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Smoke Study Review:

Five Parameters to be Focused……

- **Laminarity**
- **GMP**
- **Aseptic intervention**
- **Containment efficiency**
- **Cross Contamination**

• Laminarity:

Turbulent

Laminar Mix Turbulent

• GMP Aspect:

Static and dynamic smoke study videos may provide many different views and close-up views (because of multiple camera) within the sterile core that are not visible or clearly visible through the view windows or cameras into these areas.

These close and clear views can identify following GMP issues for a regulatory inspector to pursue….

- ✓ **Gowning Procedure,**
- ✓ **Cleaning ,Sanitization & Disinfection program**
- ✓ **PM & BM Program**
- ✓ **Design & Condition of filling line etc**
- ✓ **EM Locations rational**

- ## Aseptic intervention:

✓ The same aseptic practices/technique and/or interventions to be followed for smoke studies, successful media fill and routine operations
✓ a clear view of the aseptic technique used in complex interventions could lead to further review of the technique for reproducibility as practiced currently.

- ## Containment Efficiency & Cross Contamination:

✓ **Airflow Visualization Studies should include the testing of cleanroom and barrier system doors (including pass-throughs) to document proper airflow from areas of higher cleanliness to adjacent less clean areas.**
✓ **It is vital for rooms of higher air cleanliness to have a substantial positive pressure differential and airflow relative to adjacent rooms of lower air cleanliness (with doors closed).**
✓ **Airflow Visualization Studies should document and demonstrate when doors are open, outward airflow should be sufficient to minimize ingress of contamination.**
✓ **This information can be used in risk analysis, environmental monitoring site selection and to determine the time a door can remain ajar before alarming.**

- ## Interpretation of Results

Interpretation scale cannot be standard and it can vary organization to organization. However, a blind statement should be avoided such as complies/does not comply. Following is an example to calculate the level of compliance during the Air Flow Patter studies.

Description	Scale
Excellent	5
Very Good	4
Good	3
Poor	2
Very Poor	1

	Check	Scale				
		❶	❷	❸	❹	❺
Objective 1	Laminarity					X1
	Air flow Directions				X2	
	Turbulences				X3	
	Smoke Bubbles					X4
	Density Smoke	X5				
	Continuity of smoke flow			X6		
	Smoke Visualization from HEPA supply filter					X7
	Smoke Visualization evacuating through return filter				X8	
Objective 2	All planned intervention performed				X9	
	Interventions disturbing the air flow pattern					X10
	Interventions creating smoke bubbles				X11	
	Aseptic Behavior				X12	
	Hurdles are prompted by Operators or the Articles being handles				X13	
	Operator's body movement under the laminar air flow					X14
	Chronology of interventions is maintained					X15
	Cumulative Score	A	B	C	D	E
	Gross Total (A+B+C+D+E)					

Aberration Handling

Protocol should clearly mention where the corrections shall be triggered.

Where ever required relevant corrections should be made after interpretation of the results. Based upon the criticality of the gaps study should be demonstrated again, if required otherwise suitable corrections can be justified in the report itself.

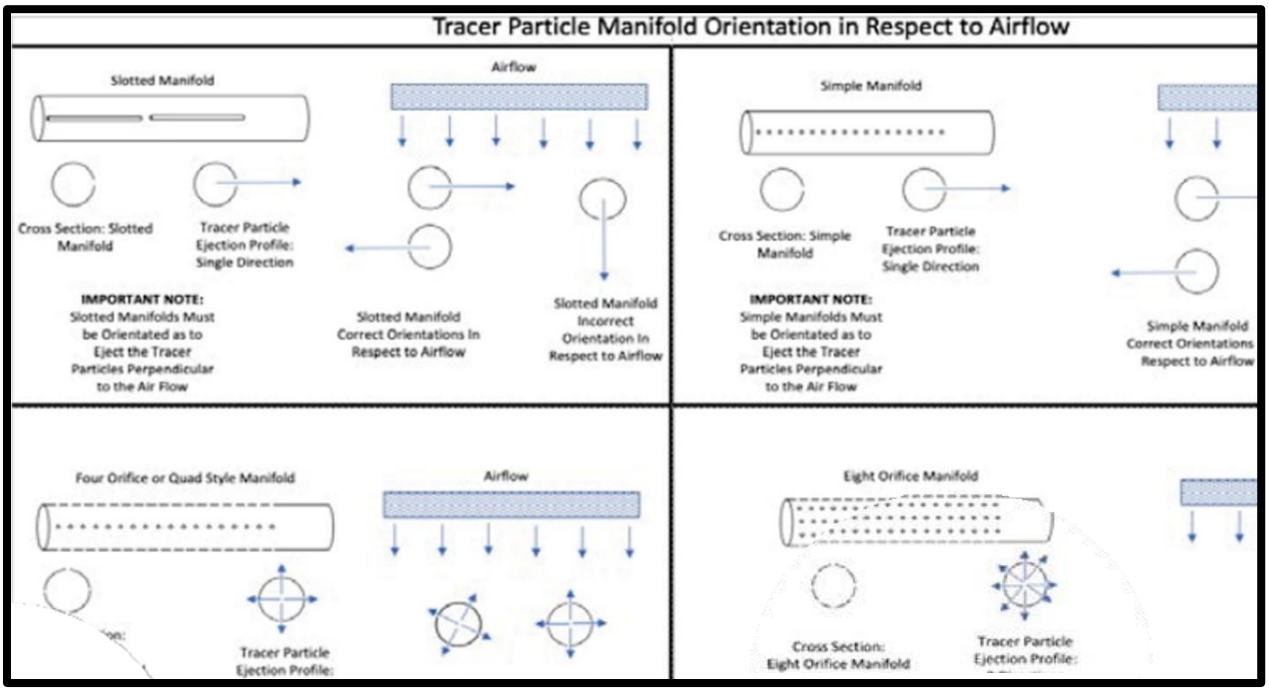
Recording format should be designed based upon user experience so that relevant justification are captured at the time of the activity such as operational difficulty, angle of recording, smoke density, Lux levels etc.

Decision matrix can be designed as exemplified below:

Gross Score	Overall Rating	Actions
≥ 61 to 75	Excellent	No Actions Required
≥ 46 to 59	Very Good	Actions Required
≥ 31 to 44	Good	Actions Required
≥ 16 to 29	Poor	Actions Required & Study to be Demonstrated Again
≤ 15	Very Poor	Actions Required & Study to be Demonstrated Again

Smoke Distribution Assemblies:

Smoke distribution assemblies should be the developed based on fluid Science. We should consider design of manifold assembly, size of pipes ,diameter of pipes, number of holes ,size of holes etc .



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Do and Don’ts:

Sometime, even successfully qualified systems can be compromised by poor personnel, operational, or maintenance practices.

Therefore, practices which should be avoided to prevent turbulences or disturbances in air flow pattern

1. **Personnel should minimize interventions into the critical zones**
2. **Traffic path for the material movement and man movement should be defined**
3. **Occupancy in each area should be defined and controlled**
4. **Equipment should not obstruct airflow and, in critical areas, its design should not disturb unidirectional airflow.**
5. **Rapid movements can create unacceptable turbulence**
6. **Keep the entire body out of the path of unidirectional airflow**
7. **Maintenance work in clean rooms should be executed with proper care.**

Conclusion:

To conclude, it is evident that smoke studies have to be demonstrated with sound understanding of the design of the HVAC system and understanding of the Aseptic Behaviour. Organization should have specific procedures laid down for conducting the smoke studies. Evaluation should be properly rationalized and a commentary for all activities should be documented with all interpretation of each step and actions recommended.

Subject Matter Experts should be involved for the interpretation of the results for Laminarity and Aseptic Behaviour.

As a GAMP Group, We have Team of SMEs and Execution Team for

- ✓ **Smoke Study Execution**
- ✓ **Smoke Study Review**
- ✓ **Smoke Study Consultation & Remediation Project**
- ✓ **CFD**
- ✓ **Smoke Study Project**