Cleanroom Training for Employees

CleanTech Systems, Inc.
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What are Cleanrooms?

- Clean room

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Definition

Cleanroom – a controlled environment in which all incoming air, water and chemicals are filtered to meet high standards of purity. Temperature, humidity and pressure are controlled, but the key element is air filtration.
Why Have Cleanrooms?

- To protect the product and process from contamination
- To restrict access to the product and process
- To contain hazards located within the cleanroom

Examples of cleanroom products:

- Pharmaceuticals
- Medical Devices
- Air Bags
- Computers
- Satellites
- Vaccines
- Flat Screen TV’s
- Cell Phones
How does a Cleanroom Work?

- All incoming air is filtered
- Clean air flows over the product at a low velocity
- Return about 80-90% of the air to the filters
- Changes the entire air volume – 20 - 600 times per hour.
- Air pressure, temperature and humidity are tightly controlled
- Rooms are finely cleaned and sometimes disinfected
Are all Cleanrooms the Same?

- **NO!**
- Cleanrooms are designed for a particular product or purpose
- All Cleanrooms are different either in function or design
- Areas within the same cleanroom can be different and have different requirements
- Always ask if you don’t understand
Creating a Cleanroom

- **Most Important test of a cleanroom**
  - Air Cleanliness Classification
    - Is it is clean as it needs to be?
    - Expected to be?

- **Second Most Important Test**
  - Pressurization
    - Positive- Leaks out (Room independent of surrounding area)
    - Negative Leaks in (Room dependent of surrounding area)

- **Third Most Important Test**
  - Air Velocity and Volume
    - How much air is being pushed into the room?
Why do we Clean Cleanrooms?

- **Dynamic environments** – continuously changing
- **Activity generates and transports contamination**
  - Personnel
  - Incoming materials, tools
  - Manufacturing Process
  - Air flow not enough!
Structural Material Requirements

- Non-particulating
- Low Outgassing (molecular)
- Non-Oxidizing
- Withstand harsh chemicals
- Cleanable
Air Supply & Return

- **Supply**
  - Supply or Make-up Air pressurizes the cleanroom to prevent air from entering from adjacent areas

- **Return**
  - Air leaves through openings in the walls and or the floor
Non-Unidirectional Airflow

1. Air inlets
2. Light fixture
3. Air exhaust grilles
4. Floor, solid
5. Ceiling

Airflow
Unidirectional Airflow Concept

1. HEPA filters
2. Room walls
3. Floor grating or perforated flooring
Classifications of Cleanrooms

- Cleanrooms are classified by the number of particles allowed in the air.
- New Cleanroom Classifications are based on an internationally agreed standard for all cleanroom manufacturing companies around the world - ISO 14644.
- Many US Cleanrooms may still be classed according to an older US Standard.
- Fewer particles = CLEANER CLEANROOM!
## Cleanroom Classifications

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Introduction to Contamination Control
What Is Contamination?

Contamination: any material, substance, or energy that is unwanted or adversely affects the product or process.

- Every operation must establish its own definition for “contamination”
- Pharmaceutical concerns are different from computer chip or aerospace companies.
Contamination Control is not a function!

It is a science and technology that interacts continuously with all products, all processes, all materials and every member of the manufacturing team.
What Is Cross Contamination?

- Is the transfer or movement of contamination from one area to another.
- One person to another…
- One thing to another…
## Types of Contamination

- **Particles** (Dust, dirt, fibers, skin)
- **Microorganisms** (Bacteria/Viruses)
- **Energy** (Light, Vibration, ESD)
- **Chemicals** (Compatibility)
How Does Contamination Happen?

- People work there
- Equipment and Materials are brought inside.
- Improper Cleaning
- Facility Damage
- Manufacturing Process
- Equipment
- Restricted Materials
- Chemicals
- ESD
- Water
Tiny invisible particles cause huge damage.

Computer chip line widths are now measured in nanometers.

- A nanometer is a unit of length in the metric system, equal to one billionth of a meter.

Cleanroom classifications use the micron or micrometer scale, which is one millionth of a meter, or equivalently one thousandth of a millimeter.

Bacteria- smallest size around .3 microns

Virus- smallest size around .2 microns
Static Generation

- Materials rub against each other and produce a charge.
- One charged object produces a charge in another object.
- Static Discharge damage
  - Causes data loss
  - Destroys materials and devices
  - Causes explosions
Prevention

- It is much easier and more cost effective to prevent and minimize the contaminants that enter a facility… than it is to remove them later.
Cleanroom Discipline

- The development of good cleanroom habits that help to minimize your personal contribution to the manufacturing environment and the product.
People in Cleanrooms
Contamination Bomb?

- We shed 100,000 particles per minute when resting
- ½ million particles per minute when using the upper body
- 5 million particles per minute when walking
Particles from People

- Skin
  - Sheds
  - Carries salts, oils, bacteria
- Oral
  - Moisture emitted from speaking, coughing, sneezing
  - Cosmetics, perfume, cologne
  - Lint
  - Hair
Particles from People

- The average human releases about **2 million particles of contamination** (skin cells, hair follicles, eyelashes, skin oil, eye moisture, etc.) per minute
Human Contamination

- **Normal Talking:**
  - Saliva spray 2 to 3 feet

- **Coughing**
  - Saliva and lung tissue spray 4 to 6 feet

- **Sneezing:**
  - Saliva and lung tissue spray 10 to 15 feet, at 200 MPH, emitting 1,400,000 particles into the air

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Human Contamination

Chemicals we release that contaminate the cleanroom environment:

Perspiration: sodium, potassium, chlorine, sulfur, aluminum, carbon, and nitrogen

Cosmetics: Iron, aluminum, carbon, titanium, magnesium, potassium, sulfur, and calcium

Fingerprints: Sodium, potassium, chlorine, and phosphorus

Spittle: Potassium, chlorine, phosphorus, magnesium, and sodium

Dandruff: Calcium, chlorine, carbon, nitrogen

Bacteria & Viruses
Personal Health

- Skin Conditions
  - Eczema
  - Hives
  - Dandruff
  - Sunburn
  - Medicated Skin Creams?

- Respiratory Conditions
  - Asthma
Comparative Sizes

This is a human hair on a semiconductor chip
Cleanroom Protocol

Cleanroom protocol begins long before you get to work!

- Shower and wash your hair
- Clothing should be in good condition without holes or fraying
- Shoes should be free of mud and dirt
- Remove non-cleanroom items from pockets
- NO jewelry, NO cosmetics, NO hair products
Microorganisms in Cleanrooms
Microorganisms (Microbe)

- Organisms that are microscopic:
  - Virus
  - Bacteria
  - Fungi
Microbial Control

- Human Body has approx 100 Trillion Bacteria
Bacterial Growth

- It’s Exponential

10 hours growth = > 1 Billion cells!
Transportation of Organisms

- Travel well in the air stream
- Tend to clump together
- Travel on moisture droplets, skin flakes, hair
- Will bond to surfaces
- Move from person to person
- Multiply rapidly
Cleanroom Protocol is in progress when you arrive at work!

- Utilize clean sidewalks and pathways from the parking areas into the building
- Try not to track debris and dirt into the building
- Utilize shoe brushes and tacky mats to remove loose dirt when entering the building
Hygiene / Temporary Problems

- Abnormal Skin Shedding
- High Acid in Perspiration
- Colds
- Sunburn
- Chapping
- Injuries
Cleanroom Garments
Cleanroom Apparel Characteristics

- Protect the environment from you!
- Should not shed
- Should block fine particles
- Should allow evaporation
Typical Gowning Requirements:
ISO 3, 4, 5

- Shoe covers
- Bouffant head cover
- Beard cover
- Safety glasses
- Face Mask
- Coveralls
- Booties
Apparel Materials

- Polyester
- Single Use Garments
- ESD Garments
Cleanroom Safety
Chemicals

- Use only approved chemicals
- MSDS understanding
- Wear protective clothing
- Mix chemicals in correct area
- Dilute chemicals with process grade water
- Face Shields must be used
Emergency Response

- Know location of emergency exits
- Know location of Fire Pulls/Panic Buttons
- Know alarm codes and tones
- Exit the building and follow emergency evacuation procedures
- Obey ERT and Fire Team
- Remove cleanroom garments only after exiting the building
Wet Floors

- Use ample Wet Floor Signs
- Floors will be slippery with phenolic use- rinse, wet vac, scrub...
- Watch for electrical hazards
- Avoid all splashing
Cleanroom Cleaning and Disinfection
This is the ONLY way to maintain the cleanroom at its design level!
Why is Cleanroom Cleaning so Important?

- Activity generates contamination - particles, bacteria!
- Large particles are generated by equipment, environment, processes, parts, people.
- Many of these will not be removed by the air stream.
- Particles tend to stick to the surfaces they come into contact with.
- Mechanical cleaning of the cleanroom is required to remove these particles.
Areas that We Clean

- Pre-Gown or Ante Rooms
- Gowning Rooms
- Equipment Airlocks
- Pass-thru’s
- Cleanroom
- Air Showers
More Service Areas

- Gray Rooms
- Work Stations
- Utility Chases
- Plenum
- Flow Hoods
CTS Usually Doesn’t Clean These Areas…

- Work Stations
- Insides of Equipment
- Laminar Flow Cabinets
Drains

- City Water Drains
- Solvent Drain
- Acid Drain
- Always ask which drain to use
Example of Cleanroom Cleaning Duties

- Remove the Trash.
- Change the Tacky Mats.
- Wet wipe general horizontal surfaces
- Vacuum and wet mop the floors.
- Vacuum and mop walls, ledges, windows.
- Vacuum and mop ceilings.
General Cleanroom Guidelines

- Get approval for all chemicals and equipment.
- Use slow movements for cleaning.
- Do the daily cleaning at non-peak times.
- Do not clean sensitive equipment.
- Wipe down all new equipment.
- Do not use spray bottles or aerosols.
General Cleanroom Guidelines, continued

- Don’t clean a HEPA or ULPA filter face.
- Follow the prescribed methods for clean-up and storage.
- Use caution when working near sensitive equipment and processes.
- All equipment must enter thru designated Equipment entry and be cleaned and wiped down prior to entry.
Equipment: Vacuums

- We use only HEPA filtered vacuums
- Attachments must be cleanroom compatible with the surfaces to be cleaned.
- System must have filtered exhausts. These filters must be certified and current dated.
Cleaning Supplies

- Wipers
- Lint-free Mops
- Sponges
- Tacky Mats
- Cleaning Agents
- Disinfectants
- Water
Some Special Cleanroom Tools
Contact or dwell time?
- Must have time to penetrate:
  - Cell Wall
  - Inner and Outer Membranes
  - Destroy the nucleus
Sequence of Cleaning

- Clean from the cleanest area to the dirtiest
- Top to bottom
- Rear wall to exit
Ceiling Vacuuming and Mopping Pattern

Start

Tool Head

X

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Changing Tacky Mats

- Check mats throughout the day.
- Peel off each layer when it is no longer effective. (60% covered)
- Pull and fold each corner toward the center of the mat.
- Lift and dispose of soiled mat in correct waste container.
Emptying Trash Procedures

- Grab the liner and twist or tie closed.
- Lift liner out of the container slowly.
- Place liner into trash or service cart.
- Wipe the inside and outside of the trash container.
- Re-line with a clean can liner. Don’t pop open the liner first.
TANDEM Method

- Vacuum first, then mop or wipe.
- Vacuum pulls loose particles
- Mopping or wet wiping removes smaller particles
Vacuuming Floors: Chemicals & Equipment

- Use Central Vacuum or a cleanroom portable HEPA or ULPA Filtered Vacuum

- Use Approved Wand and attachments that will NOT damage the surfaces.

- For Central Vacuum use only the approved hose for that system with dedicated tools.
Vacuum Floor Procedure

- Start from the back of the room and move toward the entrance.
- Work in a backward motion.
- Move the wand head toward you using single vertical overlapping strokes.
- Use crevice tool to vacuum all edges, corners, under equipment & furniture when required.
- Vacuum any wires or pipes when required.
- Clean and store vacuum.
Vacuuming Walls: Equipment

- Use Approved Cleanroom Vacuum system
- Floor tools should not be used on the walls
- Extensions are desirable
- Crevice Tools for hard to reach areas
- Fiber Glass Ladders may be necessary
Vacuuming Walls Procedures

- Begin at the far corner of the room & work to the entrance.
- Start at the ceiling and move wand and head down the wall surface to the floor.
- Move to the right or left and repeat the pattern overlapping the previous pass.
- Vacuum the ceiling edges and corners.
Pull - Lift Stroke for Walls or Floors

From ceiling toward floor for walls.
From wall toward aisle for floors.
Procedures, continued

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Procedures, continued
Wet Mopping Floor Procedure

- Place WET FLOOR signs.
- Start from the furthest corner of the room & work toward the entrance.
- Apply solution to the mop head.
- Wring out until damp.
- Use overlapping strokes to mop.
- Mop two 4 foot strokes and re-moisten for pull lift or 4-foot strokes for modified figure “8”.
- Change mop water at least every 200 square feet.
Modified Figure “8”
Wet Wipe/Spot Clean: Vertical Surfaces

- Clean surfaces

- Clean the following items:
  - Table tops, Table and Chair legs
  - Telephones
  - Ledges & Lockers
  - Sinks & Eyewash stations
  - Outside of Laminar Flow Hoods

- Do not clean work stations unless specifically told to do so
Surfactants

- Influence of Surfactants on Wetting
  - Ability to displace particles
  - Penetrate soil and surface irregularities
Wet Wipe / Mop: Windows and Doors

- Clean all surfaces.
- Clean all glass surfaces with disinfectant in rotation.
- Remove smudges from door frames, facings, light switches and walls.
Vacuuming Ceilings Procedure

- Begin at far upper corner from entrance.
- Place the wand and duster tool away from you and pull it toward you in a one way motion.
- Lift and repeat process, overlapping prior stroke.
- Vacuum vents, corners and edges with crevice attachment.
Tools and Equipment

- After completion of the cleaning process – wipe down all vacuum hoses, tools and equipment and store properly.
- Check mop heads to determine if it must be replaced.
- Clean – rinse and dry all buckets and cover.
- Wipe all mop handles and store properly
- Rinse all mop heads and hang.
Wipe Down Procedures

- Example: Ladders

- Top

- Rails (inside and outside)

- Rungs (top and bottom, if rungs have grooves, each groove must be cleaned)

- Feet must be wiped and in good condition. Do not cover (with cleanroom tape or shoe covers).
Regulations, Compliance and Standards
Regulatory and Standards Groups

- FDA
- EU
- International Groups
- IEST
- ISO Cleanroom
Good Manufacturing Practices

- “cGMP” is part of a quality system covering the manufacture and testing of active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices.

- GMP’s are guidelines that outline the aspects of production and testing that can impact the quality of a product.
GMP Guidelines Follow a Few Basic Principles

- Manufacturing and operational processes are clearly defined and controlled.
- All critical processes are validated to ensure consistency and compliance with specifications; any changes to the process are evaluated.
- Instructions and procedures are written in clear and unambiguous language.
- Operators are trained to carry out and document all work.
- Complaints about products are examined, the causes of quality defects are investigated.
SOPs

- An **SOP** is a written document or instruction detailing all steps and activities of a process or procedure. These should be carried out without any deviation or modification to guarantee the expected outcome.
Cleanroom Testing
Cleanroom Testing

- Particle Counting
Testing for Bioburden

- Rodacs and Swabs
Final Thought

- Contamination Control — Not simply a task…
  - Rather a continuous effort involving all parts of the facility, all aspects of the process, and every member of the manufacturing team.
  - A critical part of your product quality system.