Issue 142
May 2024
Division of Technical Resources
Office of Research Facilities
National Institutes of Health
Technical News BULLETIN

Effective Pass-Through Chamber Commissioning, Qualification, and Validation – Part 2

Introduction

The first article in this series explored essential planning, design, and specification considerations for effective pass-through chamber (PTC) design for biomedical facilities. During the design phase, the Integrated Project Team (IPT) should develop the acceptance criteria for the PTC and the test protocols which will be executed. This article address considerations for effective PTC commissioning (Cx), qualification (Qx), and validation (Vx), collectively referred to as CQV, which are essential for ensuring the PTCs are fit for their intended service at facility turnover.

Commissioning (Cx)

Commissioning refers to the systematic process of ensuring the PTC, as constructed and adjusted, functions according to design specifications. Cx begins during the design phase (i.e., Design Qualification, or DQ) and includes review of the design documents against the user's requirements to ensure that the information to be conveyed to the contractor, manufacturer, and CQV agent is consistent with the user's design intent. The contractor will furnish a manufacturer's submittal, including drawings, and product literature which must be reviewed to ensure conformance with the approved construction design documents.

For critical PTCs, the owner may include a Factory Acceptance Test (FAT) where the CQV agent travels to the factory to execute the FAT protocol. This demonstrates general conformance with the project requirements, though some testing, such as that which involving pressurization and airflows, may be limited at the factory. Typical FAT testing includes a visual inspection for assessing construction quality, a checklist of features and dimensions, a wipe test over all exposed surfaces to ensure there are no defects which might snag a glove or cleaning cloth, and possibly a soap bubble test to identify issues with door and glazing seals. The FAT results in a deficiency list for resolution before the units are shipped to the site. The Cx agent documents the installation process and any adjustments that need to be made to ensure the units are functioning properly, including troubleshooting as necessary.

Upon installation, a Site Acceptance Test (SAT) protocol may be executed to ensure the FAT-identified defects have been resolved and that the units have not been damaged during transit and installation. The Cx agent also documents the completion of all required facility operations and maintenance training. Cx of PTCs with supply air (SA), exhaust air (EA), or both can be a complex undertaking. Multiple active PTCs can be tied to the same air valve, which also provides airflow with the associated clean room. Each PTC is also provided with its own trimming damper to balance the airflow. Balancing the airflow to the active PTC can only be done with both PTC doors closed. The addition of active PTCs can extend the time and effort it takes to achieve airflow and pressure stability and successfully commission the space.

Qualification (Qx)

Qualification involves the systematic evaluation of Cx data to establish a documented record that the chamber consistently performs as intended. For PTCs used in pharmaceutical applications, qualification is broken into discrete sections, including:

- Installation Qualification (IQ): verifies that the PTC has been manufactured, installed, and configured according to the approved-for-construction design documents and any manufacturer's specifications or installation checklists.
- Operational Qualification (OQ): verifies that the PTC is functioning correctly and that the cleaning protocol can maintain the user's required cleanliness level. OQ also verifies airflow and ensures particles from the lower-classified side are prohibited from traversing the PTC to the better-classified side.
- Performance Qualification (PQ): verifies that the PTC is functioning consistently over time, at rest, and under simulated routine operations.

Validation (Vx)

Validation involves the evaluation of the data generated in Cx and IQ/OQ/PQ, ensuring the documentation is complete and conforms with Good Documentation Practice (GDP). Vx should also confirm the traceability of the features of the PTC as it was designed, manufactured, installed, commissioned, and qualified to fulfill the applicable regulatory, risk assessment, and user requirements. Please note that Qx and Vx are typical only in Aseptic Processing Facilities and are not typical of all active PTC installations.

Conclusion

Cx is indispensable for establishing the reliable function of PTCs in biomedical applications, while Qx and Vx are necessary in certain critical environments. Meticulous documentation and adherence to regulatory standards are key factors in ensuring that PTCs meet the rigorous demands that are put on them, contributing to the success and integrity of scientific endeavors.