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วัสดุ และสถาปัตยกรรมที่ใช้ในระบบ CLEANROOM

การออกแบบ ก่อสร้าง และ ประเมินราคา

ชนิด คุณสมบัติ และความเหมาะสมในการใช้งานของวัสดุ

การตรวจรับระบบ CLEANROOM (DQ, IQ, OQ, PQ)

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Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

8 APRIL 2005

Presented by
Usa Panpunuan

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

About the presenter : *Usa Panpunuan*

Professional Experience

- Experience in many aspects of mechanical engineering ranging from design of
  - HVAC System and Cleanroom
  - Sanitary System
  - Fire Protection System
  - Utility System (e.g. Compressed Air System, and Gas System, etc.)
- Experience in design of many industrial and commercial projects
  - For Pharmaceutical Industrial : The Government Pharmaceutical Organization, Better Pharma, Capsulgel
  - For Electromechanical Industrial : Canon, Toshiba, Hitachi, Pemstar, NEC
  - For Petrochemical Industrial : Bayer, Starsoleil
  - For Eye glasses lens Industrial : Hoya, Rodenstock
  - For Food and Beverage Industrial: Pepsi, Ajinomoto
  - For Automobile Industrial : Thai–Honda Manufacturing, NHK Spring, Tripetch Isuzu, Asian Auto Part
  - For Commercial Building & Hotel : MTRA underground train, All seasons place, Conrad hotel, Oriental hotel, many office buildings, many condominiums

Educational Background

- M. Eng. (Industrial Engineering), Chulalongkorn University
- B.Eng. (Mechanical Engineering), Kasetsart University

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Objectives

- To outline the basic principles of Cleanroom
- To outline the basic principles of Cleanroom for Pharmaceutical Industry
- To review facilities for Pharmaceutical Plant
- To outline standards and guidelines that are the technical concern for Cleanroom
- To outline the concept of Design, Construction, and Cost Estimate for Cleanroom

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Key points to be discussed

- What is Cleanroom ?
- Design of Cleanroom and Facilities for Pharmaceutical Industry
- Cleanroom Construction In Pharmaceutical Industry
- Cost Estimate of Cleanroom In Pharmaceutical Industry

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

What is Cleanroom ?

- Introduction to cleanroom
- Definition of Contamination
- Sources of Contamination

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Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

What is Cleanroom ? : Introduction to cleanroom

- It is clear that a cleanroom is a room that is clean !!!
- A cleanroom now has a special meaning !!!
  - **Federal Standard 209 E**
    "A room in which the concentration of airborne particles is controlled and which contains one or more clean zones"
  - **ISO 14644-1**
    "A room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particle inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled and necessary"

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Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

What is Cleanroom ? : Definition of Contamination

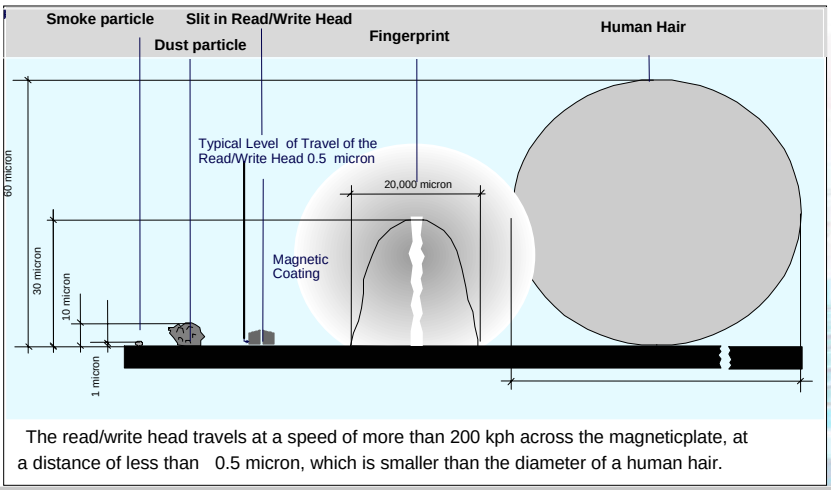
- In cleanroom technology, contaminates are understood to be not only dustparticles in the strict sense, but any disturbing effects of a solid, liquid, gaseous, thermal or electromagnetic nature capable of having a negative influence on the course of a process and the quality of a product.
- The size of particles is defined in microns (abbreviated µm) i. e. "small" in Greek. One micron is a millionth of a meter or a thousandth of a millimetre.

  As a comparison, one human hair has a diameter of about 60 - 80 microns; all particles from about 5 microns down are present in the air and are therefore called suspended particles.

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

What is Cleanroom ? : Definition of Contamination

Particle Sizes and Distribution

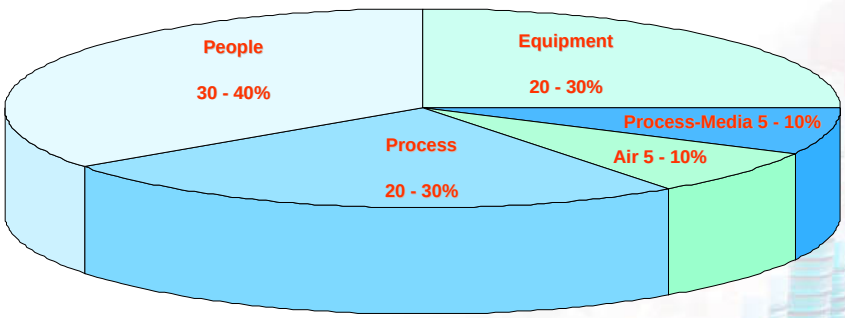


The read/write head travels at a speed of more than 200 kph across the magneticplate, at a distance of less than 0.5 micron, which is smaller than the diameter of a human hair.

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

What is Cleanroom ? : Sources of Contamination

Percentage Distribution of the Sources of Contamination



It is important to take the contamination from people into account , which contributes considerable 30% of the total contamination in the cleanroom.

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

What is Cleanroom ? : Sources of Contamination

External Impuritities	Internal Impurities
Introduction of contaminated outside air or circulating air *	Staff
Staff	Process
impure process media or raw materials	Production equipment, machines, tools etc.
Inadequately cleaned materials,tools etc.	Unsuitable building materials,work materials
	Mechanical abrasion in the cleanroom

* poor filter quality, none airtight filter seal surfaces, leakage in the ducting system, abrasion in air recirculation equipment and in the ducting system

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Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

What is Cleanroom ? : Sources of Contamination

Emission of Particles by People making various Movements without Cleanroom Clothing

Particle Emission per Minute and Person	Type of Activity
100 000	Standing and sitting without moving
500 000	Sitting with gentle movement of head, hand or lower arm
1 000 000	Sitting with moderate body and foot movement
2 500 000	Standing up with full body movement
5 000 000	Slow walking - approx. 3,5 km/h
7 500 000	Walking at about 6 km/h
10 000 000	Walking at about 9 km/h
15 - 30 000 000	Gymnastics and sports

Germ emission per minute (according to Botzenhart)
1 000 - 13 000 CFU depending on activity

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

Design step

1. Define User Requirements
2. What facilities are needed to be designed follow URS ?
3. Review cleanroom technology for pharmaceutical industry
4. Basis of design
5. Conceptual design
6. Detail design

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Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

1. Define User Requirements

Key Point

- To understand the requirement to develop the project
  - Production purpose and process
  - Activity flow (human, materials, products, equipment and others)
- To discuss and confirm design conditions and utility which are required by the project

What is URS ?

- URS = User Requirement Specification
- URS = Approved statements prepared by the user which define what is required by the project

Importance of URS

- URS should be sufficiently detailed to enable design specifications to be developed

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

1. Define User Requirements

From URS, the design team will know / define in cleanroom design:

- Process
  - Process Equipment
  - Capacity and qualification for process equipment
  - Product segregation philosophy
  - Material Flow
  - Process Flow
  - Personnel flow
  - Process and product support facilities
  - Space for Manufacturing process equipment and storage
- Utility
  - Types of utilities
  - Qualification philosophy to determine Critical and Non-critical utilities
  - Capacity and qualification for utilities

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

2. What facilities are needed to be designed follow URS ?

- **Process**
  - Process flow
  - Personnel flow
  - Material flow
  - Waste flow
  - Process equipment & Layout
  - Facilities to support process
    - WFI
    - Purify Water
    - DI Water
    - Tap Water
    - Drainage
    - Process Steam
    - Compressed Air
    - Nitrogen Gas
    - Vacuum
- **Building (Architectural, Civil & Structural works)**
- **HVAC & Cleanroom system**
- **Building facilities**
  - Electrical system
  - Fire protection system
  - Sanitary & Plumbing system

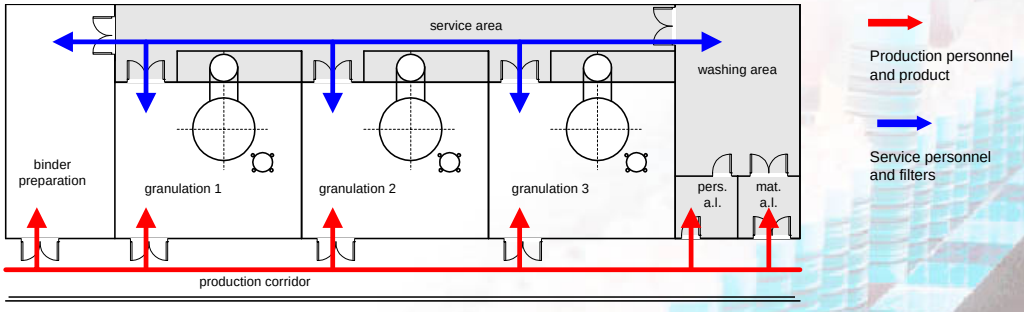
Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

2. What facilities are needed to be designed follow URS ?

Process layout and activity flow



Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

2. What facilities are needed to be designed follow URS ?

Cleanroom **WFI**

Vacuum **Purify Water**

Compressed Air **DI Water**

Liq. nitrogen **Tap Water**

Process steam **Drainage**

Electrical **Fire Protection**

Design of Cleanroom and Facilities for Pharmaceutical Industry :
Cleanroom and Facilities Design

3. Review Cleanroom Technology for Pharmaceutical Industry

- Classification of Cleanroom
- Guidelines and standards for the design of cleanroom and facilities
- Pharmaceutical Cleanroom Classification
- Pharmaceutical Cleanroom Structure
- How to keep room clean ?

Review Cleanroom Technology for Pharmaceutical Industry : Classification of cleanroom

1 Federal Standard 209 E

Table 1: Federal Standard 209 class limits

Class	**Particles / ft³**				
	≥ 0.1 µm	≥ 0.2 µm	≥ 0.3 µm	≥ **0.5 µm**	≥ 5.0 µm
1	35	7.5	3	**1**	NA
10	350	75	30	**10**	NA
100	NA	750	300	**100**	NA
1,000	NA	NA	NA	**1,000**	7
10,000	NA	NA	NA	**10,000**	70
100,000	NA	NA	NA	**100,000**	700

Review Cleanroom Technology for Pharmaceutical Industry : Classification of cleanroom

2 ISO Standards

Table 2: Selected ISO 14644-1 airborne particulate cleanliness classes for cleanrooms and clean zones

ISO Classification number	Maximum concentration limits (particles/m³ of air) for particles equal to and larger than the considered sizes shown below					
	≥ 0.1µm	≥ 0.2µm	≥ 0.3µm	≥ 0.5µm	≥ 1µm	≥ 5.0µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1 000	237	102	35	8	
ISO Class 4	10 000	2 370	1 020	352	83	
ISO Class 5	100 000	23 700	10 200	3 520	832	29
ISO Class 6	1 000 000	237 000	102 000	35 200	8 320	293
ISO Class 7				352 000	83 200	2 930
ISO Class 8				3 520 000	832 000	29 300
ISO Class 9				35 200 000	8 320 000	293 000

Review Cleanroom Technology for Pharmaceutical Industry : Classification of cleanroom

Comparison between FS 209 and ISO 14644-1

Table 3: Comparison between selected equivalent classes of FS 209 and ISO 14644-1

ISO 14644-1 Classes	Class 3	Class 4	Class 5	Class 6	Class 7	Class 8
FS 209 Classes	Class 1	Class 10	Class 100	Class 1000	Class 10 000	Class 100 000

Review Cleanroom Technology for Pharmaceutical Industry :

Guidelines and standards for the design of cleanroom and facilities

A. Guidelines for design of cleanroom and pharmaceutical

GMP	Good Manufacturing Practice
ISPE	International Society of Pharmaceutical Engineering

The most used GMP guides for cleanroom

PIC : GMP and Guidelines	Valid in European countries outside the EU and Australia
FDA cGMP	Valid for the United States
EU GGMP	Valid for the EU area

Review Cleanroom Technology for Pharmaceutical Industry :

Guidelines and standards for the design of cleanroom and facilities

B. Standards for design of cleanroom and facilities

ASHRAE	American Society of Heating, Refrigerating, and Air Conditioning Engineers
ARI	Air Conditioning Refrigeration Institute
FED-STD-209E	Clean Room, Federal Standard No. 209E of U.S.A.
SMACNA	Sheet Metal and Air Conditioning Contractor's National Association Inc.
ASME	American Society of Mechanical Engineers
ASTM	American Society of Testing and Materials
ANSI	American National Standard Institute
IEC	International Electromechanical Commissions
NEC	National Electrical Code
NFPA	National Fire Protection Association
NPC	National Plumbing Code
ISO	International Organization for Standardization
TIS	Thai Industrial Standard
EIT	The Engineering Institute of Thailand

Review Cleanroom Technology for Pharmaceutical Industry :

Pharmaceutical Cleanroom Classification

European Union Guide to Good Manufacturing Practice

Table a: Airborne classification in the EU GGMP

	Maximum permitted number of particles/m^3 equal to or above			
Grade	**at rest**		**in operation**	
	0.5 µm	5 µm	0.5 µm	5 µm
A	3 500	1	3 500	1
B	3 500	1	350 000	2 000
C	350 000	2 000	3 500 000	20 000
D	3 500 000	20 000	not defined	not defined

Review Cleanroom Technology for Pharmaceutical Industry :

Pharmaceutical Cleanroom structure

- Larminar flow type cleanroom
- Turbulent flow type cleanroom

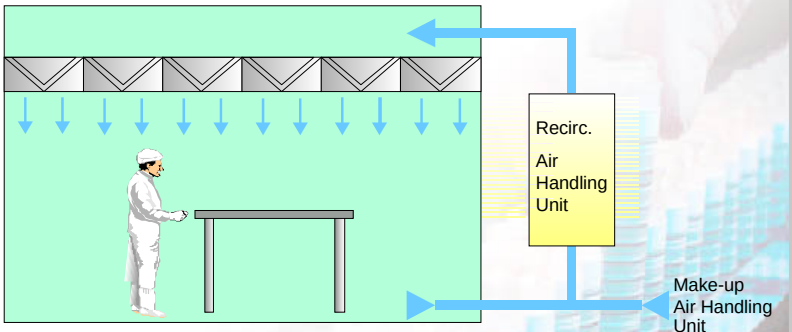
Review Cleanroom Technology for Pharmaceutical Industry :

Pharmaceutical Cleanroom structure

Laminar Flow Type Cleanroom

Ceiling with integrated HEPA Filter

Cleanroom Class 100 (A/B) with laminar airflow



Advantages: easy operator access, flexible layout

Disadvantages: high investment and operation costs

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Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Review Cleanroom Technology for Pharmaceutical Industry :

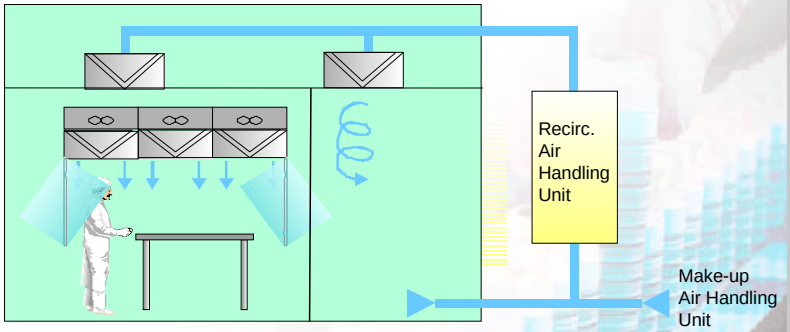
Pharmaceutical Cleanroom structure

Turbulent Flow Type Cleanroom

HEPA Filter installed in filterbox

Cleanroom Class 10 000 (C/D) with turbulent airflow

Clean Cabin Class 100 (A/B) with laminar airflow



Advantages: Low investment and operation cost

Disadvantages: Limited flexibility and operator access

Review Cleanroom Technology for Pharmaceutical Industry :

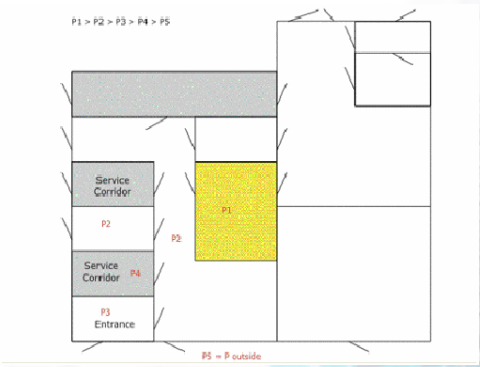
How to keep room clean ?

- Do not allow the dust to flow into or bring into the room
- To minimize the dust generating source
- Do not accumulate and redisperse the dust
- To remove the generated dust before it spread

Review Cleanroom Technology for Pharmaceutical Industry : How to keep room clean ?

- Do not allow the dust to flow into or bring into the room
  - **Air tight and positive pressure room structure to prevent dust**

    e.g. Positive pressure room layout

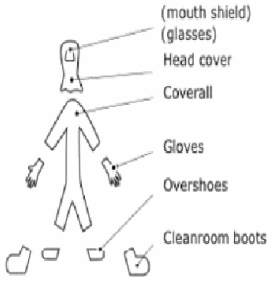


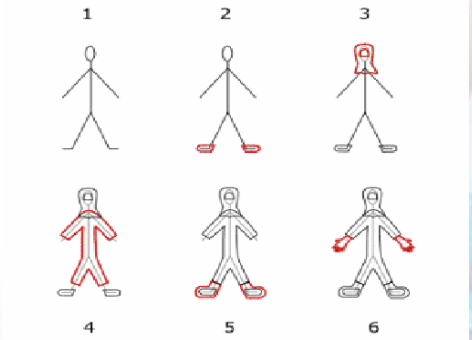
  - **Air filtration**
  - **Make up clean air**
  - **Clean up system**
    - **Air lock room**
    - **Air shower**
    - **Pass box**

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Review Cleanroom Technology for Pharmaceutical Industry : How to keep room clean ?

- To minimize the dust generating source
  - **e.g. dress code**





Dress step
1. Prior to entering
2. Blue overshoes over your own shoes
3. Headcover: make sure all hair is inside, tighten if possible
4. Coverall: hold in sleeves and waist, step in as high as possible, tighten if possible
5. Cleanroom boots: tighten under knees and over shoes
6. Gloves: do not touch outside of fingertips with bare hands

Note: Taking off: the other way around

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Review Cleanroom Technology for Pharmaceutical Industry : How to keep room clean ?

- Do not accumulate and redisperse the dust
  - **Clean up system for room and equipments**
  - **Exhaust system**
- To remove the generated dust before it spread
  - **e.g. Staff working instruction**

Don't
- Touch your face or skin with gloves
- Touch building hardware, oily machinery, or wafer loading areas
- Lean on equipment
- Wear cosmetics, powders or colognes
- Wear anything on fingers: remove all rings and bracelets
- Use paper, pencil or markers that leave dust or lint

Do
- Wear hair under head cover
- Shave regularly
- Change gloves whenever dirty or torn
- Use a fresh pair of gloves whenever handling wafers
- Wipe down wafer handling areas with isopropanol
- Use cleanroom paper and dust-free ballpoint pens
- Remove used items
- Clean spills immediately

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

4. Basis of Design

Key Point

- To outline the following concept to develop the project
  - The site (Area Size and Location)
  - Production requirements
  - Room layouts and operation
  - Process & plant utilities
- To establish budget to develop the project (with contingency ± 20 %)

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

4. Basis of Design

Example of basis of design of utilities

*** Chilled Water**
Chiller plant will provide water in the range of 5° / 11°C to the AHU systems cooling coils. Process chilled water for vessel cooling may be required but will be determined during the design development.

*** Instrument Air**
Instrument air will be provided as a separate system. The plant will include oil-free compressors, receivers, air dryer and pressure control equipment. The air must be oil-free and should conform to the requirements of ISO. 8573 Quality Class 2.

*** Plant Steam**
The usage for plant steam will be minimal and may be used for the generation of hot water for domestic or process use. The provision of a small electrode type boiler may be sufficient.

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Key Point

- To outline description of process, building, facility and utilities which are required to develop the project
- To outline system description for process, building, facility and utilities
- To outline criteria for process, building, facility and utilities
- To calculate capacity of utilities (e.g. cooling load calculation)
- To summarize machine, equipment, and material for process, building, facility and utilities
- To provide equipment schedule of main equipment for process, building, facility and utilities
- To prepare building layout
- To prepare equipment layout
- To provide schematic of process, facility and utilities
- To establish budget to develop the project (with contingency ± 15 %)

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

HVAC System design consideration

- Proper design consideration
- Design cleanroom complying guidelines and standards (e.g. GMP, ASHRAE, FS 209 E)
- Separation and local treatment of heat, generation and contamination materials
- Operation ratio and demand factor
- Minimize high grade area (e.g. cleanroom class 100A)
- Partial load operation
- Flexibility for production layout change
- Backup system and trouble shooting
- Environmental issue
- Safety
- Energy conservation

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Construction Material and Surface Finishes for Cleanroom

Material design consideration

- Non-dust generation from surface
- Easy to clean
- Air tight
- Conductivity
- Out-gas
- Chemical resistance
- Fire safe

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

Construction Material and Surface Finishes for Cleanroom

- **Architectural works**
  - Wall
  - Ceiling
  - Floor
  - Door
  - Window

Utility Columns

Cleanroom Solutions
Cleanroom Partitions

GMP-conform ceilings for the Pharmaceutical Industry
Cleanroom ceilings with dry and fluid seals

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

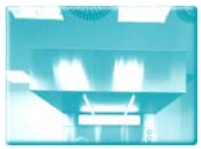
Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

Construction Material and Surface Finishes for Cleanroom

- **Accessories for cleanroom**
  - Air shower
  - Pass-box
  - Cross-over bench
  - Cabinet


Air Showers

Weighing Cabinet
Dispensing Area

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

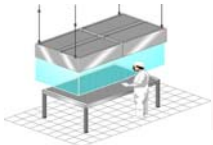
Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

Construction Material and Surface Finishes for Cleanroom

- **HVAC system for cleanroom**
  - Air handling unit
  - Air filter
  - Fan filter unit (Laminar flow)
  - Air grille
  - Relief damper


Air Handling Units



Modular LF-Units
CWIC® Systems
Filter-Fan-Units
Pharmaceutical
Ceiling Outlets
HEPA Filters

Air grille
(Turbulent supply air)

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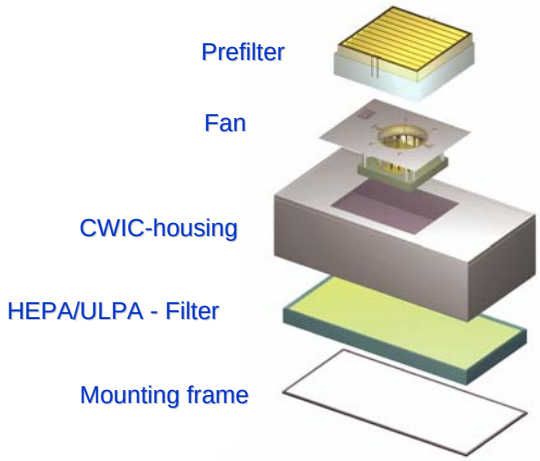
CWIC® -Modular-System



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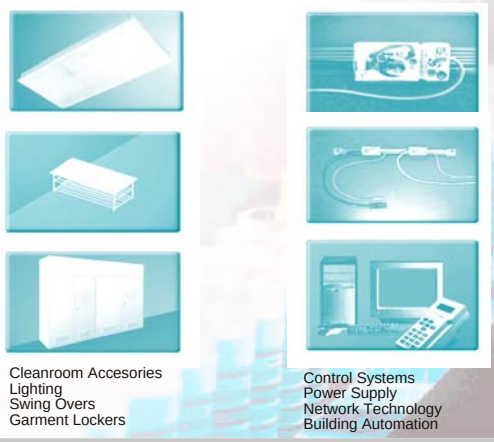
Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

Construction Material and Surface Finishes for Cleanroom

- **Other facilities for cleanroom**
  - Lighting fixture
  - Automatic control system



Cleanroom Accesories
Lighting
Swing Overs
Garment Lockers

Control Systems
Power Supply
Network Technology
Building Automation

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Example of conceptual design of HVAC system

System description for HVAC system

The HVAC system provided for medicinal product buildings shall be the centralized chilled water system served by water-cooled chillers.

HVAC system for Clean Room Class 100,000 will conform to the ISO standard 14644 and Federal Standard No. 290E of U.S.A. Air Conditioning System shall be the conventional clean room system (Turbulent Flow).

Air handling units shall be double skin module type.

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Example of conceptual design of HVAC system

Criteria for HVAC system

1. Cleanliness
2. Temperature
3. Humidity
4. Air flow pattern
5. Noise level
6. Vibration
7. Room air pressure
8. Electro static charge
9. Chemical gas
10. Odor
11. Lighting

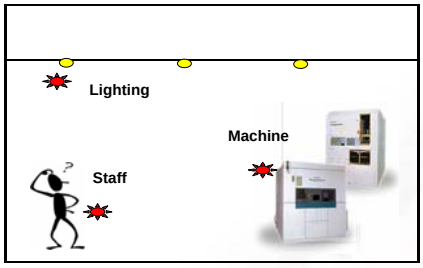
Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Example of heat source in cleanroom for design of HVAC system



Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Example of conceptual design of HVAC system

Criteria for HVAC system

Room Name	Condition					
	Temp (C)	Rel. Humidity (% RH)	Pressure (Pa)	Cleanliness (Class)	Cleanliness Condition	Air flow pattern
Clean corridor	22 +/- 2	50 +/- 10	+	100K	at rest	Non-unidirectional
Sterile gowning	21 +/- 2	50 +/- 10	+++	100B	at rest	Non-unidirectional
De-gowning	22 +/- 2	50 +/- 10	++	10K	at rest	Non-unidirectional
Mixing room	21 +/- 2	50 +/- 10	++++	100A	at rest	Unidirectional
				100B	at rest	Non-unidirectional
Preparation room	22 +/- 2	50 +/- 10	++	10K	at rest	Non-unidirectional

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Example of conceptual design of HVAC system

Room layout (plan)

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

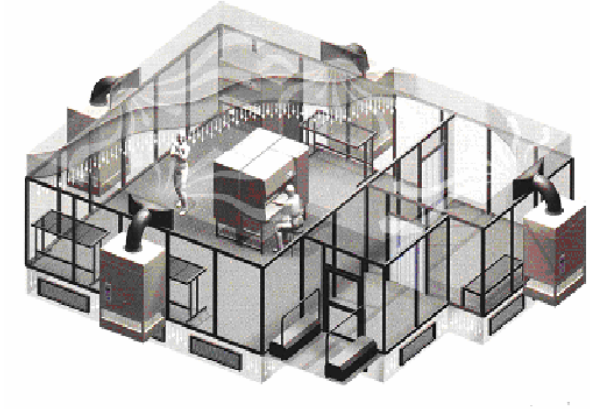
Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Example of conceptual design of HVAC system

Room layout (3D)



Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

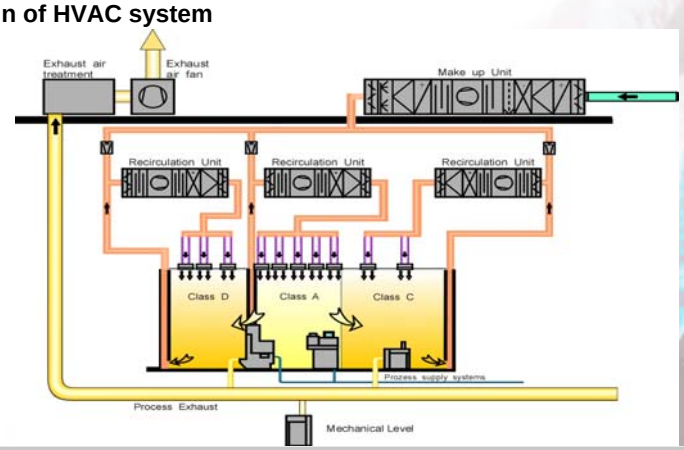
Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

5. Conceptual Design

Example of conceptual design of HVAC system

Schematic of HVAC system



Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

6. Detail Design

Key Point

- To develop drawing follows conceptual design for construction and installation work
- To prepare technical specification of equipment and material for construction and installation work
- To establish budget to develop the project (with contingency ± 15 %)

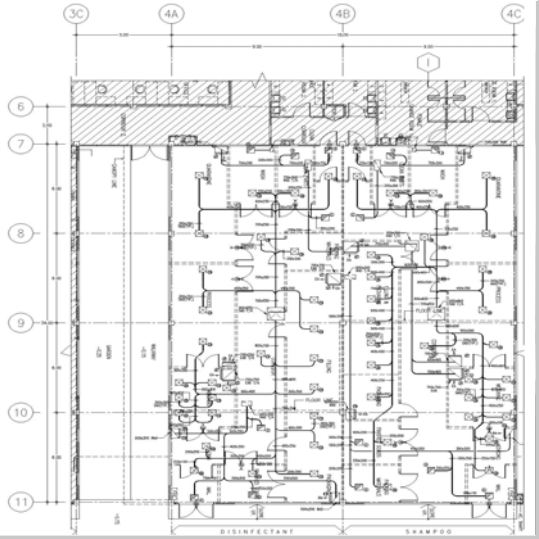
Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

6. Detail Design

Example of detail design of HVAC system
Room layout (Plan)



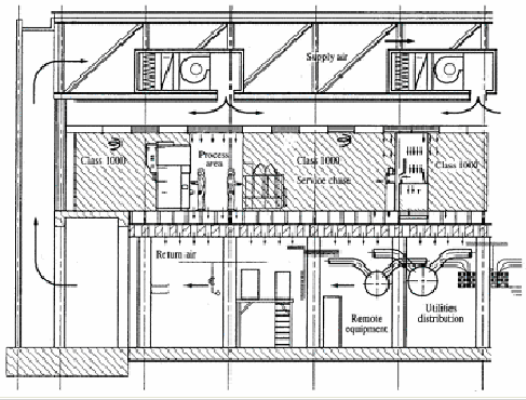
Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Design of Cleanroom and Facilities for Pharmaceutical Industry :

Cleanroom and Facilities Design

6. Detail Design

Example of detail design of HVAC system
Room layout (Section)



Construction of Cleanroom and Facilities for Pharmaceutical Industry

■Facilities needed to be constructed

- Building (Architetural, Civil & Structural)
- HVAC & Cleanroom system
- Building facilities
  - * Electrical system
  - * Fire protection system
  - * Sanitary & Plumbing system
- Process facilities

❖ WFI	❖ Tap Water	❖ Compressed Air
❖ Purify Water	❖ Drainage	❖ Nitrogen Gas
❖ DI Water	❖ Process Steam	❖ Vacuum

Construction of Cleanroom and Facilities for Pharmaceutical Industry

■Clean Construction Protocol

- Stages of Construction Cleanliness :
  - * Normal Clean
  - * Very Clean
  - * Ultra Clean
- Quality Assurance :

*** Clean Working Protocol**

Use lint-free paper & cleanroom-approved pens
Visitors should not enter the cleanroom, if not necessary
No eating, drinking or smoking, cosmetic
Do not allow both doors of the cleanroom and of the smock area to be opened at the same time
No hydrocarbon lubricants

*** Gowning**

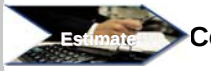
Garmrnts : wear a head cover, facemask, jumpsuit, and shoe cover
Use properly fitting vinyl or rubber disposable gloves

Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry

Project Management and Construction

- Project Planning
- Construction Analysis
- Projects Scheduling
- Cost Maintain
- Construction Management & Supervision Quality Management
- Procurement Services & Materials Management
- Field Engineering
- Safety Management
- Commissioning & Start-Up

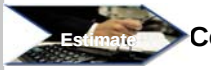
Design, Construction and Cost Estimate of Cleanroom for Pharmaceutical Industry



Cost Estimate of Cleanroom and Facilities for Pharmaceutical Industry

■ Cost estimate step

Period	Contingency
➢ Fesibility study	+/- 30 %
➢ Basis of design	+/- 20 %
➢ Conceptual design	+/- 15 %
➢ Detail design	+/- 15 %



Cost Estimate of Cleanroom and Facilities for Pharmaceutical Industry

■Facilities needed to be estimated

- Architetural
- Civil & Structural
- HVAC & Cleanroom system
- Building facilities
  - * Electrical system
  - * Fire protection system
  - * Sanitary & Plumbing system
- Process facilities
  - WFI
  - Purify Water
  - DI Water
  - Tap Water
  - Drainage
  - Process Steam
  - Compressed Air
  - Nitrogen Gas
  - Vacuum