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AIRFLOW VISUALIZATION BEYOND COMPLIANCE

June 2026

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EXECUTIVE SUMMARY

Airflow Visualization Study (AVS), commonly referred to as a smoke study, has become an increasingly important component of contamination control programs within pharmaceutical, biotechnology, and cell therapy manufacturing environments. Historically performed to support qualification activities and regulatory compliance, airflow visualization has evolved into a valuable process understanding tool that provides direct insight into airflow behavior under actual operating conditions.

As regulatory expectations continue to emphasize contamination control strategies, quality risk management, and scientific process understanding, organizations are expected to demonstrate not only that airflow systems function as designed, but also that they effectively protect products, processes, and critical surfaces during routine manufacturing activities. AVS supports these objectives by allowing organizations to evaluate airflow patterns, identify potential airflow disturbances, verify first air protection, and assess the impact of personnel, equipment, and operational practices on contamination control.

When performed using a risk-based approach, airflow visualization provides benefits that extend far beyond compliance. The observations generated during these studies can support facility design decisions, improve operating procedures, strengthen contamination control strategies, enhance operator training, and contribute to overall process robustness. Organizations that leverage airflow visualization as a process understanding tool gain valuable insight into contamination risks that may not be apparent through qualification testing or environmental monitoring alone.

This paper explores the evolving role of airflow visualization within pharmaceutical manufacturing, examines key regulatory expectations, discusses the principles of airflow protection, and outlines practical considerations for planning, executing, and interpreting airflow visualization studies as part of a comprehensive contamination control strategy.

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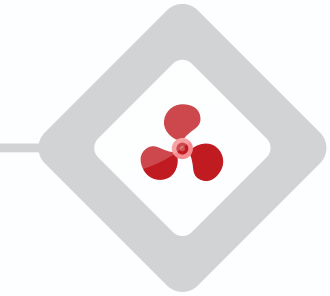
INTRODUCTION



In pharmaceutical, biotechnology, and cell therapy manufacturing environments, maintaining effective contamination control is essential for ensuring product quality and patient safety. As manufacturing processes become increasingly complex and regulatory expectations continue to evolve, organizations are expected not only to demonstrate compliance with established standards but also to develop a thorough understanding of the factors that influence contamination risk within their facilities.

One area that has received significant attention in recent years is AVS. Historically referred to as a smoke study, airflow visualization has long been used to demonstrate airflow patterns within cleanrooms, laminar airflow workstations (LAFWs), biological safety cabinets (BSCs), restricted access barrier systems (RABS), isolators, aseptic filling lines, downflow booths, pass-throughs, and other controlled environments. While these studies have traditionally been performed to satisfy qualification requirements or regulatory expectations, their value extends far beyond compliance. When properly designed and executed, airflow visualization studies provide critical insight into how air behaves during actual manufacturing operations and help organizations identify conditions that may compromise product protection.

The publication of the revised EU GMP Annex 1 further reinforced the importance of understanding airflow behavior within aseptic manufacturing environments. The guidance emphasizes the need for contamination control strategies that are based on scientific understanding and risk management principles. As a result, airflow visualization is increasingly viewed not simply as a qualification exercise, but as an important tool for evaluating process risks, verifying first air protection, and supporting the overall contamination control strategy.

Organizations that approach airflow visualization solely as a regulatory requirement often miss opportunities to gain valuable operational insight. By adopting a risk-based approach, manufacturers can leverage airflow

visualization to improve process understanding, optimize facility design, strengthen inspection readiness, and ultimately reduce contamination risk.

Regulatory agencies worldwide continue to place increased emphasis on the quality, scientific justification, and execution of airflow visualization studies. Inadequately designed studies, failure to challenge critical interventions, poor documentation, insufficient video evidence, or the inability to demonstrate first air protection have been cited during inspections and may contribute to regulatory observations, warning letters, delayed product approvals, remediation efforts, and increased regulatory scrutiny. As a result, organizations must ensure that airflow visualization studies are not only performed, but are scientifically sound, representative of actual operations, and capable of withstanding regulatory review.

“Airflow visualization should be viewed as a process understanding tool rather than a qualification exercise."

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UNDERSTANDING THE PURPOSE OF AIRFLOW VISUALIZATION

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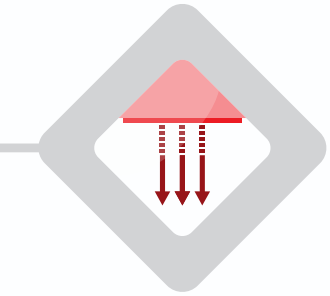
UNDERSTANDING THE PURPOSE OF AIRFLOW VISUALIZATION



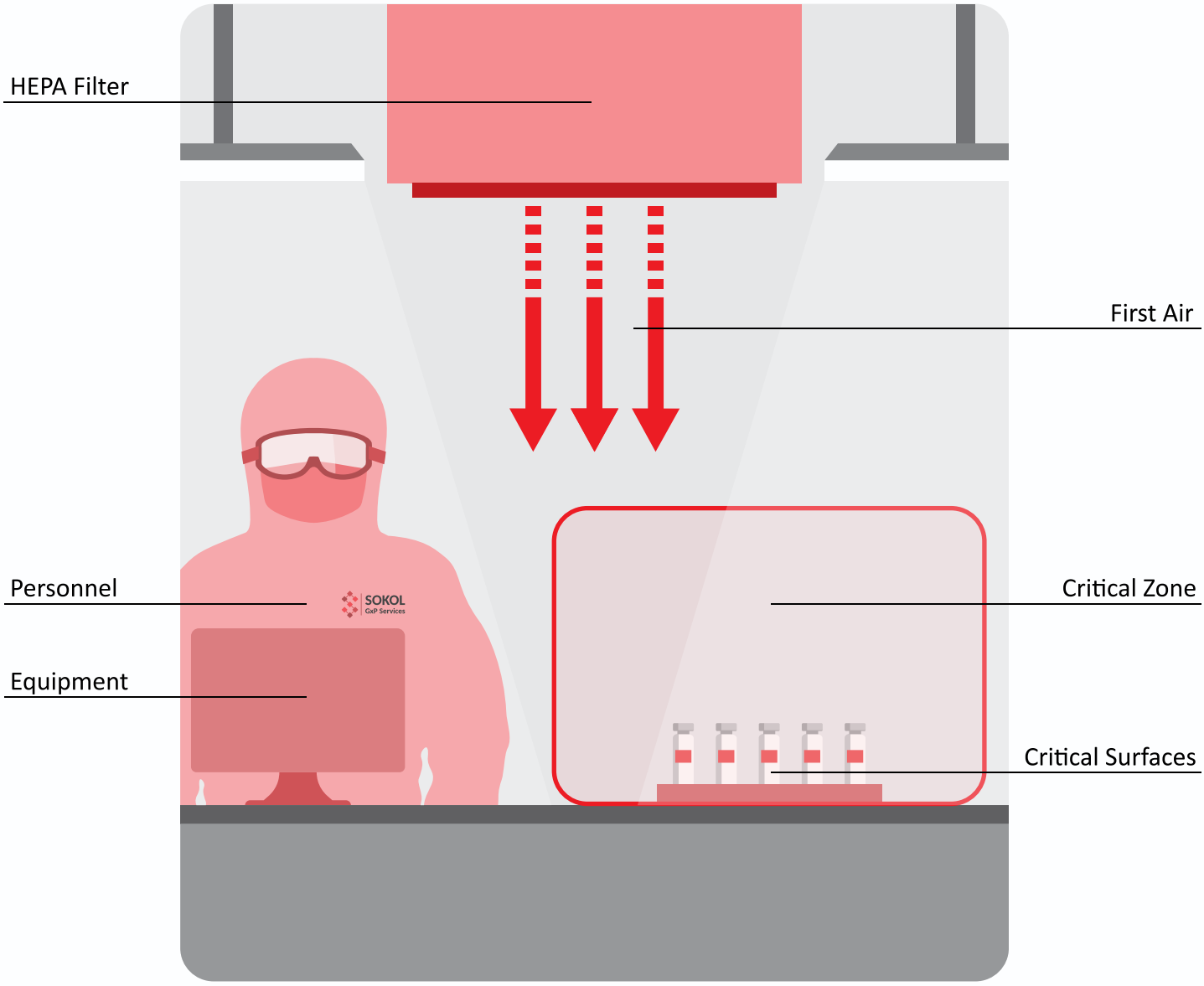
Airflow plays a critical role in maintaining the cleanliness and integrity of controlled manufacturing environments. In aseptic processing operations, properly designed airflow patterns help remove particles, protect exposed product and critical zones, and minimize the likelihood of contamination. While engineering drawings, airflow calculations, differential pressure readings, and environmental monitoring data provide valuable information regarding facility performance, they do not always reveal how air behaves during actual operations.

Airflow visualization bridges this gap by allowing organizations to observe airflow patterns under dynamic conditions. Using a visible challenge medium, airflow can be observed as it moves around equipment, personnel, materials, and other obstacles present during routine manufacturing activities. This visual representation provides a unique opportunity to evaluate whether critical areas remain protected and whether airflow behaves as intended when the process is actively being performed.

The importance of this understanding becomes particularly evident when considering the complexity of modern manufacturing environments. Even facilities that meet all classification requirements may experience localized turbulence, airflow disruption, or unintended recirculation caused by equipment placement, operator movement, or process design. These conditions may not be readily apparent through traditional qualification testing but can become visible during a properly executed airflow visualization study.

Rather than serving solely as documentation for regulatory inspections, airflow visualization provides a means of understanding the interaction between facility design, equipment configuration, and human activity. This understanding enables organizations to identify vulnerabilities before they contribute to contamination events or inspection observations.

Figure 1. Relationship Between Airflow, Personnel, Equipment, and Product Protection
HEPA Filter → First Air → Critical Surface → Product Protection
with Personnel and Equipment acting as potential airflow disruptors.



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REGULATORY EXPECTATIONS AND INDUSTRY GUIDANCE

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REGULATORY EXPECTATIONS AND INDUSTRY GUIDANCE

The increasing emphasis on airflow visualization within pharmaceutical manufacturing is closely tied to the industry's evolving approach to contamination control. Regulatory agencies no longer view contamination prevention as a collection of isolated activities. Instead, manufacturers are expected to develop comprehensive systems that identify, assess, and control potential sources of contamination throughout the product lifecycle.

The revised EU GMP Annex 1 represents one of the most significant drivers behind this shift. The guidance places substantial emphasis on contamination control strategies (CCS), requiring manufacturers to demonstrate a scientific understanding of their facilities, processes, equipment, personnel practices, and environmental controls. Within this framework, airflow visualization serves as an important tool for verifying that airflow patterns provide adequate protection to critical processing areas and exposed products.

Similarly, FDA guidance for aseptic processing highlights the importance of maintaining appropriate airflow conditions and understanding how manufacturing activities can influence contamination risk. While the guidance may not prescribe specific study methodologies, it reinforces the expectation that firms understand the relationship between airflow and product protection.

These regulatory expectations align closely with the principles outlined in ICH Q9 Quality Risk Management. Rather than relying solely on prescriptive requirements, organizations are encouraged to evaluate risks based on scientific knowledge, process understanding, and objective evidence. Airflow visualization supports this approach by providing direct observations of airflow behavior under actual operating conditions.

As inspections increasingly focus on contamination control strategies and quality risk management programs, organizations that can demonstrate a comprehensive understanding of airflow behavior are often better positioned to justify facility designs, operational practices, and contamination control decisions.

"The value of airflow visualization lies not in demonstrating that air moves, but in understanding how airflow protects products during routine operations."

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THE SCIENCE OF AIRFLOW PROTECTION

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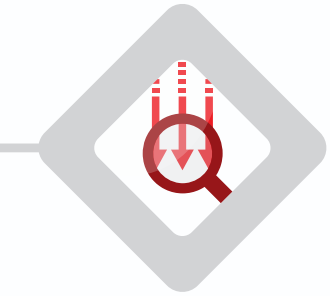
THE SCIENCE OF AIRFLOW PROTECTION



The effectiveness of contamination control within pharmaceutical manufacturing environments depends heavily on the ability to establish and maintain airflow patterns that continuously remove particles and protect critical processing areas. While cleanroom classifications, air change rates, and environmental monitoring programs provide important indicators of facility performance, they do not independently confirm that airflow is adequately protecting exposed products or critical surfaces during routine operations.

At the core of aseptic processing is the concept of first air. First air refers to air that originates from a high-efficiency particulate air (HEPA) filtration source and reaches a critical surface without first passing over personnel, equipment, materials, or other potential sources of contamination. The preservation of first air is one of the fundamental principles of contamination control and serves as a primary focus during airflow visualization studies.

In practice, maintaining first air is often more challenging than it appears. Manufacturing operations involve personnel movement, equipment interaction, material transfers, and routine interventions that can alter airflow patterns in subtle but meaningful ways. A work area that appears adequately protected under static conditions may experience localized turbulence or airflow disruption during normal operations. These disturbances may not be readily apparent through traditional qualification testing, yet they may have a direct impact on product protection.

Unidirectional airflow systems are designed to minimize these risks by establishing a consistent flow of filtered air across critical processing areas. However, airflow does not behave in a perfectly linear manner once it encounters obstacles. Equipment, operators, carts, tubing, process components, and even hand movements can influence airflow direction and velocity. Understanding these interactions is essential for determining whether the intended level of protection is maintained throughout the manufacturing process.

Airflow visualization provides a practical means of evaluating these conditions. By making airflow visible, organizations can assess whether first air remains intact, whether airflow recovery occurs following interventions, and whether critical work zones remain protected during routine operations. The resulting observations contribute to a more complete understanding of contamination control performance than numerical measurements alone can provide.

"A room can meet classification requirements while still exhibit airflow patterns that increase contamination risk."

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PLANNING EFFECTIVE AIRFLOW VISUALIZATION STUDIES

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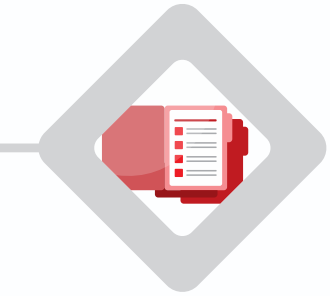
PLANNING EFFECTIVE AIRFLOW VISUALIZATION STUDIES



The value of an airflow visualization study is largely determined during the planning phase. A well-designed study should be structured to answer specific questions regarding contamination control, process risk, and airflow performance. Conversely, studies performed without clear objectives often generate large volumes of video footage while providing limited insight into actual process risks.

Effective planning begins with a thorough understanding of the manufacturing process. Critical process steps should be identified, with particular attention given to operations involving exposed product, sterile components, aseptic manipulations (interventions), or activities performed within critical work zones. These activities represent the areas where airflow protection is most important and where airflow visualization can provide the greatest value.

Once critical operations have been identified, study conditions should be developed to reflect actual manufacturing practices. Regulatory guidance increasingly emphasizes the importance of dynamic assessment rather than reliance on static demonstrations. Airflow patterns observed in an empty room or inactive biological safety cabinet may differ significantly from those observed during routine manufacturing activities. As a result, airflow visualization studies should incorporate representative personnel movements, equipment configurations, material staging practices, and process interventions.

The concept of worst-case conditions is also an important consideration. Worst-case does not necessarily imply unrealistic or artificially challenging scenarios. Rather, it refers to conditions that represent the greatest reasonably foreseeable challenge to airflow protection during normal operations. Evaluating these situations allows organizations to better understand process robustness and identify vulnerabilities before they contribute to quality issues.

Cross-functional collaboration can further enhance study quality. Quality assurance personnel, manufacturing operators, engineers, validation specialists, and contamination control experts often bring unique perspectives regarding process risks and operational practices. Incorporating these perspectives during study design helps ensure that assessments address meaningful operational concerns rather than simply satisfying procedural requirements.

Ultimately, effective planning transforms airflow visualization from a compliance activity into a valuable process understanding exercise that supports long-term contamination control objectives.

Figure 2. AVS Study Planning Workflow

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AIRFLOW VISUALIZATION METHODOLOGIES AND TEST APPROACH

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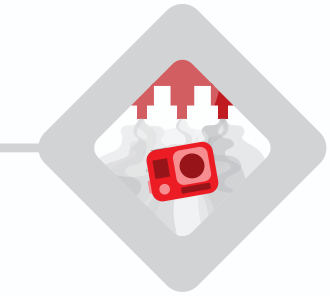
AIRFLOW VISUALIZATION METHODOLOGIES AND TEST APPROACH



While the principles of airflow visualization are straightforward, the quality of the study depends heavily on the methodology used to generate, capture, and interpret airflow patterns. Careful consideration of study execution is therefore essential for obtaining meaningful and defensible results.

Visualization Medium:

The selection of an appropriate visualization medium is one of the first considerations when planning an airflow visualization study. The tracer must be sufficiently visible to allow airflow patterns to be clearly observed and documented while minimizing any impact on the airflow being evaluated. Consistent tracer generation techniques, equipment setup, and injection methods are essential to ensure that airflow behavior is represented accurately, reproducibly, and in a scientifically defensible manner.

Several tracer technologies are available, including **liquid nitrogen (LN_2), glycol-based,** and **ultrasonic fog** systems. Each technology offers distinct advantages and limitations related to visibility, particle behavior, residue generation, environmental compatibility, cleanroom classification, equipment configuration, and study objectives. The selection of the appropriate tracer should be based on the specific application, facility and equipment design, cleaning and residue control requirements, operational constraints, and the objectives of the study.

Regardless of the tracer selected, the visualization medium should generate a clearly visible plume that follows the natural airflow without introducing excessive momentum, turbulence, or thermal effects that could distort the actual airflow patterns being evaluated. Proper selection and use of the tracer medium are critical to obtaining meaningful, representative, and regulatory-defensible results.

Video Recording:

Camera positioning is another critical factor. Poor camera placement can obscure important observations or create misleading perspectives regarding airflow direction and behavior. Multiple camera angles are often beneficial when evaluating complex processes, particularly in environments where personnel movement or equipment configuration may limit visibility. The objective is not simply to record airflow but to capture sufficient evidence to support meaningful interpretation and discussion.

Test Approach:

Organizations should consider both **Static** and **Dynamic** evaluations. Static studies may provide useful baseline information regarding airflow patterns under controlled conditions. However, dynamic studies generally provide greater value because they evaluate airflow performance during representative manufacturing activities. Personnel interventions, material transfers, equipment operation, and process manipulations frequently influence airflow behavior and therefore should be considered when designing studies.

Documentation:

Documentation practices also play an important role. Airflow visualization studies generate valuable visual evidence that may be reviewed by quality personnel, engineering teams, auditors, inspectors, and regulatory agencies. Clear documentation of study objectives, conditions, observations, and conclusions helps ensure that the results remain useful throughout the lifecycle of the facility and process.

Organizations should also recognize the limitations of airflow visualization. AVS provides a qualitative assessment of airflow behavior and should be interpreted in conjunction with other sources of information, including environmental monitoring data, facility qualification results, process

knowledge, and risk assessments. Airflow visualization is most effective when used as one component of a broader contamination control strategy rather than as a standalone evaluation tool.

Figure 3. Static vs Dynamic

Static Assessment	Dynamic Assessment
Equipment at rest	Equipment operating
No personnel movement	Routine operator interventions
Baseline airflow pattern	Actual manufacturing conditions
Useful for initial characterization	Useful for evaluating contamination
Limited representation of operations	Representative of real-world

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REGULATORY OBSERVATIONS AND LESSONS LEARNED

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REGULATORY OBSERVATIONS AND LESSONS LEARNED

Recent regulatory inspections continue to demonstrate that airflow visualization remains an area of significant focus during aseptic processing assessments. Regulatory observations frequently identify deficiencies not only in airflow visualization execution, but also in how organizations interpret and apply the resulting data to contamination control programs.

Common observations include insufficient smoke generation to adequately visualize airflow patterns, studies that fail to represent dynamic manufacturing conditions, inadequate assessment of critical interventions, and failure to evaluate airflow disturbances created by personnel activities or equipment configuration. Regulatory agencies have also identified situations where routine interventions resulted in loss of first air protection or where process simulations failed to adequately represent actual manufacturing operations.

These observations reinforce an important lesson: performing an airflow visualization study is not, by itself, sufficient. The study must be designed to challenge the process in a meaningful way and generate information that can be used to assess contamination risks. Studies that are limited in scope or fail to evaluate realistic operating conditions may provide little value in supporting contamination control decisions.

Recent inspection findings have highlighted several recurring themes. Organizations frequently underestimate the impact of personnel movement on airflow patterns, fail to adequately evaluate routine interventions, or perform studies under conditions that do not accurately reflect actual manufacturing practices. In some cases, airflow visualization was conducted using insufficient smoke coverage, making it difficult to evaluate airflow behavior in critical areas. In others, studies failed to challenge worst-case conditions or did not adequately assess airflow recovery following interventions.

These observations support the industry's broader movement toward science- and risk-based contamination control strategies. Airflow visualization should be viewed as an ongoing process understanding activity rather than a one-time qualification requirement. Organizations that use AVS to identify, evaluate, and mitigate contamination risks are better positioned to support inspection readiness and demonstrate a comprehensive understanding of their manufacturing operations.

"Dynamic studies provide insight into contamination risks that static assessments may fail to identify."

Examples of Regulatory Observations on Airflow Visualization

FDA Form 483 Observations Issued to a Vaccine Manufacturer

"Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, Airflow visualization studies (Smoke studies) were not performed for the following inherent and corrective interventions performed during aseptic process of ABC vaccine.

A. On DDMMMYYY, during the fill line setup of ABC vaccine batch using aseptic (b)(4), we observed a Grade (b)(4) operator using an empty tray for removing the entire vials from the vial (b)(4), as a vial storage (b)(4) was accidentally slipped and fell over the vials. This intervention was never evaluated in the airflow visualization studies.

B. The (b)(4) changeout is a corrective intervention during the (b)(4) process. This was never evaluated through smoke studies.

C. On DDMMMYYY, during the (b)(4) set-up for ABC vaccine batch (b)(4), the (b)(4) had alignment issues. The grade (b)(4) operator inside the protective enclosure around the (b)(4) to complete the set-up process. This intervention was never evaluated in the airflow visualization studies. (b)(4) were present in the (b)(4) during this corrective intervention."

FDA Form 483 Observations Issued to a Compounding Pharmacy

"Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of aseptic process.

Specifically,

A. During the observation of air visualization study SO# XXXXXXX for your dynamic aseptic filling operation in Buffer Room (b)(4), Unit ID: (b)(4), the following deficiencies were noticed:

1. *The setup of vials, stoppers, and caps at the edge of the hood results in air arching and dragging, which prevents these critical components form receiving first air.*
2. *The filter needle is (b)(4) oriented within a (b)(4) laminar flow hood blocking unidirectional airflow.*
3. *The viable air monitor's functionality was not demonstrated during operation, therefore, there is no evidence to show that its placement could affect airflow in the critical area.*

B. Dynamic FPC50 air visualization study:

1. *Air visualization studies show air arching over stoppers, caps, and seals, indicating that these critical components are not receiving first air.*
2. *The filter needle is (b)(4) oriented within a (b)(4) laminar flow hood blocking unidirectional airflow.*
3. *The auto-filler's setup within the tubing that carries the sterile solution to the needle, is not included in the air visualization study, preventing an accurate assessment of airflow in the critical zone.*

C. (b)(4) Dynamic and Loading air visualization study:

1. *Air arching was observed over open vials and incompletely seated, stoppered vials.*
2. *Turbulence and smoke drag were present in the middle of the turntable, within the critical zone of the open vials.*
3. *The video angle was inadequate to fully assess the filling and stoppering process."*

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APPLYING A RISK-BASED APPROACH

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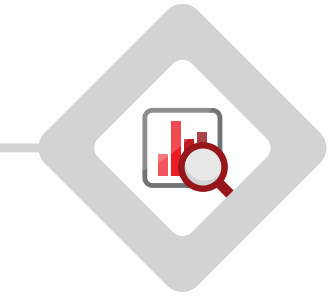
APPLYING A RISK-BASED APPROACH



A risk-based approach to airflow visualization begins with understanding how airflow contributes to contamination control and identifying the activities that present the greatest potential risk to product quality. Rather than viewing AVS as a stand-alone qualification activity, organizations should consider how airflow behavior influences critical operations throughout the manufacturing process.

Open manipulations, aseptic connections, sterile transfers, product exposure events, and routine interventions within critical work zones typically warrant particular attention. These activities often represent the points at which contamination risks are highest and where airflow protection is most important. By focusing studies on these areas, organizations can obtain information that directly supports contamination control decision-making.

A risk-based approach also requires evaluation under representative operating conditions. Personnel movement, equipment configuration, material staging practices, routine and non-routine interventions, equipment adjustments, maintenance activities, and process disturbances can all influence airflow behavior and should be considered during study design. Airflow patterns observed under static or idealized conditions may not accurately represent those present during actual manufacturing operations and may fail to identify vulnerabilities that become apparent during routine processing. Therefore, airflow visualization studies should be designed to challenge critical operations, worst-case interventions, and realistic operating scenarios to verify that first air protection is maintained and contamination control remains effective throughout the manufacturing process.

The principles outlined in ICH Q9 Quality Risk Management provide a useful framework for this approach. Airflow visualization should generate information that can be used to identify hazards, evaluate risks, implement

controls, and verify the effectiveness of contamination control measures. When integrated into a broader risk management process, AVS becomes a valuable tool for continuous improvement rather than a periodic compliance exercise.

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INTERPRETING AIRFLOW VISUALIZATION RESULTS

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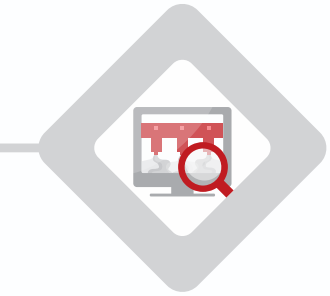
INTERPRETING AIRFLOW VISUALIZATION RESULTS



One of the most challenging aspects of airflow visualization is determining what constitutes acceptable airflow performance. Unlike many qualification activities, airflow visualization does not typically produce simple pass-or-fail criteria. Instead, interpretation often requires an understanding of contamination control principles, process risks, and operational realities.

The primary objective is to determine whether airflow continues to provide adequate protection to critical surfaces and exposed products during manufacturing activities. This evaluation requires consideration of both airflow behavior and process context. Minor airflow disturbances may be observed during certain activities without creating meaningful contamination risks, while seemingly insignificant disruptions may warrant further investigation depending on the location and nature of the activity.

The preservation of first air frequently serves as a key consideration during interpretation. Observations that indicate loss of first air protection, airflow obstruction, excessive turbulence, air arching, or unexpected airflow recirculation should be carefully evaluated to determine their potential impact on product quality. These evaluations often benefit from collaboration among quality, engineering, manufacturing, and contamination control personnel.

It is equally important to avoid overinterpreting observations. Airflow is dynamic by nature, and some degree of movement, variability, or temporary disturbance may be expected during routine operations. The goal is not to eliminate all airflow variation but rather to ensure that airflow continues to fulfill its intended contamination control function.

When interpreted within the broader context of process knowledge and risk management, airflow visualization results provide valuable insight into the effectiveness of contamination control measures and support informed

decision-making regarding process improvements and risk mitigation strategies.

"The goal of airflow visualization is not to eliminate all airflow variation, but to ensure that airflow continues to protect critical surfaces and exposed product throughout routine operations."

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AIRFLOW VISUALIZATION IN CELL AND GENE THERAPY MANUFACTURING

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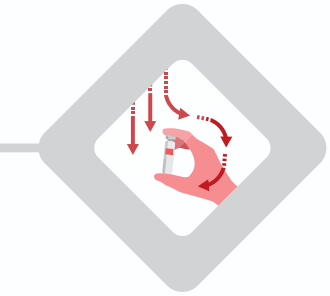
AIRFLOW VISUALIZATION IN CELL AND GENE THERAPY MANUFACTURING



Cell and gene therapy manufacturing presents unique challenges that further emphasize the importance of airflow visualization. Unlike many traditional pharmaceutical processes, these operations frequently involve open manipulations, manual interventions, and handling of highly valuable patient-specific materials.

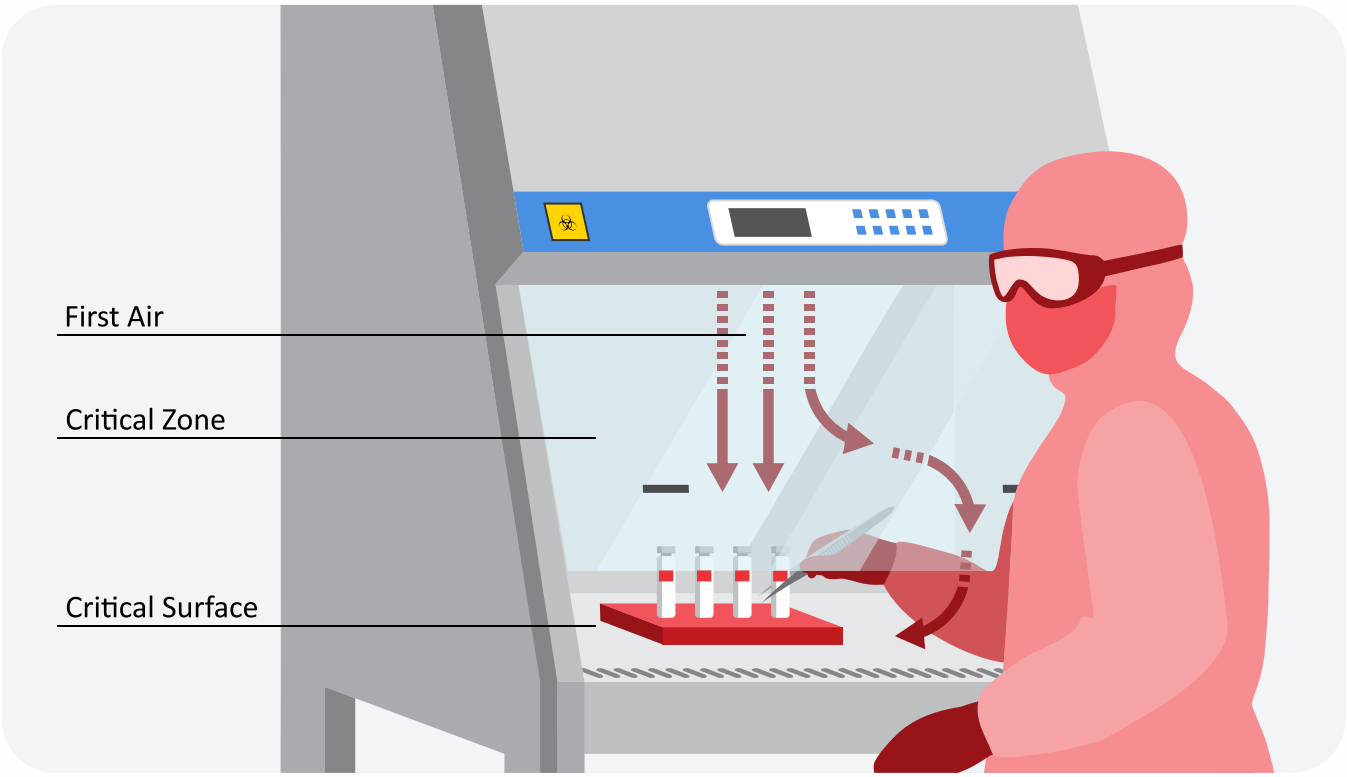
Biological Safety Cabinets (BSC), clean benches, and other critical work environments often serve as primary barriers between the process and potential sources of contamination. Maintaining effective airflow protection within these environments is essential for preserving product quality and ensuring patient safety.

The complexity of cell therapy operations can create situations where airflow behavior is influenced by numerous variables, including equipment configuration, material staging practices, operator technique, and workflow design. Because many processes involve direct interaction with exposed materials, even small disruptions to airflow may warrant evaluation.

Airflow visualization provides manufacturers with a practical means of understanding how these variables interact during routine operations. By observing airflow patterns during actual process activities, organizations can identify opportunities to strengthen contamination control strategies and improve operational consistency.

As the cell and gene therapy industry continues to expand, the ability to demonstrate a scientific understanding of airflow behavior will remain an important component of facility qualification, process development, and ongoing contamination control efforts.

Figure 4. Operator Performing Interventions Within Biological Safety Cabinet



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INTEGRATING AIRFLOW VISUALIZATION INTO THE CONTAMINATION CONTROL STRATEGY

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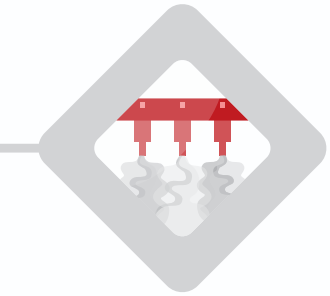
INTEGRATING AIRFLOW VISUALIZATION INTO THE CONTAMINATION CONTROL STRATEGY



Modern contamination control programs increasingly emphasize lifecycle management rather than one-time qualification activities. Airflow visualization aligns naturally with this approach because airflow behavior may evolve as facilities, equipment, processes, and operational practices change over time.

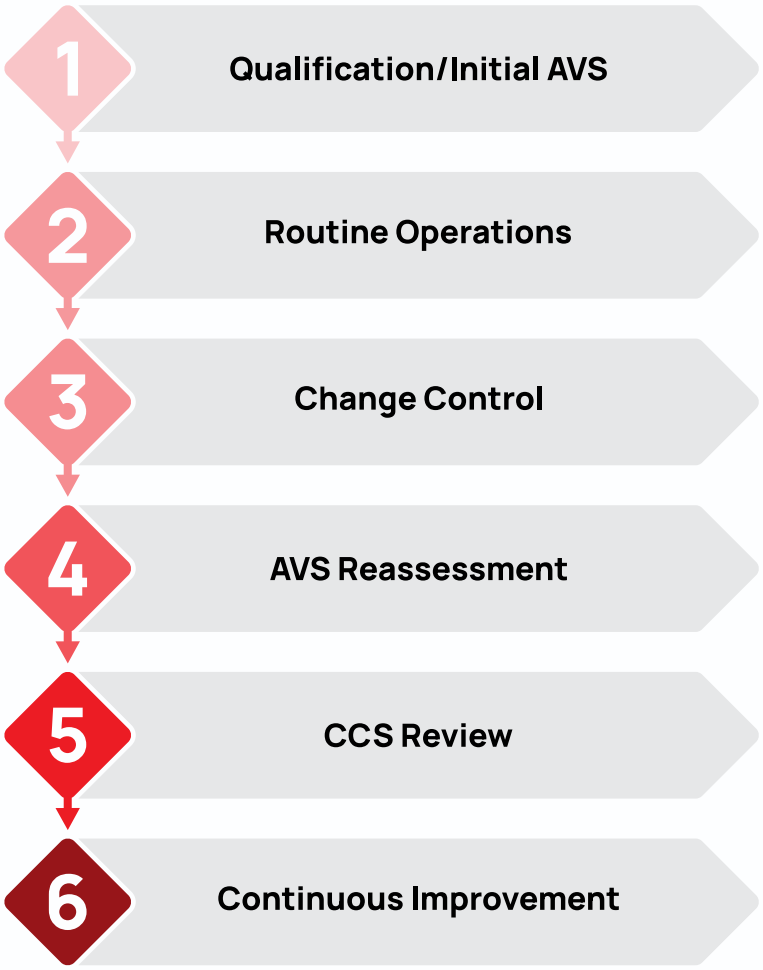
The revised Annex 1 guidance introduced a heightened focus on contamination control strategies, encouraging organizations to evaluate contamination risks holistically rather than through isolated compliance activities. Within this framework, airflow visualization can serve as a valuable source of information supporting risk assessments, facility modifications, process improvements, and change management activities.

For example, changes to equipment configuration, workflow design, material staging practices, or operating procedures may influence airflow behavior in ways that are not immediately apparent. Airflow visualization can help organizations assess the impact of these changes and determine whether existing contamination control measures remain effective.

Periodic reassessment may also provide value even when significant changes have not occurred. Manufacturing operations evolve over time as personnel gain experience, processes mature, and facilities adapt to changing business needs. Periodic airflow visualization studies can help verify that airflow protection continues to perform as intended and can identify opportunities for continuous improvement.

When integrated into a comprehensive contamination control strategy, airflow visualization becomes more than a qualification requirement. It becomes an ongoing source of process understanding that supports proactive risk management and long-term operational excellence.

Figure 5. AVS Within the Contamination Control Lifecycle



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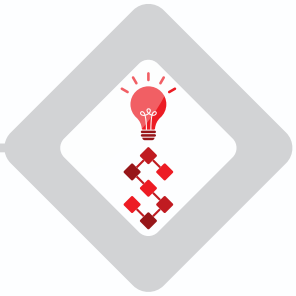
CONCLUSION



Airflow visualization has evolved from a traditional qualification exercise into a valuable process understanding and contamination control tool. While regulatory requirements continue to drive the performance of these studies, their true value lies in the insight they provide into the interaction between airflow, equipment, personnel, and manufacturing operations.

Organizations that embrace a risk-based approach to airflow visualization gain a deeper understanding of how their processes function under real-world conditions. This understanding supports more informed decision-making, strengthens contamination control strategies, enhances inspection readiness, and contributes to the protection of products, processes, and ultimately patients.

As pharmaceutical and cell therapy manufacturing environments continue to advance, airflow visualization will remain an essential component of modern contamination control programs. When integrated into a broader quality risk management framework, these studies provide far more than evidence of compliance—they provide the knowledge necessary to build and maintain robust, scientifically justified manufacturing operations.

SOKOL GxP Services

ABOUT SOKOL GXP SERVICES

SOKOL GxP Services provides commissioning, qualification, validation, contamination control, and technical consulting services to pharmaceutical, biotechnology, and cell therapy organizations. Our expertise includes airflow visualization, cleanroom qualification, contamination control strategy support, equipment qualification, and lifecycle validation services.

Through a combination of practical field experience and industry best practices, SOKOL helps clients develop compliant, efficient, and sustainable manufacturing operations. Our team supports organizations throughout the facility lifecycle, helping ensure regulatory compliance while promoting process understanding and operational excellence.

"See the Air. Control the Risk. Partner with SOKOL GxP."

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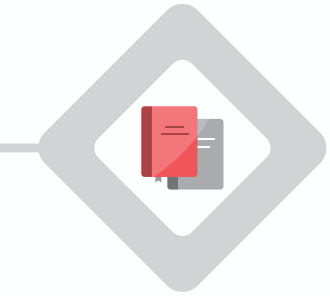

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