# Supplementary Training Modules on GMP

#### **Air Handling Systems**

Heating
Ventilation and
Air Conditioning (HVAC)

**Part 2: Components** 

Purpose of an air handling system

Air Handling System

Production Room
With
Defined
Requirements

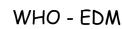
Outlet Air



Supply

Air





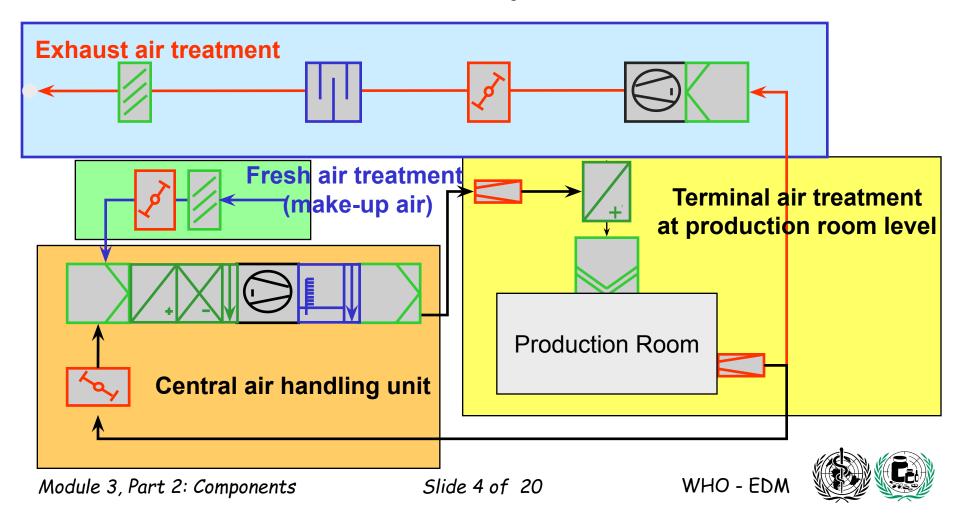


#### **Objectives**

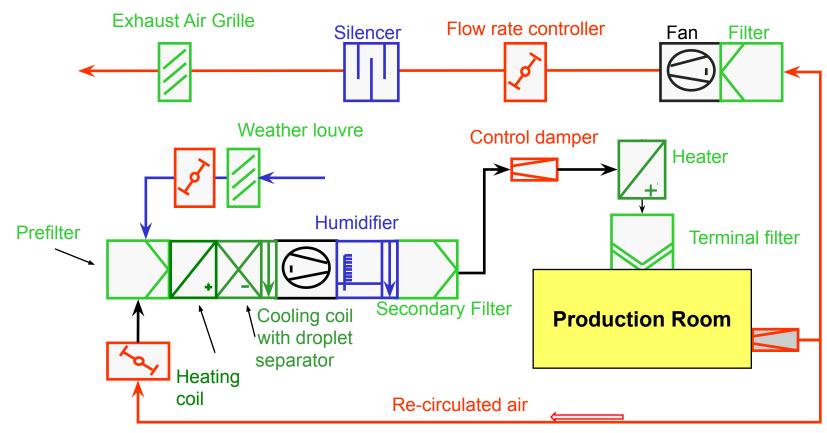
In the following slides, we will study the components of air handling systems in order to:

- 1. become familiar with the components
- know their functions
- 3. become aware of possible problems

#### Main subsystems



#### **Overview components**



#### Components (1)

Weather louvre To prevent insects, leaves, dirt and

rain from entering

Silencer To reduce noise caused by air

circulation

Flow rate controller — Automated adjustment of volume of

air (night and day, pressure control)

Fixed adjustment of volume of air

Control damper

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#### Components (2)

Heating unit

To heat the air to the proper temperature

Cooling unit/dehumidifier

To cool the air to the required temperature or to remove moisture from the air

Humidifier

To bring the air to the proper humidity, if too low

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Filters

To eliminate particles of pre-determined dimensions and/or micro-organisms

Ducts

To transport the air



#### **Problems with components**

Flow rate controller Blocked

Control damper Poorly adjusted, bad pressure differential system

Humidifier Bad water/steam quality/poor drainage

Cooling battery No elimination of condensed water/poor drainage

Incorrect retention rate/damaged/badly installed

Inappropriate material/internal insulator leaking

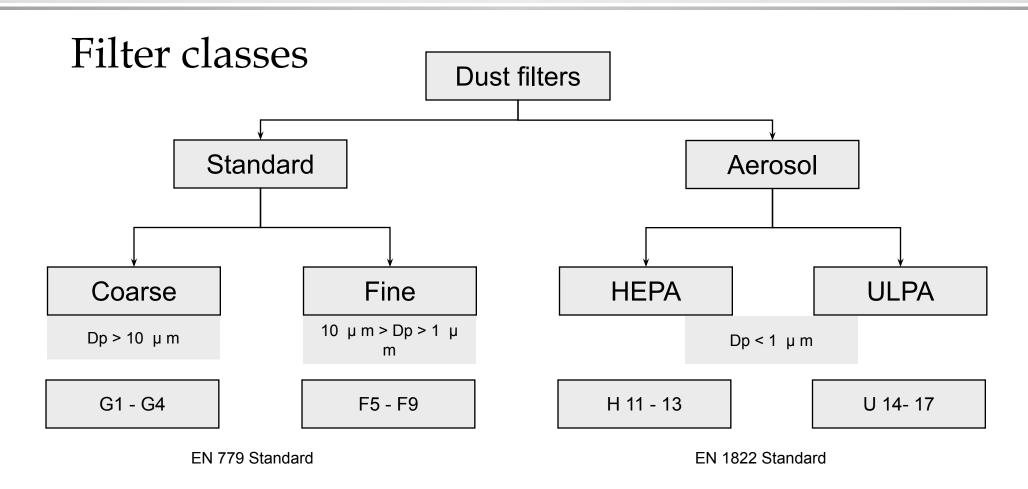
Ducts

**Filters** 

### Air types **Exhaust** Fresh air Supply air (make-up air) air **Production Room** Return air (re-circulated)

#### **Comparing International Cleanroom Classifications**

Particles / m <sup>3</sup>	US 209D	US 209E	EC cGMP	Germany	UK	Japan	ISO 14644-
□ 0.5µm	non- metric	1992 metric	Annex I 1997	VDI 2083 1990	BS 5295 1989	JIS B 9920 1989	1
1							
3,5				0		2	2
10		M 1					
35	1	M 1.5		1		3	3
100		M 2					
353	10	M 2.5		2		4	4
1.000		М3					
3.530	100	M 3.5	A, B A= unidirectional B= turbulent	3	E or F	5	5
10.000		M 4					
35.300	1.000	M 4.5		4	G or H	6	6
100.000		M 5					
353.000	10.000	M 5.5	С	5	J	7	7
1.000.000		M 6					
3.530.000	100.000	M 6.5	D	6	K	8	8
10.000.000		M 7					



#### Classification of filters according to their efficiency

	_	Efficiency Il Value	Peak Arrestance Local Value		
	Retention in %	Penetration	Efficiency	Penetration	
F9	85	0.15			
H11	95	0.05			
H12	99.5	5x10 <sup>-3</sup>	97.5	25x10 <sup>-3</sup>	
H13	99.95	5x10 <sup>-4</sup>	99.75	25x10 <sup>-4</sup>	
U14	99.995	5x10 <sup>-5</sup>	99.975	25x10 <sup>-5</sup>	



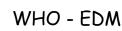
Primary panel filter



Secondary filter

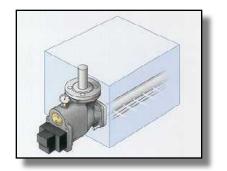
HEPA or tertiaary filter







Humidifier

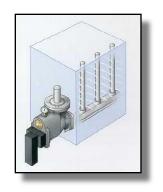


Silencer cooling units



Heating and









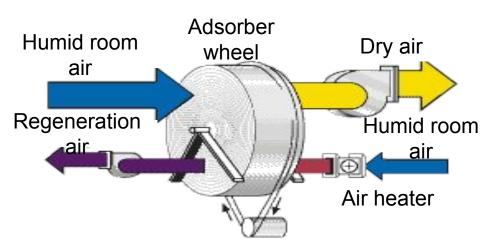


Slide 14 of 20

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Control damper for air flow



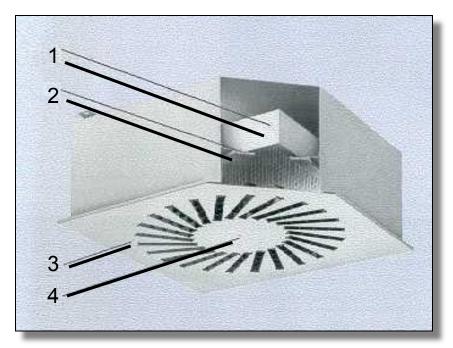
De-humidification

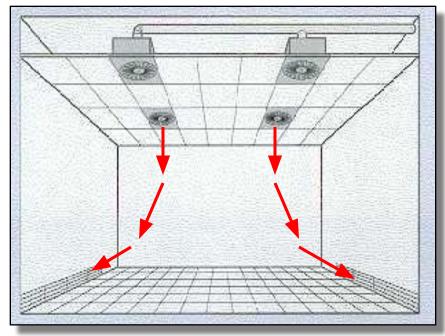
Module 3, Part 2: Components



Air handling unit

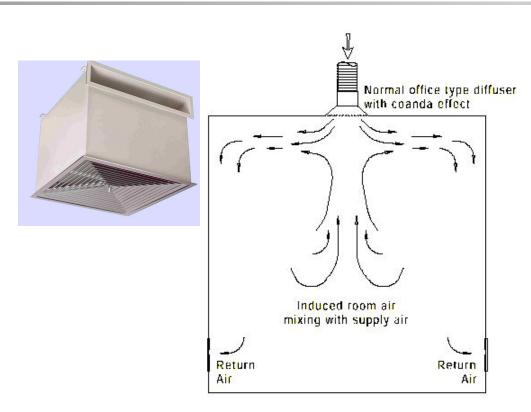


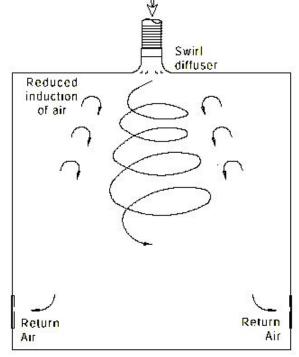




- 1 Filter Swirl Type air diffusors with
- 2 Tightening frame
- 3 Register outlet
- 4 Screw fixation for register

terminal filters







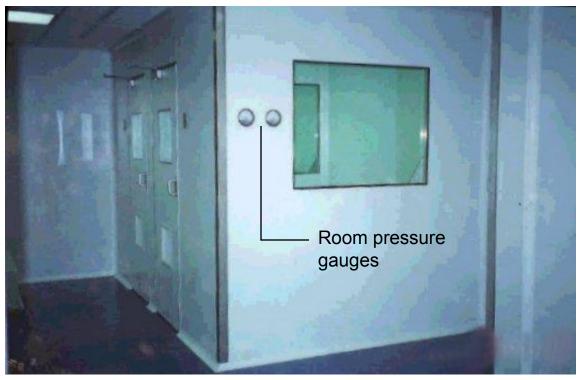
High induction office type diffusor (avoid)

Low induction swirl diffusor (preferred)



#### Regulation of room pressure – pressure differentials concept

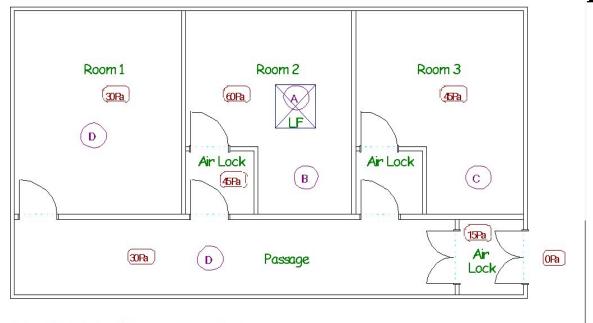




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Annex 1, 17.26

#### Pressure cascade injectables Protection from micro-organisms and particles



Note: Direction of door opening relative to room pressure

Annex 1, 17.24, 17.25



#### Pressure cascade solids Protection from cross-contamination

