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Esco Lifesciences Group
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When to Consider Material and Personnel Airlocks for Downflow Booths

A Risk-Based Approach to Facility Integration and Contamination Control

1. Introduction

Downflow booths (DFBs) are widely used in pharmaceutical manufacturing for powder dispensing, sampling, and general material handling operations. These systems provide localized operator protection and dust control through directed airflow and high-efficiency filtration.

In many installations, DFBs are deployed as open-front containment devices within production rooms or warehouse environments. However, as facilities handle increasingly potent compounds and adopt more structured contamination control strategies, integration of the booth into the surrounding facility design becomes an important consideration.

Material Airlocks (MALs) and Personnel Airlocks (PALs) can provide controlled transition spaces for material and personnel movement when a downflow booth forms part of a classified or pressure-controlled suite. When properly integrated with facility HVAC and operational procedures, these features contribute to improved pressure stability, operational segregation, and controlled material flow.

This paper discusses scenarios where airlocks may be beneficial for DFB installations and outlines a risk-based framework for determining when such features may support facility contamination control strategies.

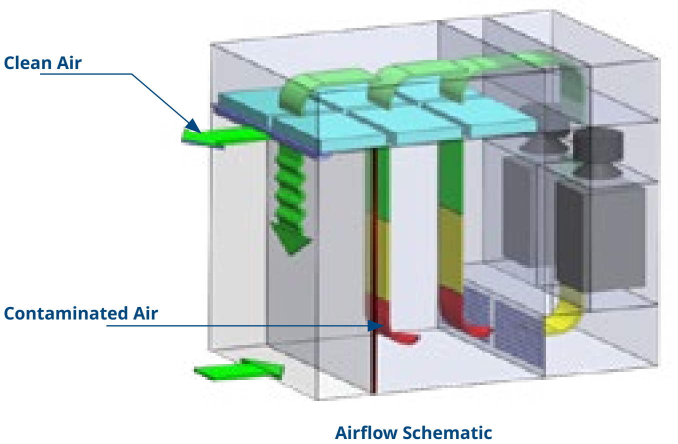

Figure 1. DFB Airflow Principles

2. Understanding Downflow Booth and Role of Airlocks

A downflow booth is an open-front containment workstation designed to control airborne particulate generated during powder handling operations such as weighing, dispensing, and sampling. The system operates by drawing room air through a high-efficiency particulate air (HEPA) filter located at the ceiling of the booth and directing it vertically downward as a uniform airflow curtain. This downward airflow captures dust generated at the work surface and transports it toward low-level exhaust grilles positioned behind or beneath the working zone. The contaminated air is then filtered before being either recirculated within the booth or discharged through the facility exhaust system. By establishing a controlled airflow path from clean supply to filtered exhaust, the booth reduces particulate dispersion into the surrounding room while maintaining operator visibility and ergonomic access to the process area.

Material and personnel airlocks are intermediate spaces designed to manage transitions between areas with different environmental classifications or pressure regimes.

Typical functions of airlocks may include:

- Supporting pressure cascade control between rooms
- Reducing direct airflow disturbances between adjacent spaces
- Providing controlled entry and exit points for personnel
- Enabling staged material transfer procedures
- Supporting facility contamination control strategies

It is important to note that airlocks function as facility-level design elements, and their effectiveness depends on integration with the surrounding HVAC system, pressure differentials, and operational procedures.

When a downflow booth is installed within a pressure-controlled suite, airlocks support more consistent environmental separation between the booth area and adjacent spaces.

3. Exposure Control Considerations in Powder Handling Operations

The engineering controls required for powder dispensing and handling operations are primarily determined by the toxicological properties of the materials being processed. In pharmaceutical manufacturing, these risks are commonly defined through Occupational Exposure Limits (OELs) or categorized using Occupational Exposure Bands (OEBs).

An OEL represents the maximum airborne concentration of a substance to which workers may be exposed without unacceptable health risk, typically expressed as a time-weighted average concentration (μg/m^3 or mg/m^3). OEB classifications are company-specific and may vary across organizations, reflecting differences in internal toxicological assessment methodologies.

These classifications of OEL guide the selection of engineering containment strategies. While open containment systems such as downflow booths may be appropriate for certain powder handling activities, the required level of protection depends on the target exposure limit, the nature of the operation, and the effectiveness of engineering and procedural controls.

4. Facility Airflow Architecture and Containment Integration

Containment performance in powder handling operations depends not only on equipment design but also on the broader facility airflow architecture in which that equipment operates.

Pharmaceutical facilities are required to implement both technical and organizational measures to control airborne contamination. These include localized dust extraction close to the source, and the appropriate use of airlocks and pressure cascades to confine potential airborne contaminants within defined areas as outlined in Chapter 5: Production of EudraLex EU GMP Volume 4.

A layered facility airflow strategy for powder handling areas typically comprises the following elements:

4.1. Local containment at the source

Equipment such as downflow booths, enclosed charging systems, or isolators provide primary engineering control where powder release may occur.

4.2 Room-level airflow management

Ventilation systems maintain directional airflow and appropriate air change rates throughout the processing room.

4.3 Pressure cascade control

Rooms where powders are handles are typically maintained at negative pressure relative to adjacent areas to prevent migration of airborne particulates.

4.4 Transitional buffer spaces

Airlocks, MALs, or PALs serve as intermediate spaces that minimize airflow disturbances during opening, personnel movement and material transfer.

This layered approach supports environmental stability and reduces the risk of cross-contamination during routine operation.

It is important to distinguish between cleanroom airflow systems designed primarily for product protection and containment systems intended to control operator exposure during powder handling. While both rely on controlled airflow and filtration, their design objectives and performance criteria differ significantly.

Downflow booths, for example, generate localized airflow intended to capture airborne particulate at the operator interface. However, their containment performance is influenced by surrounding room airflow patterns, operator positioning, and material handling techniques. For this reason, facility-level integration plays an important role in achieving consistent and reliable containment performance.

Where downflow booths are installed within or adjacent to classified zones, airlock arrangements may be used to buffer airflow disturbances and support pressure relationships between controlled and less controlled spaces. The pressure regime within these airlocks depends on the facility containment strategy and HVAC design. In some powder handling facility configurations, airlocks may be maintained slightly positive relative to the downflow booth and surrounding areas, allowing air to flow from the airlock toward the booth and helping stabilize airflow conditions during personnel or material transfer. In other facility designs, airlocks may be neutral or negative depending on the overall containment philosophy and pressure cascade of the facility.

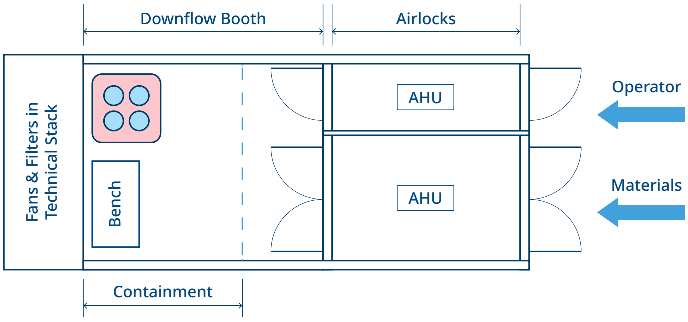

Figure 2. An example of DFB layout with airlocks.

5. Factors That May Support the Use of Airlocks in Downflow Booths

The decision to incorporate MALs or PALs should be based on a structured risk assessment considering product characteristics, facility layout, operational workflow, and contamination control requirements. Several common drivers are discussed below.

5.1 Handling of Potent Active Compounds

Facilities handling potent APIs commonly adopt layered containment strategies integrating engineering controls, procedural controls, and personal protective equipment. Within this framework, downflow booths are widely used where occupational exposure limits permit open-front containment systems.

The addition of airlocks can meaningfully enhance operational performance by providing a controlled transition zone for personnel entry and material transfer. This helps minimize airflow disruption at the booth face, supports consistent pressure management around the containment zone, and reduces the risk of particulate migration during routine operations, contributing to a more robust and defensible containment strategy.

Containment performance nonetheless remains dependent on the combined effect of multiple factors: booth airflow design and face velocity, air change rates within the booth and surrounding room, booth geometry and configuration, operator technique and workflow, material transfer practices, and room airflow patterns. Airlocks are best understood as a considered enhancement to an already sound containment design, not a standalone solution.

5.2 Operational Workflow, Personnel Flow, and Containment Control Strategy

Current pharmaceutical manufacturing practices emphasize comprehensive contamination control strategies that address facility design, material flow, and personnel movement in an integrated manner. As operations scale with increased personnel movement, material transfers, batch changeovers, and shift transitions, structured entry and exit pathways become increasingly valuable.

Airlocks can support defined personnel and material pathways, reduce unnecessary disturbances between rooms, and may simplify documentation of facility controls within a formal contamination control strategy (CCS). Their value in this context is often operational as much as it is containment driven. Implementation should nonetheless be justified through facility-specific risk assessment rather than treated as a universal requirement.

5.3 Pressure Cascade Integrity and Classified Area Integration

Where downflow booths are located within classified production rooms or areas with defined pressure cascades, airlocks can serve as transitional buffer spaces that help maintain stable room pressure relationships during door openings or personnel movement. In such layouts, MALs or PALs may form a functional part of the facility's pressure cascade architecture.

It is important to note that the effectiveness of these features is dependent on the overall HVAC design and facility airflow architecture.

Where air cleanliness within the booth is a specific requirement, a positively pressurized airlock supplying HEPA-filtered make-up air may be warranted to maintain stable conditions at the booth interface. In such configurations, the airlock should meet at least ISO Class 7 requirements in accordance with ISO 14644-1, with interlocked doors to prevent simultaneous opening toward the booth and the external environment.

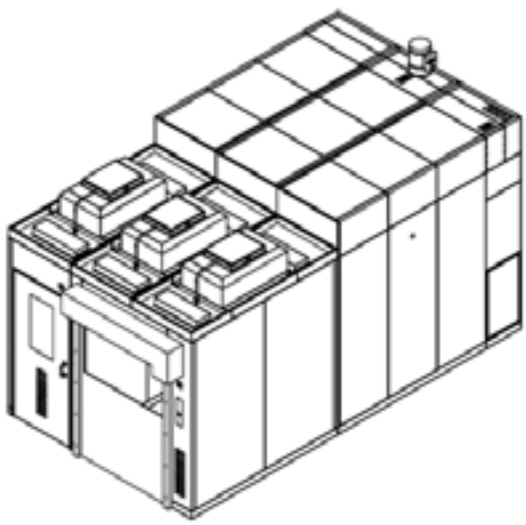

Figure 3. Esco's DFB with MAL roll up door and PAL swing door

When appropriately integrated into facility design, MALs and PALs may provide several operational advantages:

Potential Benefit	Operational Consideration
Pressure buffering	Helps reduce transient pressure fluctuations during door operation
Controlled personnel movement	Supports defined gowning and entry procedures
Structured material transfer	Enables staged movement of materials between rooms
Environmental segregation	Assists separation of areas with different classifications
Operational consistency	Standardizes workflow in higher-traffic environments

These benefits depend heavily on proper integration with the facility's HVAC system and operational procedures.

6. Situations Where Airlocks May Not Be Required

Not all downflow booth installations require additional airlock infrastructure.

In many applications, standard open-front booths provide adequate dust control and operator protection without the need for dedicated MAL or PAL spaces.

Examples may include:

- Booths installed in non-classified or uncontrolled warehouse environments
- Operations with relatively low personnel and material traffic
- Processes involving materials with higher occupational exposure limits
- Facilities without defined room pressure cascades
- Operations where a formal CCS does not mandate defined pressure differentials at the booth interface

In these situations, implementing additional lock spaces may provide limited operational benefit and should be evaluated carefully against cost, footprint, and workflow considerations.

7. Decision Framework: Evaluating the Need for Airlocks

Rather than applying fixed rules, facilities are encouraged to evaluate airlock implementation through a structured risk assessment considering factors such as:

- Product potency and occupational exposure limits
- Facility classification and pressure cascade requirements
- Personnel and material traffic frequency
- Integration with contamination control strategies
- Overall facility layout and HVAC architecture

The case for airlocks is strongest where multiple factors overlap, particularly where high operational traffic coincides with the handling of potent compounds, as the combined effect of frequent airflow disturbance and elevated exposure risk makes controlled transition spaces most defensible and operationally advantageous.

This risk-based position is reinforced by WHO guidance on HVAC systems for non-sterile pharmaceutical products, which explicitly recognizes the role of containment booths, MALs, and PALs in weighing and dispensing area design. The guidance recommends that such areas maintain at least the same classification as other production areas where materials are exposed to the environment, supported by appropriate pressure differentials, dust control, and air exchange rates. Notably, it frames MAL and PAL implementation as a conditional consideration, applicable "where needed", and acknowledges that alternative means such as closed systems and pressure gradients may equally serve the containment objective. This positions airlocks as one well-recognized option within a broader engineering toolkit as facility-specific approach for containment.

8. Conclusion

The integration of MAL/PAL into downflow booth installations is not a universal requirement, but rather a facility-specific decision informed by a structured assessment of product potency, facility classification, operational workflow, and contamination control obligations. As discussed throughout this paper, airlocks can provide meaningful value in environments where potent compounds are handled, where pressure cascade integrity must be maintained, or where structured personnel and material pathways are needed to support a formal contamination control strategy. In these contexts, MALs and PALs contribute to a more robust and defensible containment architecture, not by replacing sound booth design and operational discipline, but by enhancing the consistency and resilience of the overall system.

Facilities considering airlock integration are encouraged to evaluate their need through the risk-based framework outlined in this paper, weighing the operational and containment benefits against practical considerations such as facility footprint, cost, and workflow complexity. Where the driving factors are absent or well-managed through existing controls, standard open-front downflow booth configurations may remain entirely appropriate. Ultimately, the goal is not to maximize engineering complexity, but to ensure that the chosen containment strategy is proportionate, well-integrated, and fit for the specific facility and process it serves.

9. Practical Implementation: Configurable Downflow Booth Solutions

The integration of downflow booths within pharmaceutical facilities often requires adaptation to site-specific layouts, operational workflows, and containment strategies. As discussed throughout this paper, the decision to incorporate features such as Material Access Locks (MALs) or Personnel Access Locks (PALs) is typically driven by facility airflow architecture, operational throughput, and risk-based contamination control considerations.

To support these varying requirements, downflow booth systems can be configured to accommodate different facility integration strategies.

Esco Lifesciences designs and manufactures downflow booth systems that can be adapted to project-specific requirements, including configurations with integrated material or personnel access locks when required by facility design.

Available configuration options may include:

- Integration of Material Access Locks (MALs) and Personnel Access Locks (PALs)
- Selection of various door types, including hinged, sliding, or interlocked doors
- Customized booth dimensions and layout configurations to accommodate different room footprints
- Multiple materials of construction depending on process and cleaning requirements
- Wide selection of control systems and monitoring options for airflow management and facility integration
- Adaptation to different HVAC strategies and airflow architectures

These configurable features allow downflow booth systems to be incorporated into a broader containment strategy that aligns with facility-specific operational and environmental requirements.

Facilities evaluating powder handling solutions may benefit from considering how equipment configuration, facility airflow design, and operational workflow interact within a comprehensive contamination control strategy.

Additional information on configurable downflow booth systems and containment equipment can be found at:

- Esco Pharma Website
- Esco Downflow Booth - G2
- Esco Downflow Booth - G3

Reference

European Commission. EudraLex — The Rules Governing Medicinal Products in the European Union, Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Part I, Chapter 5: Production. Brussels: Health and Consumers Directorate-General; 2014 [revised, came into operation 1 March 2015]

World Health Organization. Annex 2: Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. Part 2: Interpretation of guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products. In: WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-third report. Geneva: WHO; 2019. (WHO Technical Report Series, No. 1019).