Smart Notes

How can the choice of orbital shaker affect GMP quality standards in your cleanroom laboratory?

The greatest source of particles in the cleanroom and, consequently, the greatest contributor of contamination, comes from the personnel working there. The second greatest source is the equipment. Poorly designed features can hugely contribute to passive particle dispersion through the air and to active generation of new airborne particles during normal equipment operation, affecting the air purity and quality of your work.[1]

Since clearly defined rules emerged in 2016,[2] it is required that the cleanroom compatibility of equipment be assessed under normal operating conditions, by measuring the concentration of airborne particles released. To make sure that your orbital shaker meets the requirements of particle control, look for documentation proving that the design has been tested for use in cleanrooms according to the ISO 14644 and VDI 2083 standards.[3,4]

The standards emphasize optimal equipment design, which results in low particle emission for minimal contribution to the whole room particle count. For an orbital shaker, this means that the design is purposely built using materials such as stainless steel, which have lower electrostatic properties so that particles don't stick. In contrast, materials including plated, painted, or coated steel can shed particles and are burdensome to clean and sterilize.[2,5] Furthermore, shakers should be designed with a sealed electronic system and fewer components including seals or ball screws, which will reduce active generation of new airborne particles. Finally, a shaker should be easy to clean and disinfect for a cleanroom setting.

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What should you consider when choosing a cleanroom compatible orbital shaker?

Look for documented proof of testing

Not all orbital shakers can be used in an ISO Class 5 cleanroom. Therefore, proof of testing documenting such compatibility is required, in accordance with ISO 14644 and VDI 2083.[3,4] The standard outline sets the rules for the various cleanroom aspects, including equipment suitability. Since the cleanroom is designed to continuously maintain a required maximum particle count – within strict limits, it is critical to assess the compatibility of equipment used.

In such a test, a visual inspection is performed, and then the device is tested for the number of particles emitted with sizes ≥ 0.1 µm per cubic meter (m^3) of air. The results of the emission test are evaluated in line with maximum allowable concentrations (particle/m^3 of air) for particles sizes ranging from 0.1 µm to 5.0 µm. With this information, compatibility per ISO class (ranging from 1 to 9) can be established (Figure 1).[2]

Look for a design promoting cleanability

The manufacturer of a cleanroom-compatible shaker should be able to provide recommendations for cleaning and disinfection. The shaker features, such as a sealed electronic system and an easily disassembled platform and clamps, should promote regular cleaning and disinfection to aid in better particle and contamination control. The hidden areas where particles are more likely to settle and accumulate, like under the platform, should be easily accessible for cleaning, minimising any possibility for particles and contamination to hide. Thus, look for a platform and clamps which are easy to remove. Infrequent or delayed cleaning and disinfection can negatively affect your work and impact the reproducibility of your results (Figure 2).

Summary

Choose a cleanroom-compatible orbital shaker that offers proof of emission testing and key features that enhance particle and contamination control.

Figure 1: In accordance with the ISO 14644-1 and VDI 2083 standards, an orbital shaker should be tested for particle emission from all suspected particle hot spots, like edges, seals and openings. [3,4]

Figure 2: Rounded corners, flask clamps with one screw or less, easily removable platforms, sealed electronics systems and a touchscreen user interface all facilitate easy, frequent cleaning to minimize particle emission and prevent contamination.

References

1. CLEANROOM TECHNOLOGY. Design of cleanroom equipment to achieve particle control [online]. London: Cleanroom Technology, 2017 [viewed 29 May 2020]. Available from: https://www.cleanroomtechnology.com/news/article_page/Design_of_cleanroom_equipment_to_achieve_particle_control/132329
2. ISO 14644-14:2016 Cleanrooms and associated controlled environments. Assessment of suitability for use of equipment by airborne particle concentration, International Standards Organisation, Geneva Switzerland.
3. VDI 2083 Part 9.1 Cleanroom technology - Compatibility with required cleanliness and surface cleanliness; December 2006.
4. DIN EN ISO 14644-1 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (DIN EN ISO 14644-1:2015)
5. Whyte W, Agricola K, Derks M. Clean Air and Containment Review. 24, 4–9, 2015.

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