiology. In rooms having to meet special requirements, such as laboratories, the supply air has further functions. The air handling system must also act as a barrier screening the specified protected area, reduce the concentration of microorganisms, provide temperature and humidity control and remove odours and contaminants.

Air cleanliness

Air cleanliness is of particular importance in pharmaceutical applications. Air filters here fulfill a combination of several tasks: They protect staff and material from infections, and air handling units (AHUs) and the ductwork from contamination. Scrupulous checking of filters for clogging prevents the ingress of dust and cuts the operating cost of the system as the pressure drop across filters is reduced.

Aerosol ports



Aerosol ports support the effectiveness of HEPA filter walls.
Moreover, aerosol ports allow to control and qualify the installation in a fast and safe way.

Excellent hygiene

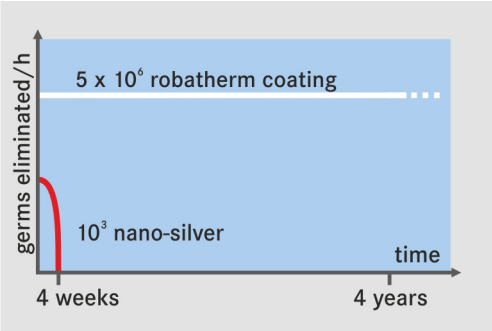
Plain floor made of stainless steel without grooves or riffles. Maximum safety and hygiene since all components and materials are resistant to disinfectants, including certifications. Inside surfaces are galvanized, powder-coated or made of stainless steel.

Periodic maintenance ensures hygienic conditions throughout the life time. The maintenance-friendly robatherm AHUs ensure impeccable cleaning as all components are arranged in the unit to be easily accessible.

Plug fan

Plug fans are cost efficient by reduced air on and off flow losses. The open design eases cleaning. Moreover, plug fans guarantee high operation safety and maintenance friendliness due to direct drive with frequency control.

Antimicrobial powder coating



Although standard antibacterial coating achieves initial, recognizable results, the effect usually dwindles in just weeks. In comparison, robatherm's powder coating exhibits its effectiveness even after several years. In addition and unlike antibacterial agents, it also counteracts algae, yeast fungi and mildews. The antimicrobial powder coating of air handling units inhibits the growth even of multiresistant germs.
A long-term study has examined and confirmed the high effectiveness and long-acting antimicrobial effect.

Certified hygiene characteristics

TÜV NORD

ZERTIFIKAT

Hiermit wird der

robatherm GmbH + Co. KG
Industriestraße 26
89331 Burgau

bestätigt, dass die

raumlufttechnischen Geräte in Hygieneausführung der Gerätebaureihe

"RM / RL"

den Anforderungen für Hygieneklimageräte gemäß

DIN 1946 Teil 4: 2008	DIN EN 13779: 2007
DIN EN 1886: 2009	DIN EN 1751: 1999
DIN EN 13053: 2007	VDI 3803: 2010
VDI 6022 Teil 1: 2011	SWKI VA 104-1: 2006
ÖNORM H6021: 2003	SWKI 99-3: 2003
ÖNORM H6020: 2007	

entsprechen.

Die ausführliche Dokumentation der im Februar 2012 durchgeführten Baumusterprüfung des Innenraumgerätes RM 09/09 kann dem Prüfbericht Nr. 81 08 25 34 76 des TÜV NORD entnommen werden. Da es sich um anlagenbezogene Normen / Richtlinien handelt, kann die Baumusterprüfung nicht die an einer fertig gestellten Anlage vorgeschriebenen Prüfungen ersetzen.

TÜV NORD Systems GmbH & Co. KG
Bereich Engineering
Prüfstelle für Kälte-, Klima- und Lüftungstechnik
Langemarckstraße 20, 45141 Essen

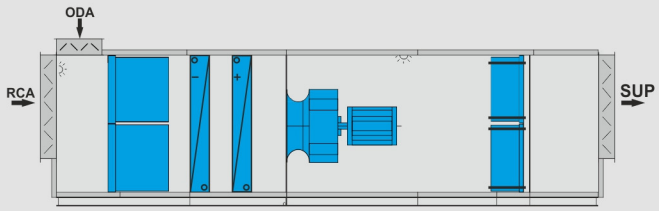
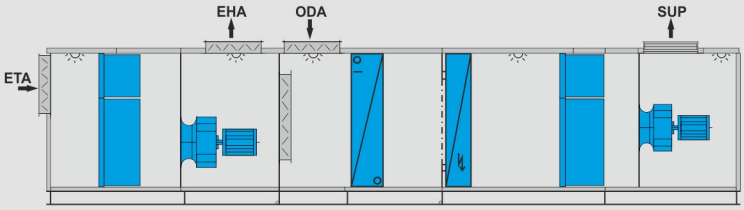
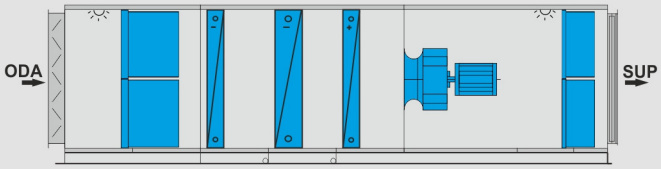
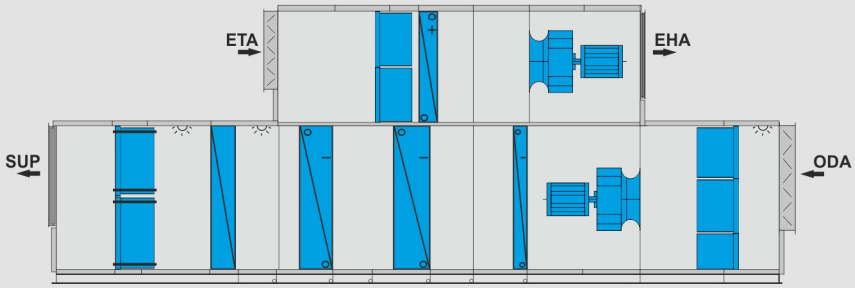
Die Sachverständige

Essen, 10. Februar 2012 — Dipl.-Ing. Marion Klein

Excellent hygiene characteristics of the robatherm AHUs were tested and certified by the TÜV Nord. Proper operation and maintenance provided, our hygiene AHUs will ensure hygienically impeccable air quality. Moreover, the operating costs of the optimally configured AHUs have been reduced to a minimum.

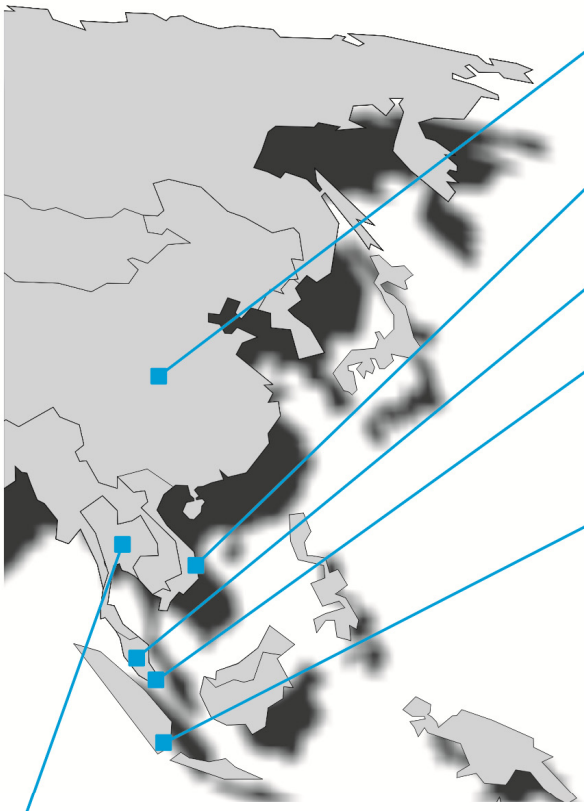
Sample AHU configuration specially for pharmaceutical applications

robatherm offers AHU concepts specifically optimized for pharmaceutical applications.

Sample AHU Configuration 1	
	Recirculation unit
Sample AHU Configuration 2	
	Unit with return and supply air fan
Sample AHU Configuration 3	
	Pre-cool unit with free reheating and pre-cool
Sample AHU Configuration 4	
	Pre-cool unit with heat recovery from exhaust air

Best choice and best references

Trust and confidence emerge from quality
That is why many well-known companies of the chemical or pharmaceutical sector favor robatherm‘s solutions.



China
Bayer
BD Pharmacy

Vietnam
Sanofi
Terumo

Malaysia
B Braun

Singapore
Baxter
GlaxoSmithKline plc (GSK)
Merck & Co. (MSD)
Wyeth

Indonesia
AstraZeneca plc
Bayer
Bernofarm
Biofarma
Dankoss Farma
Guardian Pharmatama
Kalbe Farma
Konimex Pharmaceutical Laboratories
Lapi Laboratories
Merck & Co. (MSD)
SOHO Industri Pharmasi
Tempo Scan Pacific
Tunggal Idaman Abdi

Thailand
Advance Pharmaceutical (APM)
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