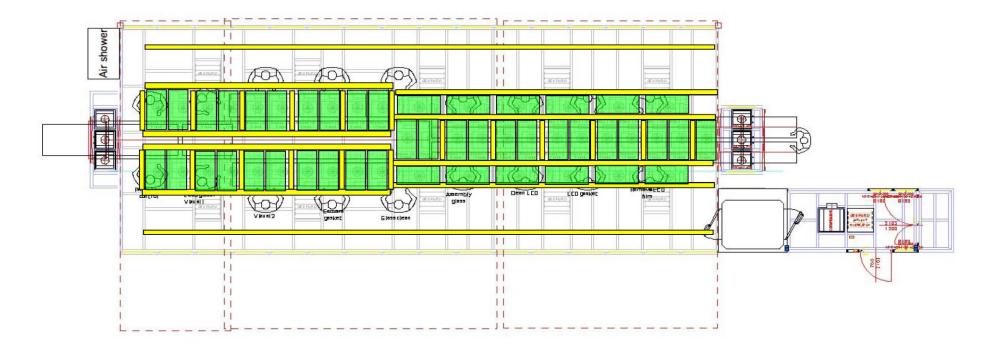




- Regulations, Air-Handling, Design & Construction -



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Contents of Presentation:

- 1. What is a Cleanroom Basics
- 2. Air-Handling Concepts & Devices
- 3. Cost and efficiency of Air-Handling devices
- 4. <u>De-Centralized Air-Handling concepts & FFU's</u>
- 5. <u>Cleanroom Design</u>
 - Avoiding Contamination
 - Walls, Ceiling, Floor
 - Work-Flow
 - Monitoring etc.







A clean area, that is designed to reduce the contamination of processes and materials.

This is accomplished by removing or reducing contamination sources.

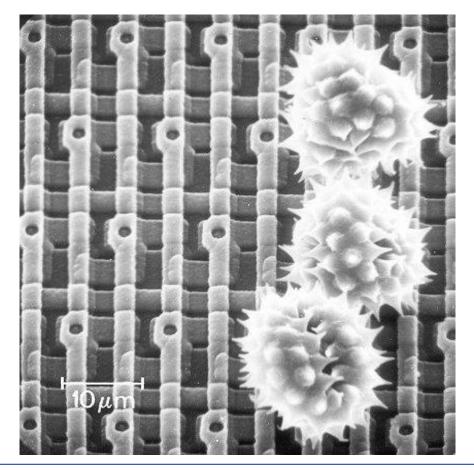
That means clean air, stable temperature, stable humidity, clean water, gases and chemicals, lighting, processing- equipment, inspection and test equipment, room infrastructure, etc.







Particles



Contamination Sources:

- People ~75%
- Ventilation ~15%
- Room Structure ~5%
- Equipment ~5%







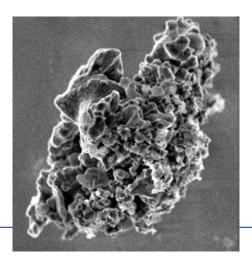
Particles

Primary Sources

- Exposed Skin/Hair / People
- Non-cleanroom Paper
- Garments
- Vinyl, PVC, Rubber, Ink
- Operations: drilling, cutting..
- Environment
- Equipment
- Chemicals
- Process

Secondary Sources

- Gloves
- Tools
- Work Surfaces
- Floor



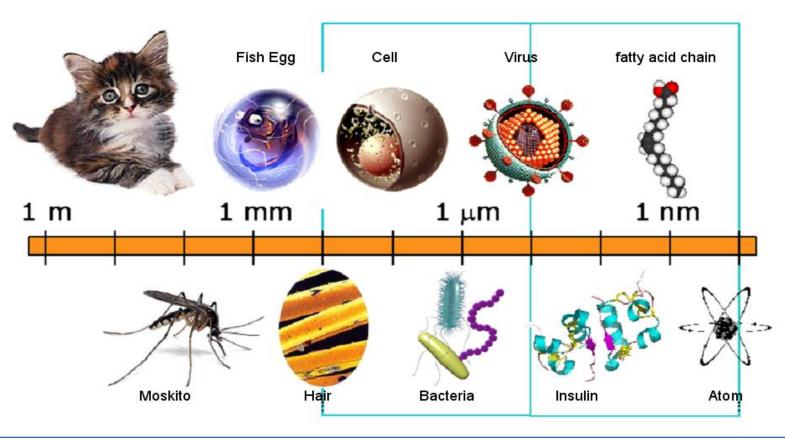






Particles

Examples:









Particles

Examples:

- Particles as small as 1 micro-meter (micron) => 0,0000001m
- The unaided eye can see particles as small as 50 microns on a good background
- The thickness of a human hair is 100 microns
- Time to fall 1 meter in still air for a 10 micron particle is 33 seconds, for a 1 micron particle is 48 minutes
- Humans generate >1x10⁵ particles per minute when motionless (fully gowned)
- Humans can generate $>1x10^6$ particles when walking in the Cleanroom







Cleanroom Standards:

ISO 14644 / GMP / DIN / WHO / BS5295 / JIS B9920 etc.

Example: Fed-Std. 209E

CLASS	Number of Particles per Cubic Meter by Micrometer Size						
	0.1 um	0.2 um	0.3 um	0.5 um	1 um	5 um	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		
ISO 4	10,000	2,370	1,020	352	83		
ISO 5	100,000	23,700	10,200	3,520	832	29	
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	
ISO 7				352,000	83,200	2,930	
ISO 8				3,520,000	832,000	29,300	
ISO 9				35,200,000	8,320,000	293,000	

Cleanroom Class	Airflow Type	Airflow Velocity	Air Changes per Hour
+1	Unidirectional	60-100 fpm	360-600
1	Unidirectional	60-90 fpm	360-540
10	Unidirectional	50-90 fpm	300-540
100	U/N	40-80 fpm	240-480
1 000	Nonunidirectional	25-40 fpm	150-240
10 000	Nonunidirectional	10-15 fpm	60-90
100 000	Nonunidirectional	1-8 fpm	5-48







Cleanroom Standards: Example: Fed-Std. 209E

FS209E requires 10 sample locations, 19.6 liter minimum sample volume (0.85 cf), and a sample time of 51 seconds. This yields a total minimum sample time of 510 seconds and 10 equipment moves.

ISO 14644-1 requires 5 sample locations, 19.6 liter minimum sample volume (0.85 cf), but also a minimum sample time of one minute yielding three samples of one cubic foot. This yields a total sample time of 180 seconds and three equipment moves.







The manufacturing environment is critical for product quality. Factors to be considered include:

- Light
- Temperature
- Relative humidity
- Air movement
- Particulate contamination
- Uncontrolled environment can lead to poor product quality => loss of product and profit







Parameters influencing the Cleanroom class:

- Number of particles in the air or on surfaces
- Number of air-changes for each room
- Air velocity and airflow pattern
- Filters (type, position)
- Air pressure differentials between rooms
- Temperature, relative humidity
- Facility Layout and Work-Flow

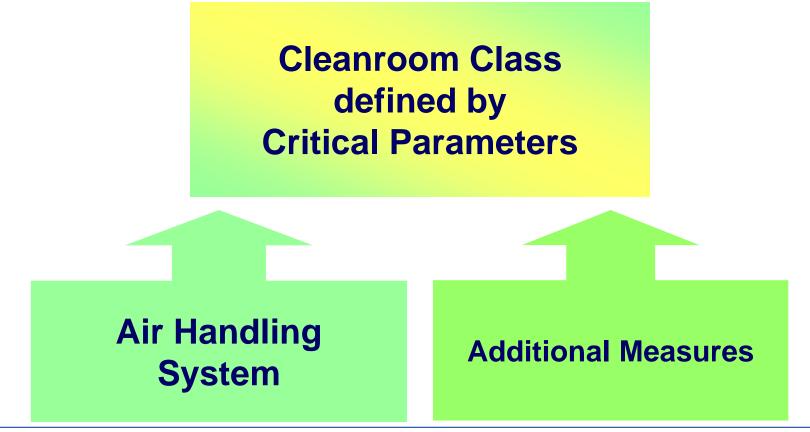
Part of the Solution:

Air-Filtration-Systems, Air-Conditioning-Systems















2. Air Handling Concepts & Devices

Air Handling System







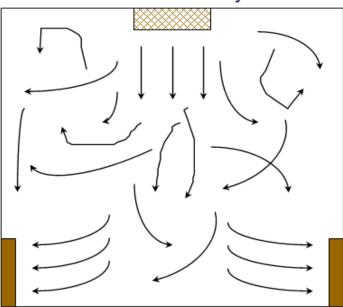


2. Air Handling Concepts & Devices

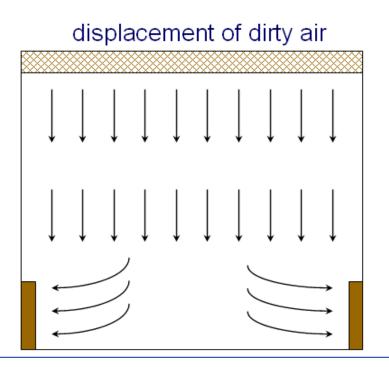
Airflow patterns

Turbulent





Unidirectional/laminar

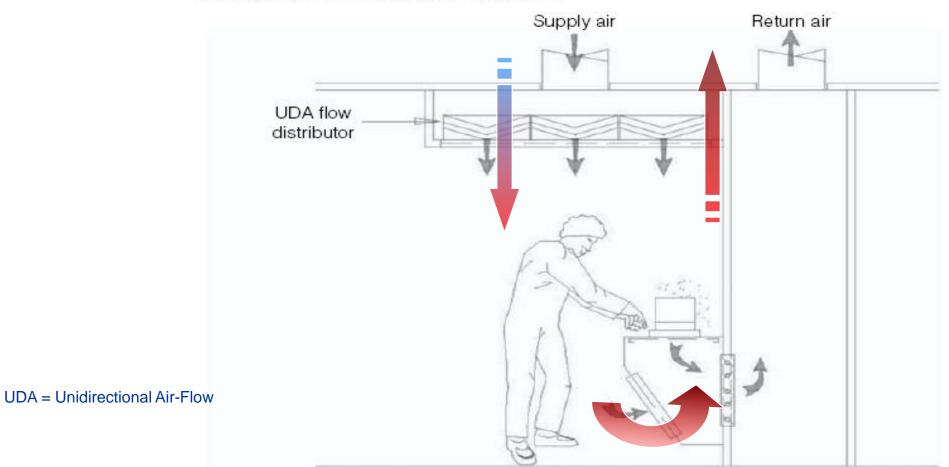








Operator protection at weighing station



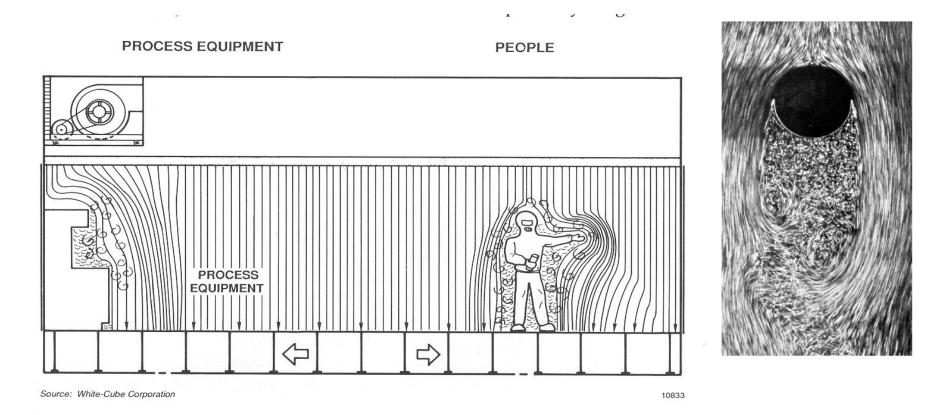








2. Air Handling Concepts & Devices



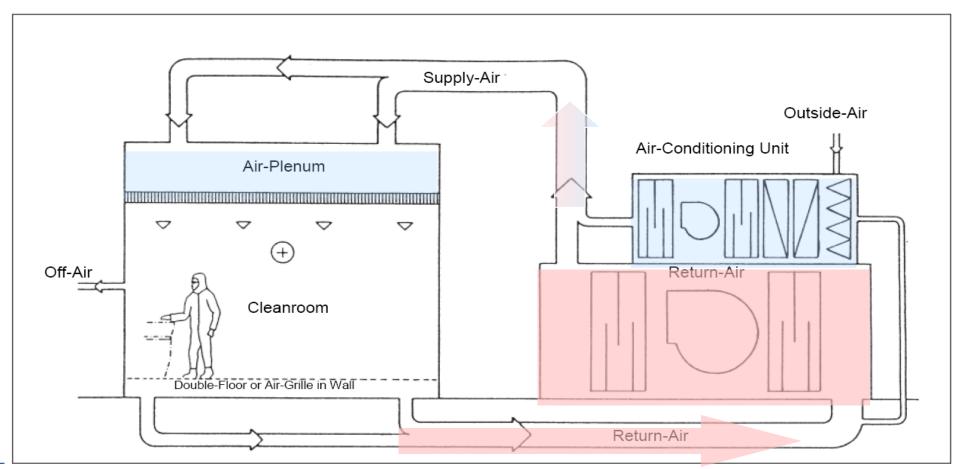








Centralized Air-Conditioning System:



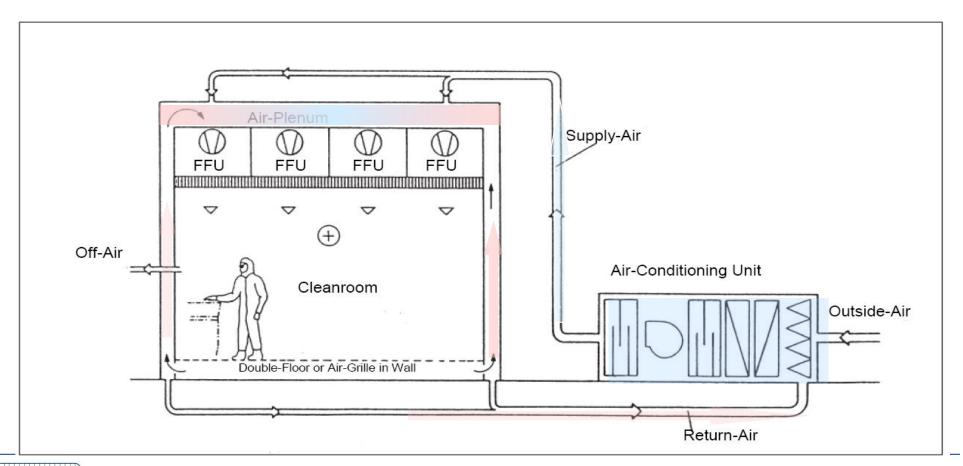






2. Air Handling Concepts & Devices

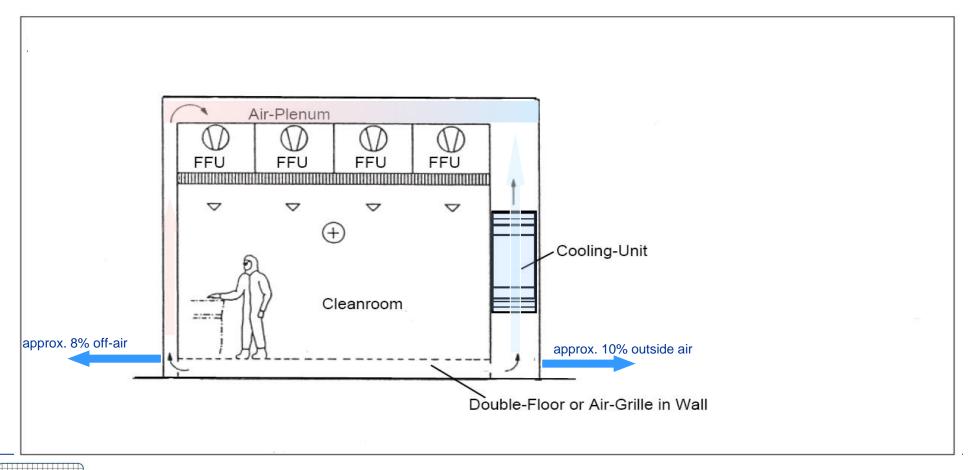
De-Centralized System: Air-Conditioning in combination with Fan Filter Units







De-Centralized System: Fan Filter Units & Cooling



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2. Air Handling Concepts & Devices

De-Centralized System: Fan Filter Units & Cooling







In regard to the design and use of an Air-Handling System, the following aspects need to be considered.

- Cleanroom conform realisation of production areas with a <u>focus on contamination</u> sources and safety aspects.
- Modular Cleanroom concepts for future changes and maintenance work.
- Independent supply systems (HVAC)
- Low investment cost, a good price- / product-ratio, avoiding falsely placed investments.
- Low running- and maintenance-cost







Cleanroom projects can be divided into three groups:

Cleanrooms that are being integrated into existing buildings by using the given building structure. The air-handling concept is almost always linked to the existing HVAC concept.

Integration of a Room-in-Room solution into an existing building with an independent air-handling system.

Cleanroom concept that is being designed and built together with a new building.







In a first planning phase is important to <u>analyze the needs of a customer</u> and to compare the requirements to the currently used Cleanroom / production process.

=> Often only small areas of the production have to be classified clean areas.

Most important it is to <u>find the sources of contamination</u> and to analyze how they can be controlled or avoided.

=> The biggest source of contamination is often people working within the Cleanroom. Proper clothing, Cleanroom "etiquette" training and discipline help to keep the levels low.

At the same time it is needed to create a scheme of <u>cascaded room pressures</u>. =>Thus having the highest air-pressure within the room of the highest class all the way to the lowest or no over-pressure into the "grey" or "black" areas with no classification.

Large areas of filter covered ceiling should be avoided for cost reasons,- "<u>bay-solutions</u>" are more cost-efficient.

=> Design of the Air-Handling system







The <u>temperature difference</u> between conditioned air and re-circulated air needs to be as big as possible. => This allows the amount of conditioned air versus the non-conditioned (re-circulated) air to be small.

<u>Heat-exchange systems</u> might also prove to be an additional means of lowering the running cost of a Cleanroom facility.

<u>De-centralized Air-Conditioning</u> (AC) units are more and more becoming an option that not only allows independence from existing building installations, but also in regard to their modularity, maintenance and price.

<u>Short distances</u> between the Cleanroom and the AC-system avoid pressure drops within the system.







Further into the planning process low air-exchange rates need to be realized.

Sections of high <u>heat-emission</u> have to be separated from the Cleanroom area. => This helps to keep the amount of cooling low and saves energy too.

<u>Air-speed</u> under the ceiling can be lowered in certain areas,- achieving the same Cleanroom class by saving on filter media and energy cost.

Finally, the <u>air-handling concept</u> needs to be defined.

=> The best results have so called "return-air" systems. Here 80% (or so) are being re-circulated to the Cleanroom, whilst 10-20% of the air are being conditioned via an Air-Conditioning system and/or are outside air.







The energy use of Cleanroom environmental systems varies with the system design, Cleanroom functions and critical parameter control including filtration, temperature and humidity.

"...A review of studies on Cleanroom operation costs indicated that energy cost could amount to 65 – 75% of the total annual cost associated with Cleanroom operation and maintenance..." (LBNL-51549, Contamination Control Society)

Comment:

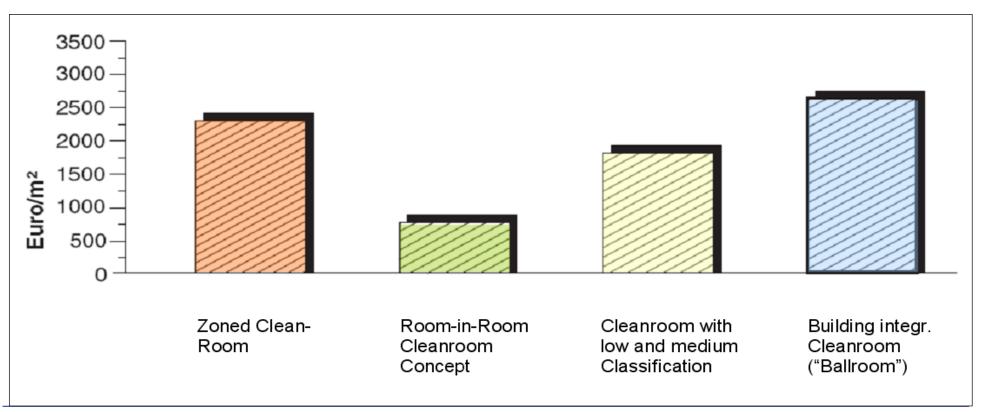
- Energy cost
- Cost of a Cleanroom C\$ 350 depending on class and system
- Investment cost HVAC C\$ 800 Depending on class and system







Cost of Cleanrooms, without AC-System, walls and flooring (Source: Dipl. Ing. W. Gerk, KI, 2003)









Cost for Cleanroom Modules, based on the supply-air concept, without AC-System, walls and flooring.

Type (values per m ² Cleanroom):		Centralized	De-Centralized
Supply-Air velocity	(m/s)	0,45	0,45
Supply-Air Volume	(m³/h)	1620	1620
Return-Air Volume	(m³/h)	1460	1460
Outside-Air Volume	(m³/h)	160	160
Efficiency of AC-Unit	(ŋ)	0,8	0,8
Air-Differential Pressure AC-Unit	(Pa)	1250	1250
Efficiency of Fan-Motor	(η)	0,8	0,65
Total Air-Pressure difference of Fan	(Pa)	800	350
Energy Consumption	(W)	475	288
(Energy Savings	(W)	-	187)
Energy Saving from motors/fans:	0,187W x 8760h/a x 0,092€	= approx. €	150,00/a
Energy Saving (electrical) for Cooling: 0,187V	V x 0,33 (eff.) x 8760h/a x 0,092€ = app	rox. € 50,00/a	
Total amount of energy savings per m ² Clean	= approx. €	200,00/a	
(values based on projects sized $200m^2 - 1.000m^2$, Dipl. Ing. W. Ger	k, Kl, 2004)		







The types of recirculation systems, design details, and layout, can largely affect the magnitudes of overall air system efficiency.

The bottom line is that reducing resistance in the air path throughout air systems can lower pressure drops, and thus require less fan power and energy to re-circulate the air needed to maintain effective contamination control.

(Excerpt taken from: Airflow Design for Cleanrooms and its Economic Implications, by Tengfang Xu, Ph.D., PE, Lawrence Berkeley National Laboratory, 2007)

Amongst other aspects, the following issues are important as well.

- Optimizing exhaust flows on tools
- Lowering cleanroom airflow through HEPA filters
- Measuring key tools to optimize heat removal

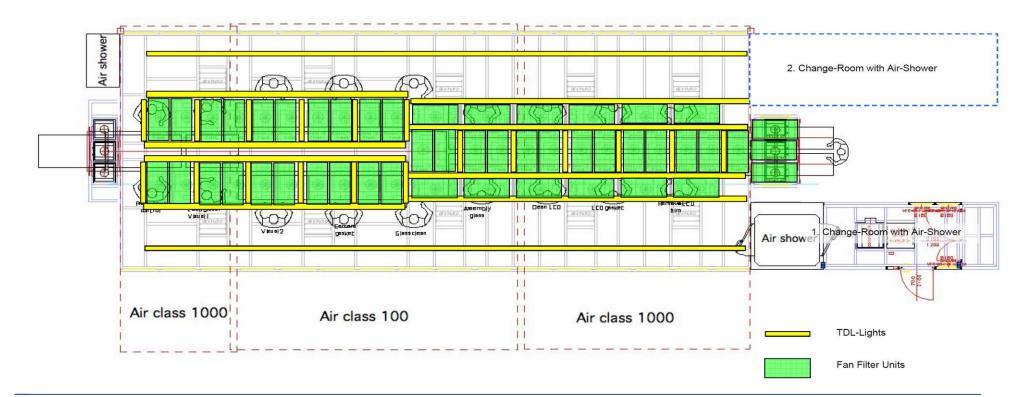






4. De-Centralized Air Handling Concept – FFU's

Example of a Cleanroom with different Zones:





Example of a Cleanroom with different Zones:





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4. De-Centralized Air Handling Concept – FFU's

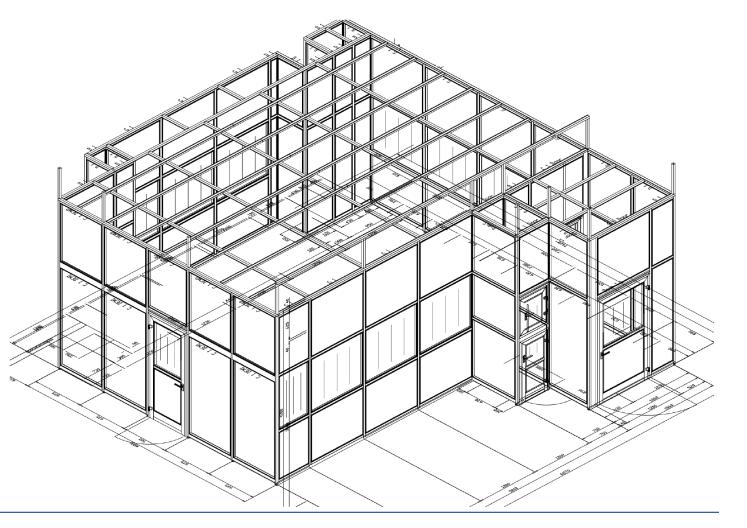
Example of a Cleanroom with different Zones:







3-D view of a Cleanroom construction

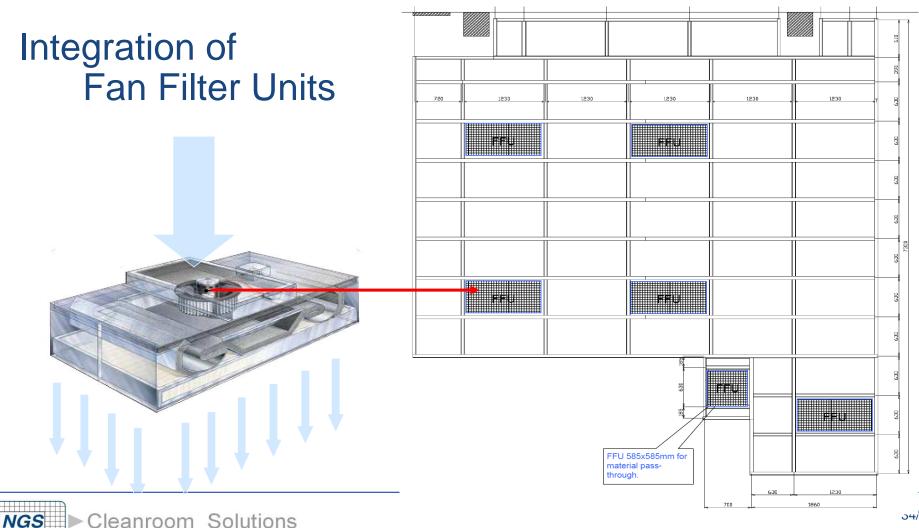








4. De-Centralized Air Handling Concept – FFU's

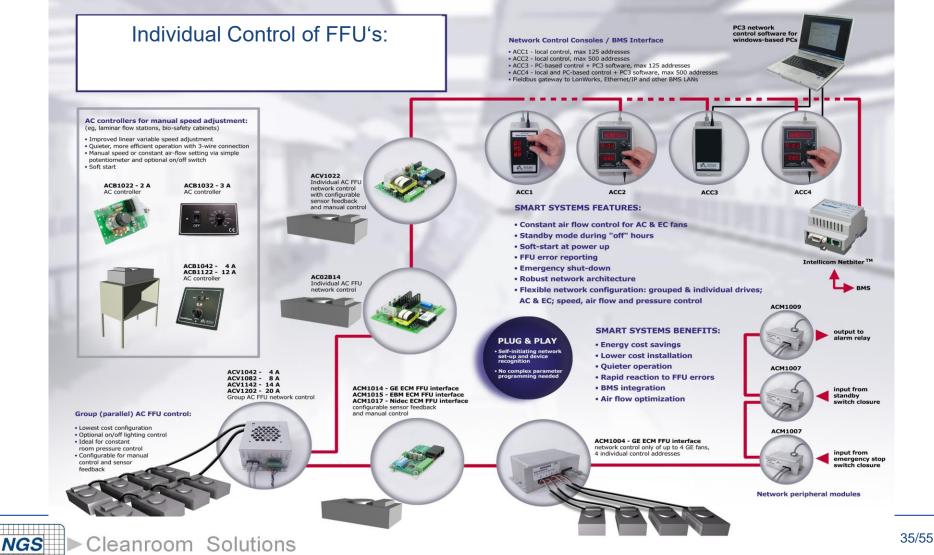




CLEANROOM ENVIRONMENTS

Innovative Process Engineering

4. De-Centralized Air Handling Concept – FFU's







5. Optimizing a Cleanroom

- Cleanroom Design
- Avoiding Contamination / Cleanroom Discipline
- Material Exchange / Air-Showers
- Enclosures for Machinery
- Reducing Power Consumption
 - Machines / Process
 - Lighting (T8 / T5 / other lamps)
- Work-Flow
 - Storage next to end of production line
 - Warehouse / Stock centralized







5. Cleanroom Design:

- Wall Systems
- Ceiling Systems
- Flooring
- Doors & Windows
- Control Systems
 - Light
 - Interlock
 - Monitoring etc.







5. Cleanroom Design: Walls Systems

-Mono-Block Systems:

One block wall sytem, 50 or 60mm thickness, surface powder coated steel, joints often covered with silicone. Panel core mineral wool, polyurethane or honey-combe. These walls types often are used for pharmaceutical Cleanrooms. Heavy duty construction, more for fixed room layouts.

- Modular Wall Systems:

Singles shell or double shell framed wall systems. Modular structure with glass, aluminium or other type panels. Ideal for semiconductor applications, as the Cleanroom can be easily adapted to production layout changes.









5. Cleanroom Design: Mono-Block Systems









5. Cleanroom Design: Mono-Block Systems

- Advantages:
- -Insulation properties
- -Solid structure
- -Smooth surface and joints
- -Use in high Cleanroom classes

Dis-Advantages:

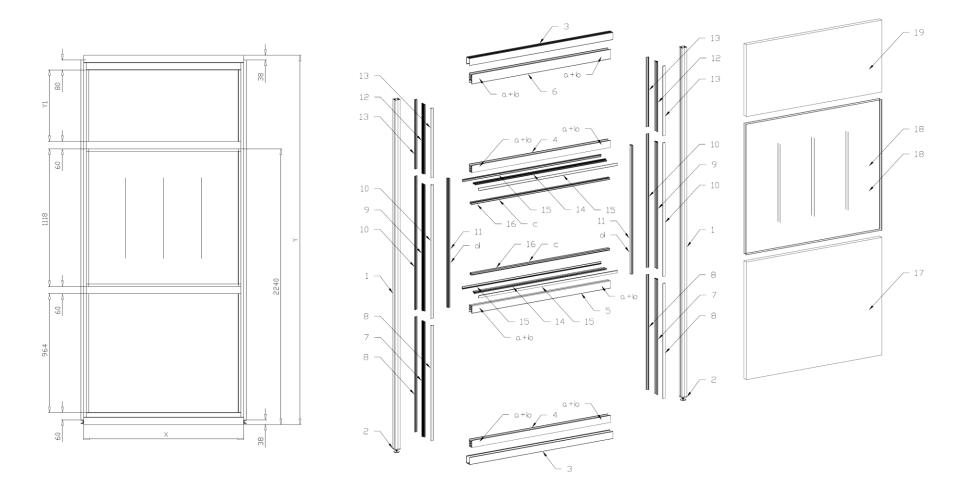
- Higher in price
- Not easy to change room layout
- Integration of horizontal ducts







5. Cleanroom Design: Modular Systems

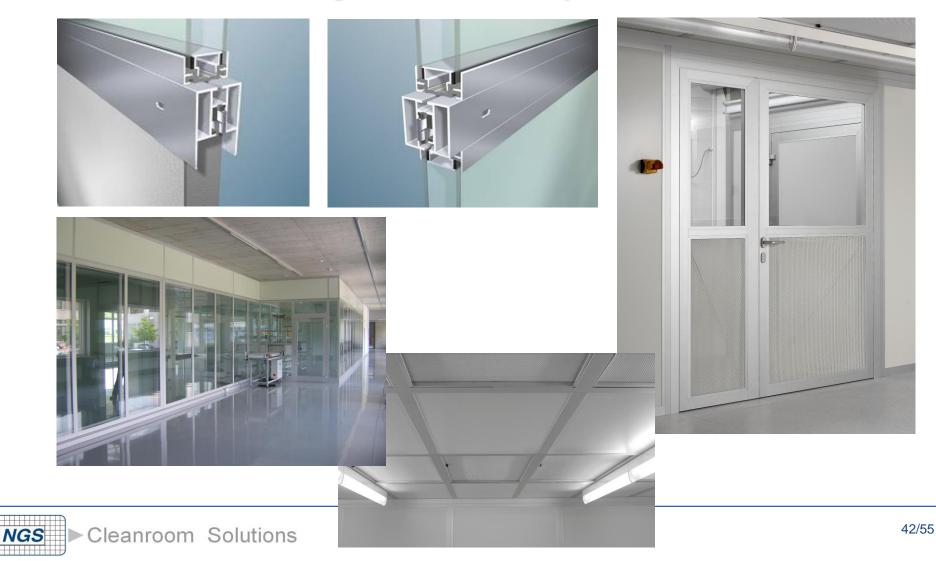








5. Cleanroom Design: Modular Systems







5. Cleanroom Design: Modular Systems

Advantages:

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- lower in price
- modular, easy to change

Cleanroom Solutions

Dis-Advantages:

- Reduced insulation properties
- Suface flush, but with joints
- Integration of horizontal ducts Less load bearing
- -Use in high Cleanroom classes





5. Cleanroom Design: Wall Systems







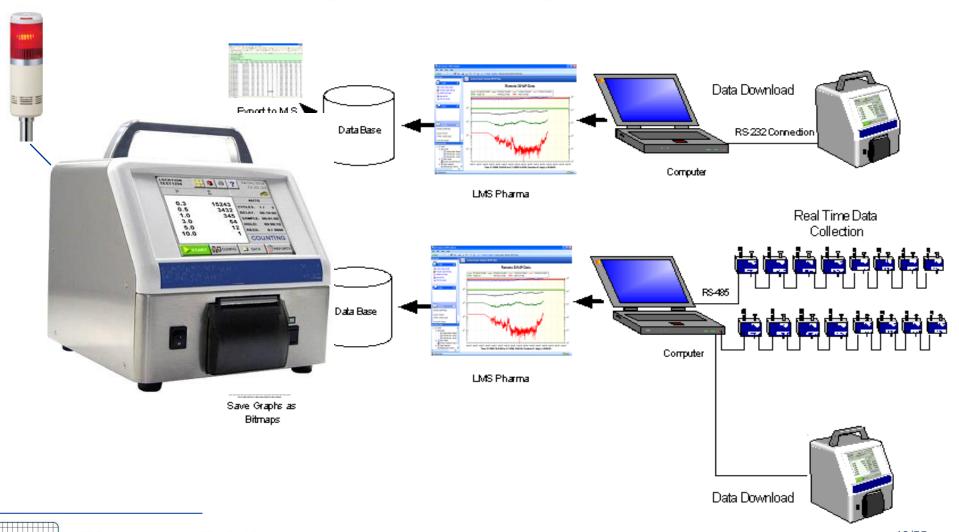
5. Cleanroom Design: Room-in-Room structures







5. Cleanroom Design: Monitoring Systems



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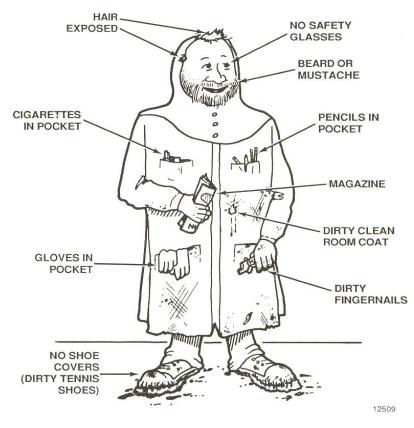


Figure 1-9. The Dirt Generator







The following rules are to be observed by all persons qualified to work in the Cleanroom:

- 1. Only personal qualified through the Cleanroom Access Training program are allowed to enter the Cleanroom.
- 2. No makeup shall be worn inside the Cleanroom
- 3. Food and drinks are prohibited in the Cleanroom.
- 4. No smoking is allowed before entering the Cleanroom.
- 5. Clothing Requirements. Everyone must wear full-length pants and closed shoes, such as safety shoes (no sandals, no open-toed shoes). In addition to that suitable cleanroom gowning, e.g. head-caps and shoe-covers have to be used.







- 8. Only use pens. Pencils are not allowed in the Cleanroom.
- 9. Hair nets, shoe covers, safety glasses, mustache/beard nets, and gloves must be worn at ALL times.
- 10. Nonessential items (tools, books, backpacks etc...) must be kept outside the Cleanroom or in the gowning room lockers.
- 11. Try not to sneeze, cough or breathe directly on a clean surface or into the product area.
- 12. Do not let your skin touch any surface in the Cleanroom. Do not touch your face with your gloved hand. Do not touch the outside of a glove (except for the wrist edge) with your ungloved hand.
- 13. Always clean up your work area before you leave.









Lab Coat / Gown



Hood



Shoe Cover



Beard Protection



Gloves







5. Material Exchange / Air-Showers



Source of pictures: Internet







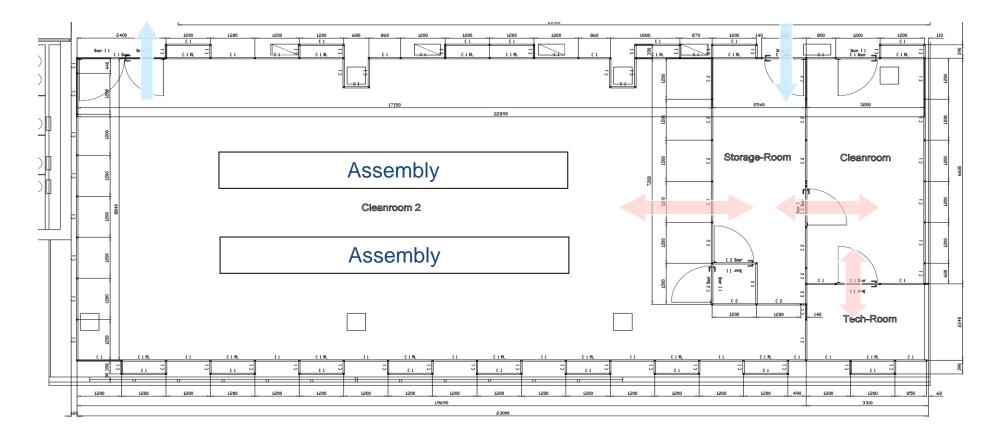
5. Enclosures for Machinery





5. Work-Flow





Source of pictures: Internet







5. Summary:

What needs to be done?:

- Understand what you want and what you do
- Optimize your Building Structure
- Optimize your Air-Handling Concept
- Enforce a Cleanroom "etiquette"
- Train and certify all levels of personnel.
- Write & update process procedures.
- Create short ways to stock materials, supplies and storage
- Establish quality assurance.







A Clean-Room starts in your head!

THANK YOU!