VISUALISING CLEANROOM AIRFLOW PATTERNS

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WHY PERFORM SMOKE STUDIES?

- Smoke studies tell us about the airflow characteristics particularly in our ISO Class 5 environment (Grade A).
- Specifically, if you have a particle or an airborne contaminant entrained in the air within your clean room, the smoke test will demonstrate where the particle is likely to move. It is desirable that the particle will be driven in one direction (unidirectional airflow) past the product path and towards the floor, and then to the room air returns.
- Studies are usually performed with new installations or when there are changes to existing systems. There should also be periodic verification that there are no changes in a given time-frame.
Desired Airflow Characteristics In Class 5 Environment

- Airflow moves toward potential sources of contamination and away from the product path. For example, HEPA filtered air should not flow over cleanroom personnel and then over the product path.
- Air should be flowing smoothly in one direction with no turbulence or eddies
- For movement within the air stream, such as a person manipulating materials or product, air disruption should recover quickly (within seconds) to regain unidirectional flow.
- When doors are opened within Class 5 areas, air flow is disturbed and becomes turbulent. Smoke studies should capture the effects of the disturbance and document the air recovery to smooth unidirectional airflow.
Photography is an art and unless this is a hobby for those involved, it can be very tricky to record in a cleanroom environment.

Everything in a typical cleanroom tends to be white, such as gowns and walls. The smoke generated is often lost and becomes invisible to the camera because it is white and introduced against the white walls in the background.

To overcome the issue, it is useful to hang a dark material in the background such as black plastic sheeting taped to the wall. This way the smoke can clearly be seen and the plastic can easily be removed and moved to other areas of filming until the smoke studies are completed.
Filming the Smoke Study

Reflections

Filming smoke in the air stream from the ceiling moving downward to stainless surfaces can be challenging.

In highly-reflective stainless areas, the surfaces can have mirror-like properties. Smoke can look like it is moving downward, hitting the surface, and then changing direction and moving upward. This is due to the reflections from the shiny surfaces of the stainless steel. To overcome this, the photographer should be aware of this phenomenon, and even film from different angles in order to present the actual airflow.
FILMING THE SMOKE STUDY

- **Starting At The Top**
  - Be sure to capture the area where the HEPA-filtered air is introduced, commonly at the ceiling, and slowly move camera down following the smoke direction as it flows towards work surfaces and equipment.
  - The smoke should be introduced with the nozzle pointed into the air stream. This will demonstrate that the room air supply is sufficient to carry the smoke in the direction of the airflow. Use zoom function of the camera to capture the area around the product path and pay particular attention to open product.
  - The use of a tripod can help, but often the areas being filmed are restricted and without a lot of room to allow for tripod equipment. Be sure to hold the camera very steady. When moving the camera, move slowly and deliberately in one direction.
FILMING THE AT-REST (STATIC) SMOKE STUDY

- This portion of the study is intended to capture air flow without the effects of personnel or manufacturing.
- The areas that will be captured are corridors, equipment protrusions, and work surfaces that are a potential pathway for the product. Care should be taken to film the simulated smoke where it is introduced, typically 12 to 24 inches from the filter face, and follow the smoke cascade slowly down to the work height. It may be necessary to move the smoke supply closer to the work area so that sufficient smoke is generated and can capture the air-flow patterns and their effect as the air flows over and through the equipment.
- The photographer will follow the product pathway and capture the smoke flowing over the equipment. It is ideal to follow the production sequence. For long corridors, the use of a trolley holding the smoke generator with a mounting bracket holding the nozzle in the correct position can help verify each ceiling HEPA filter. Be sure to capture all processing areas including sterile connections, conveyor systems, loading operations,
FILMING THE OPERATIONAL (DYNAMIC) SMOKE STUDY

- The focus is on the effects of moving production equipment and components and human interventions. Smoke is introduced at the entrance plane, just below the HEPA filter usually at the ceiling, and followed downward through the product path. The camera should follow the product, such as a vial moving along the conveyor system, that moves through the downward flowing smoke.

- There should be no turbulence or airflow bouncing off production equipment or any eddies (air moving in a circular pattern). Smoke should wash over process equipment and product pathways smoothly in one direction, then continue through the work area towards the floor.
Reports typically contain the following elements:

- Study number
- Date
- Production area name
- Company name
- Results and discussion
- Conclusions

The report must clearly indicate the results of the work and end with a concluding statement whether or not the smoke study demonstrated the intended objective — that the laminar airflow system is validated.
Air Flow Pattern and Number of Microorganisms

- **Air Outlet**: High Contamination
- **Rotating Air**: Medium Contamination
- **Air Outlet**: Low Contamination
- **HEPA-Filter Air inlet**
Conflicting Air Flow Pattern
Loading of a Lyophiliser

Combination of horizontal and vertical directed air stream (e.g. during loading of a lyophilizer creates conflicting air flow patterns and causes turbulent flow.)
Deflection of Air Flow Pattern

Vertically directed air flow deflected by a protruding ledge of equipment may become a source of contamination instead of protection.
Flow Visualization around Equipment
WHO GMP FOR STERILE PHARMACEUTICAL PRODUCTS Working document QAS/09.295 Rev.1

“Grade A: The uniformity and effectiveness of the unidirectional flow shall be demonstrated by **undertaking airflow visualization tests**”

EU GMP Annex 1 Revision:

“It should be demonstrated that air-flow patterns do not present a contamination risk”

PHARMACEUTICAL INSPECTION CONVENTION (PIC/S)

GMP Annex 1 Revision 2008 Interpretation Of Most Important Changes For The Manufacture Of Sterile Medicinal Products - Recommendation January 2010:

“Non-viable particles should be measured and are expected to meet grade A requirements. **Smoke studies should be performed.**”

U.S. FDA cGMP 2004:

“it is crucial that airflow patterns be evaluated for turbulence or eddy currents that can act as a channel or reservoir for air contaminants. In situ air pattern analysis should be conducted at the critical area to demonstrate unidirectional airflow.”
VISUALISING CLEANROOM AIRFLOW PATTERNS

See what is actually happening!

- Video cleanroom airflow patterns
- Visually verify fume containment
- Identify resident vortices & flow disturbances
- Trace migration paths
- Verify pressure differentials
- Dynamic smoke studies
- Witness disturbances caused by motion of people, heat & robotics
What makes the smoke – smoke machines

- The terms 'smoke machine' and 'fog machine' both refer to the same type of unit. 'Fog machine' is the term used more in the United States, and 'smoke machine' is the term mainly used in the United Kingdom and Europe.
- The most common type of smoke machine are those which use a water-based fluid, which is made up mainly of pharmaceutical grade glycol and water.
- Other types of smoke machine include dry ice machines which create a low lying heavy fog that uses dry ice (solid carbon dioxide), liquid nitrogen (which also creates a low lying fog), oil based smoke machines (similar in principle to water based machines, but uses an oil rather than a water base).
Difference between dry ice, liquid nitrogen, oil and water based smoke machines

- Dry ice and liquid nitrogen smoke machines both create a heavy low lying fog effect. The materials they use to create this are often difficult and expensive to get hold of, hard to store, and the effect can now be easily created on demand by new electronic water based versions.
- You must be very careful when using dry ice smoke machines in confined spaces, as the carbon dioxide produced displaces oxygen in the air and can cause suffocation.
- Some people still use Titanium Tetra Chloride which is considered to be carcinogenic and corrosive and is banned in the USA. TTC is also messy and can cause major accidents. Apart from this, it stays in the HVAC system for a long time.
Artificial smoke is produced by heating a chemical above its boiling point within a heat exchanger. The chemical is then vapourised, and it is when the vapour exits the heat exchanger and mixes with the relatively colder atmosphere that rapid condensation of the vapour takes place, resulting in a visible smoke (or technically fog).

It is important that the vapourisation of the chemical within the heat exchanger is complete, otherwise the production of a smoke with a very large particle size will result.

Conversely, it is important that the heat exchanger through which the chemical is passed is not operating at too high a temperature, otherwise unpleasant and potentially hazardous pyrolysis products will be formed. Electronic circuitry ensures that the heating block in the smoke machine is kept between certain temperatures - too hot and the machine can turn into a flame thrower - too cold and it can shoot out hot liquid.
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**Important Factors to Consider are:**

- You cannot blast large volumes of smoke into an air stream without disrupting it
- You should introduce the smoke gently at low velocities
- The smoke needs to be very light and almost float in air
- The smoke should dissipate leaving little or no residue
- The smoke needs to be visible and persistent
How Safe is Artificial Smoke?

Concept do not compromise on quality or safety. They have been producing artificial smoke systems since 1962, and have a comprehensive technical library of health and safety reports, analyses, independent laboratory tests and particle distribution data second to none. The smoke or fog produced by their systems is amongst the safest available today.

Indeed, the scope of their ISO 9001 Quality Assurance certification specifically refers to "Design and manufacture of NON TOXIC smoke systems".

A comprehensive Health and Safety Data pack, incorporating MSDS sheets and independent report from Health and Safety Executive, US Navy and independent analytical laboratories is available on request.
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DUCTING SMOKE

- Smoke from Concept smoke systems can be ducted if required, using the inherent velocity of smoke produced by the systems, or incorporating fan assistance if rapid distribution of smoke is required.
- Generally a small amount of deposition should be expected in ducting systems as the smoke particles are being artificially restricted, and cannot separate and spread out as they would in free air. For best results the ducting should be as short and straight as possible, with as smooth a bore as practical, so that frictional losses within the duct are kept to a minimum.
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**DUCTING SMOKE**

- Smoke can be ducted at very low output, (as illustrated) to highlight for example laminar flow, or at high output if smoke logging areas for the purpose of training or leak testing.

- For larger volumes where dense smoke logging is required, we would normally recommend the use of fan assisted distribution systems. These allow ducting runs of typically 30 - 40m.
Particle Size – Why Small is Beautiful!

- The smaller the particle size of the smoke, (or more accurately fog) the smaller the amount of chemical is required within the atmosphere to achieve any given visibility. This can have a significant effect on running costs for heavy users of artificial smoke.

- The less the amount of chemical in the atmosphere, the safer the smoke if measured in terms of relative Occupational Exposure Levels.

- The smaller the particle size of the smoke, the lower its settling velocity (the rate at which a particle will fall, due to gravity). A smoke particle of unit density, 0.2 micron in diameter, will fall at 8mm/hr, compared to a 2 micron particle, which falls at 468mm/hr. In essence this means that the smaller the particle of smoke you produce, the less chance there is that deposition of smoke particles will occur.
MiniColt 4 - compact, portable and powerful smoke generator for airflow pattern studies in pharmaceutical and electronics cleanrooms to ISO 14644, that is incredibly easy to use. Stainless steel and battery operated models also available.
In its basic format, the MiniColt 4 from Concept Engineering, England has the ability to produce a considerable amount of smoke “off power” using the retained energy within the high mass heat exchanger block. This allows an operator to carry the generator from room to room, making smoke as required, without a trailing electrical lead.

The resulting smoke has been analysed by independent laboratories to ensure that it is both non-toxic and nonflammable. Canisters re-seal after use, so no wastage occurs, and part-used canisters can be utilised later.
MiniColt 4 Portable Smoke Generator

- MiniColt 4 is a cleanroom safe unit producing an easily seen vapour or “smoke” 0.2 microns mean diameter, not 10 microns as in other units. With MiniColt 4 you can visualize air flow patterns, turbulence, measure low air velocities, detect leaks, and balance air handling systems without contaminating your cleanroom.

- Class-leading particle size 0.2 micron mass median diameter which means that dense smoke can be achieved for substantially lower concentration of chemical in the atmosphere.
COMPARISON WITH COMPETITION

- Airtech Japan model Clean Viewer, particle size 10 microns, price Rs.2,33,700/ - + 16.48% excise duty
- Applied Physics USA model UF2 price $ 4950 ex-works USA = Rs.3 lakhs including freight & import duty
- Clean Air Solutions USA model Air Trakker, price $ 12,500 ex-works = Rs.7.5 lakhs including import duty & air freight

Our price for Concept MiniColt = Rs.1,50,000/-

Stainless steel model = Rs.1,65,000/-

Available ex-stock in Indian rupees!

Already being used by Aurobindo Pharma Unit 7 (2 nos), Aurobindo Pharma Units 3 & 5, Cipla Indore, Caryair Hyderabad, Srivin Engg Hyderabad, Hetero Drugs Hyderabad, Gland Pharma Hyderabad (3 nos), Zydus Cadila Ahmedabad, Astral Pharma Baroda, Hemair Hyderabad, USV Daman, Unimark Remedies, Validair, Indoco Remedies Goa
DISADVANTAGES OF DI WATER FOGGERS

- Here is what Applied Physics USA say about the DI water machines supplied by them:

- The DI water fog is generated by atomizing DI water into water droplets, which are nominally 3-10μm in size. The water droplets contain residual particulate matter from the DI water, and when the water droplet evaporates in the cleanroom, the particulate matter remains as a “haze particle 10nm to 100nm in diameter” adrift in the air currents.

- If the facility manager operates a class 10000 (or worse) cleanroom, the use of this fogger poses no problem. However, cleanroom engineers who manage facilities operating at Class 1 to Class 1000 performance should not use DI water fog, since the resulting Haze particles have a potential to affect the semiconductor yield or the pharmaceutical drug process.

- The 3-5lb output pressure of a DI water fogger also distorts the airflow patterns, thus adding to the turbulence.