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APF Pressurization Part I

Introduction

Aseptic Processing Facility (APF) room differential pressurization (dP) is critical for controlling the migration of contaminants. The air distribution systems in these facilities must be designed to attain a desirable pressure level within each room relative to all adjacent areas. Airlocks are a key factor in maintaining pressure differentials and the integrity of controlled spaces during entry and exit.

Space Layout

ISO 7 cleanrooms are designed with airlocks that help buffer the room from external pressures and control the migration of contaminants. If there is no airlock, room dP will drop to near zero when the door is opened.

There are three kinds of airlocks: cascading type (where air flows from high pressure spaces to lower pressure), bubble type (where air flows out to adjoining rooms) and sink type (where air flows in from adjacent areas). Cascading airlocks are used for entry to sterile non-hazardous rooms. Bubble type airlocks are used for entry to sterile hazardous rooms, or in biological processing rooms where viral vector manipulation is performed. Sink type airlocks are almost always used for exits from unidirectional sterile hazardous rooms.

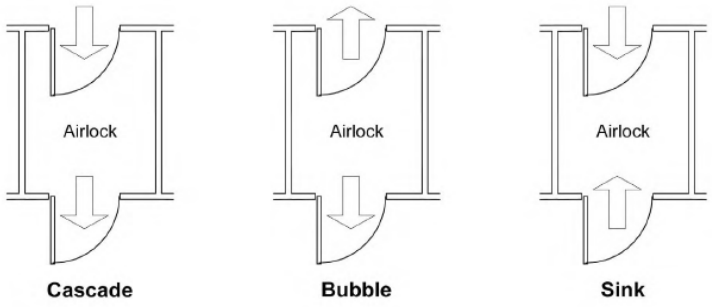

Figure 1: Airlock types

In a bidirectional layout arrangement (where entry and exit occur through a common anteroom), the airlock can be either cascading or bubble type, depending on the type of product – a facility handling hazardous products will use a bubble airlock, while one that handles non-hazardous products will use a cascading airlock.

Architectural Features

Architectural features also play a critical role when designing to maintain room pressurization and control the migration of contaminants. Wall and ceiling materials, door types, door gaskets, access doors, door gaps, and pass throughs all factor into the design of the pressurization system. There should be very minimal leakage from the walls, ceiling, and fixtures in ISO classified rooms, so all the air is transferred via door gaps. This helps control the amount and direction of air needed to maintain differential pressure.

Air Distribution Requirements

Each pressure control zone is provided with both pressure-independent supply air served from 100% outside air handlers and exhaust air terminal units connected to exhaust fans. This helps to maintain constant airflow at the terminals regardless of airflow or pressure changes in other spaces.

Differential Pressure Monitor (DPM)

Each classified space is required to have a DPM. The DPM can be mounted outside the entrance door to the room being monitored or placed in a central panel, so long as the panel location is in line of sight of the rooms being monitored.

The DPM also provides local and remote alarms when the pressure goes beyond adjustable thresholds and time durations. It is preferred that DPMs display the Environmental Monitoring System (EMS) pressure value, as the EMS is the validated system of record.

This article will continue next month with a further review of the control requirements to successfully maintain room pressure in APF facilities.