HVAC systems cross-contamination control

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August 2015
The GMP requirements

The HVAC system must achieve the following:

• Ensure appropriate conditions for the product or process – Temp; RH.

• Help prevent contamination and cross-contamination by:
  – Room pressurisation.
  – Use of filtration if recirculation of air is used. (GMPs for dosage forms and API specifically allow recirculation provided you have assessed and managed the risk of cross-contamination).
  – Proving dust extract systems for points of high emissions (these systems never recirculate).
Possible routes for cross-contamination via the HVAC

• Recirculation of contaminated air without sufficient air filtration.

• Passage of airborne dust via ducting system when HVAC is OFF or FAILED state.

• Estimating the quantity of dust that might cause a cross-contamination problem is very difficult ......therefore we tend to “overkill” to be sure.
HVAC Systems - Security

GMP accepts recirculation of air

- We can apply this to whole systems or local controlled zones (booths)
- This is the best way to save energy
- But, you must prevent unacceptable levels of cross-contamination

Filtration in recirculation pathway

- Location of filter is risk dependant
- Remember someone has to change the filter (occupational health issue)
- Specification of filter is risk dependant
OSD, API – Use of HEPA filters

- Cross-contamination control in recirculation air handling systems.
- Prevention of discharge of potent compound dust to atmosphere – security or policing filters.
- HEPA filters of H13 or H14 specification are chosen because they can be leak tested:
  - Aerosol photometer method – scan or average leak test.
  - Particle counter method.
Let’s look at some of the position options

- There are several possible locations:
  - Recirculation systems –
    - 1. Final filter in air supply AHU.
    - 2. Terminal supply to room.
    - 3. In Return air duct to AHU.
    - 4. In Return at room boundary.
  - Once through systems
    - 5. In Exhaust air duct to atmosphere.
    - 6. In Exhaust at room boundary + In Exhaust to atmosphere
Recirculation— HEPA at AHU Supply

On every room return is required due to uneven loading of return air filters. Alternative is for ONE return air filter bank and a constant volume control on return fan. Note that DP gauges on rooms and filters, room temp and RH control, and supply fan control are not shown.
Recirculation—HEPA at Room Supply Terminal

Note: 2 CVD on every room return is required due to uneven loading of return air filters. Alternative is for ONE return air filter bank and a constant volume control on return fan. Note that DP gauges on rooms and filters, room temp and RH control, and supply fan control are not shown.
Recirculation–In return duct to AHU

F7 - F7

Option H13

G4 - G4

Process Room 1

Process Room 2
Recirculation—In return at room boundary

Option H13

Process Room 1
G4 +H13/14

Process Room 2
G4 +H13/14
5. Once Through – HEPA at room exhaust (Potent Compounds)

Notes:
1. The example is appropriate for single product, multi-product campaign, or multi-product concurrent operation.
2. Optional dehumidifier not shown.
6. Once Through – HEPA at room exhaust + System Exhaust

Notes:
1. The example is appropriate for single product, multi-product campaign, or multi-product concurrent operation.
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Some other cross-contamination control strategies

- Dust control booth (managed airflow)
- Dust collectors
- Vacuum Cleaning systems
- Effective cleaning and housekeeping
- Closed materials transfer
- Contained processes
Airflow Control Booth

Sampling

Dispensing
Dust collectors

- Local
- Central
- Cross-contamination via duct system drops in process rooms.
Vacuum Cleaning

- Convenient
- Fast
- Central vs Local Equipment
- Cleaning the tools
- Emptying the bag
Floor cleaning & House-keeping

- Convenient
- Fast
- Frequent
- Avoid spreading contamination
Closed Material Transfers

Avoid manual transfers (scooping)
- Gravity
- Vacuum transfer
- Dense phase conveying
- Spiral conveyor
Contained Processes

- Closed process equipment
- Isolators around equipment & processes
  - Rigid
  - Flexible – glove bags
- Cleaning usually becomes more critical when we contain machines
Thank you for your time. Questions?

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