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Improved control of the pressure in a cleanroom environment

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Abstract

In order to protect cleanrooms from contamination from adjacent less clean spaces, the cleanroom must be built air tight and maintain an (over) pressure of sufficient magnitude and deviation. For this magnitude there are guidelines. However, there is a lack of guidelines for the required deviation of the pressure. As a result, an unstable pressure could result in an undefined air direction and increase the risk of contamination. This unstable pressure occurs especially during entering the cleanroom with an air tight cleanroom. In this paper the pressure and the entrance of the cleanroom are modeled in the SimuLink modeling environment. The model is verified and validated. The main problem addressed here is that the air tightness and the deviation of the pressure are in conflict with each other. It is concluded that the new proposed adjustment decreases the deviation of the pressure in the cleanroom and enhances the precision of control.

Keywords

cleanroom,
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1 Introduction

The International Organization of Standardization defines a cleanroom as a "room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary" (ISO 1999). To minimize the introduction of uncontrolled air supply with an undefined number of particles, the cleanroom is maintained at a higher pressure in order to protect the cleanroom from contamination from adjacent less clean spaces (ISO 2001). For this reason and the realization of the required higher static pressure, it is common practice to construct the cleanroom in an air tight manner. The pressure difference between the cleanroom and the adjacent less clean spaces should be of sufficient magnitude and deviation to prevent reversal of airflow direction from that intended (ISO 2001). Here the deviation is defined as the change of the pressure in the cleanroom as a result of a change of mass flow or conductance of the environment. The (recommend) magnitudes of this pressure difference are 5–20 Pa (ISO 2001) for cleanrooms in general, 10–15 Pa according to the Ad Hoc GMP Inspections Services Group (GMP 2003) for the manufacturing of sterile medicinal products and a minimum of 5 Pa (Walenkamp 2005) for an operation room in the Netherlands. However, there is a lack of guidelines for the required deviation of the static pressure, i.e., under which circumstances or disturbances it should be maintained. The main disturbance of the pressure is during entering and leaving the cleanroom. By opening the doors, the pressure differential changes, a reversal of the direction of the airflow is possible and contamination could enter the cleanroom. It is therefore necessary to achieve and maintain a stable pressure under all circumstances. To maintain the pressure differentials during entry and exit, airlocks are normally required (ISO 2001). It is not allowed to open both doors of the airlock simultaneously. For this reason, the airlock is often equipped with an interlock system. This ensures that

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