Issue 141
April 2024
Division of Technical Resources
Office of Research Facilities
National Institutes of Health
Technical News BULLETIN

Effective Pass-Through Chamber Design – Part 1

Introduction

Biomedical research facilities, cleanrooms, and similar facilities commonly have workflows which require efficient and reliable means for transferring materials between areas of varying levels of control. This article will explore some of the essential planning, design, and specification considerations for effective pass-through chamber (PTC) design. Next month, the second part of this series will address considerations for effective PTC commissioning, qualification, and validation.

Design Considerations

Before beginning to specify, design, or select a system, an integrated project team (IPT) should explore PTC planning and design options and address several considerations, including:

Context: While all PTCs facilitate the transfer of material between differing zones of control, it is essential to understand the implications of whether the material is transiting between differing levels of security (maintaining chain of custody, etc.), ISO classification, safety, risk, etc. This article series focuses on the higher criticality/risk end of this spectrum.

Regulatory Requirements: Critical PTCs are often used in pharmacy, radiopharmacy, and biologics processing facilities and their support spaces. These spaces are governed by various application-specific United States Pharmacopeia General Chapters, though many reference back to USP General Chapter <797> Pharmaceutical Processing – Sterile Preparations. In cleanrooms, ISO 14644 will apply. Other regulations specific to the PTC instance may also apply.

Capacities: The IPT must understand the throughput/cycle rate demanded by the workflow, whether the PTC will be operated with a cart/shelf retained inside, the size and weight of carts and/or other equipment or supplies to be passed through the PTC, etc. The orientation, net clear opening, clear door operation area, and types of doors selected must be considered in the context of the workflow and space constraints.

Administrative vs. Engineering Controls: Administrative controls are work practices which reduce the frequency, severity, or impact of risks and may include means for enhancing the detection of a risk occurrence. Examples of administrative controls include cleaning of the PTC, wipe down of materials entering/leaving the chamber, etc. Engineering controls remove or reduce a risk and may include door gasketing to ensure the chamber reliably prevents lower classified air from leaking through the chamber to the better classified air on the opposite side of the PTC; using HEPA- or ULPA-filtered supply air to dilute any particles in the air within the chamber; providing exhaust air to remove suspended particles from the chamber; etc. The need for and types of controls should be identified individually for each PTC until the net risk is reduced to below the risk tolerance of the authority having jurisdiction (AHJ) or designated responsible individual (this could be the end user, an infection control or safety officer, etc.).

Material Selection: The material selection is crucial for ensuring cleanability, maintainability, resistance to degradation when exposed to the cleaning chemicals identified in the administrative controls, and performance when exposed to any of the biological agents that the PTC can be expected to be exposed to during its service life. Type 304 stainless steel with a D-finish is a typical selection for the PTC carcass and doors because of its corrosion-resistance, hardness, non-porosity, and limited reactivity, but certain applications may require better grades of stainless steel or other materials.

Airflow and Recovery: A PTC should be considered part of both the architectural and HVAC environments. The chamber sits between differing classifications, which may include different environmental parameters, particularly absolute pressures, and ISO classifications. As such, like with an airlock or anteroom, it is critical to understand the differential pressures to each of the connected spaces (non-pressurized, bubble, cascade, or sink) to ensure directional airflow and to minimize turbulent flow, thereby minimizing the ingress of contaminants into better classified areas. Note that the time it takes to equilibrate pressures and purge the chamber volume with new, filtered supply air may significantly impact the throughput of the PTC. For chambers provided with supply and/or exhaust air (i.e., active PTCs), the small chamber volume often means that the airside controls will be operated at inefficiently low volumes. Where multiple PTCs are on the same air valve, the ability to individually trim each chamber becomes essential.

Design Features: After considering the various design features and acceptance criteria described above, the architects and engineers on the ITP can now focus on the specifications. All PTCs should be designed for cleanability, meaning they should be crack/crevice free with smooth, rounded corners and similar features. Generally, all critical PTCs should feature an interlocking system to prevent the simultaneous opening of both doors – this system may be manual or electronic (the latter may facilitate timed recovery periods to signal to the user that it is safe to open the chamber door). If using HEPA- or ULPA-filtered air, it is useful to provide challenge ports for filter certification, which would typically be installed on the dirty side of the PTC. Maintainability is also a key consideration, including ensuring door gaskets are readily replaceable and specifying reliable hinges and latching hardware. Ensure that any potentially hazardous PTC exhausts are managed appropriately to protect personnel. In critical applications, ensure that PTC electronics, fans, etc., are connected to emergency power.

Conclusion

The design and specification of PTCs requires the risk-based consideration of various administrative and engineering controls to deliver an appropriate set of requirements to the construction contractor, manufacturer, and the commissioning, qualification, and validation contractors. The IPT is responsible for bringing these elements together to provide an appropriate PTC system that promotes patient safety while meeting the user's needs for throughput safe working conditions and reliable research outcomes.