Clearing The Air – Airflow Visualization Studies Demystified

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AVS

Content

- **Equipment and smoke generating solution selection advantages and disadvantages of each and my preference.**
- **Latest AVS agency observations.**

AVS

- Airflow Visualization Studies (AVS), commonly referred to as smoke studies, is a technique used to make filtered air patterns visible for analysis and testing. These studies, which utilize smoke or fog for testing airflow, play a pivotal role in visualizing the airflow patterns within cleanrooms, isolators, and other controlled environments where aseptic processing takes place.
- This is typically achieved using devices like fog generators or smoke wands, which are essential tools in various settings, including HVAC systems, cleanrooms, and aseptic processing areas.

Equipment and smoke generation

Liquid Nitrogen (LN2)

Description:

- LN2 foggers use rapid vaporization of liquid nitrogen, often combined with water, to produce a cold, dense fog.

Pros:

- Purity: Produces clean, particle-free fog with no residues.
- Effectiveness: Dense fog is effective in high-velocity airflow environments.
- Safety: Non-toxic, with no chemical residues to interfere with pharmaceutical operations.
- Compliance: Often preferred for critical applications due to minimal contamination risk.

Equipment and smoke generation

Liquid Nitrogen (LN2)

Cons:

- Cost: LN2 can be expensive, and storage requires specialized cryogenic equipment.
- Handling Risks: Requires stringent safety measures due to the cryogenic nature of LN2.
- Portability: Less portable due to the need for insulated containers.
- Condensation: May cause condensation on surfaces, which could interfere with some studies.

Equipment and smoke generation

Ultrasonic

Description:

- Ultrasonic foggers use high-frequency vibrations to atomize water into a fine mist.

Pros:

- Low Cost: Economical operation with no consumables beyond water.
- Safety: Non-toxic and environmentally friendly, producing only water mist.
- Portability: Compact and lightweight devices are easy to move and set up.
- Ease of Maintenance: Simple design with minimal maintenance requirements.

Equipment and smoke generation

Ultrasonic

Cons:

- Visibility: Produces less dense fog, which may dissipate quickly in high-velocity environments.
- Effectiveness: Limited use in environments with turbulent or strong airflow.
- Compatibility: Requires deionized water to prevent mineral deposits, increasing operational complexity.

Equipment and smoke generation

Glycol

Description:

- Glycol foggers use a mixture of glycol and water, heated to produce a dense, white vapor.

Pros:

- Visibility: Produces dense and persistent fog suitable for high airflow visualization.
- Control: Adjustable density and flow provide precise control over visualization.
- Portability: Lightweight and portable systems are available.
- Availability: Glycol mixtures are readily available and cost-effective.

Equipment and smoke generation

Glycol

Cons:

- Residue: Glycol can leave a residue, requiring post-visualization cleanup.
- Safety: Glycol vapors may irritate skin, eyes, or respiratory systems in poorly ventilated areas.
- Regulatory Concerns: Residues may interfere with pharmaceutical cleanliness standards, requiring validation for specific applications.
- Cost: Long-term operational costs may be higher due to consumable glycol solutions.

Agency Observations

Regulations

- EU GMP Annex 1, and US FDA guidance recommend airflow visualization studies to characterize and document airflow patterns.
- These studies help assess airflow direction and uniformity against design specifications and are integral in choosing locations for Environmental Monitoring as part of risk assessments in cleanrooms.

Agency Observations

- No Dynamic smokes only Static
- Not performing smoke studies for changes to the equipment
- Not filming all interventions
- Poor smoke quality
- Smokes aren’t representative of actual processing
- Insufficient camera angles

Conclusion

- When selecting an AVS vendor be sure they have the proper equipment and can provide a finished product that will be accepted by regulatory agencies.
- When performing the studies ensure that an approver of the studies are present. This individual should be knowledgeable of the process and of smoke studies to give a go or no go during the execution.

Q/A

Any questions?