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CLEANROOM GOWNING

Lighthouse Worldwide Solutions

Overview

Properly donning cleanroom apparel is an essential prerequisite for ensuring the integrity of controlled environments. Much like a delicate dance, it demands precision, attention to detail, and adherence to specific guidelines tailored to the unique requirements of each cleanroom facility. The stringency of these procedures varies in accordance with the facility's ISO cleanroom classification, underlining the importance of a customized approach. While there is no one-size-fits-all gowning procedure, there are fundamental steps that remain consistent.

What Are the Regulatory Requirements?

Although there are no federal regulations for sterile cleanroom garments used in the pharmaceutical industry, guidance for the industry is available from The Institute of Environmental Sciences and Technology (IEST), which publishes a recommended practice IEST-RP-CC003.3, "Garment Considerations for Cleanrooms and Other Controlled Environments."
Regulatory guidelines advising on the suitability of garments for the various cleanroom classifications include:

- EudraLex, Volume 43
- International Standard ISO 14644-4:2001(E) Annex A4
- Rules and Guidance for Pharmaceutical Manufacturers and Distributors, Annex 15
- 21 CFR 211 (b)6

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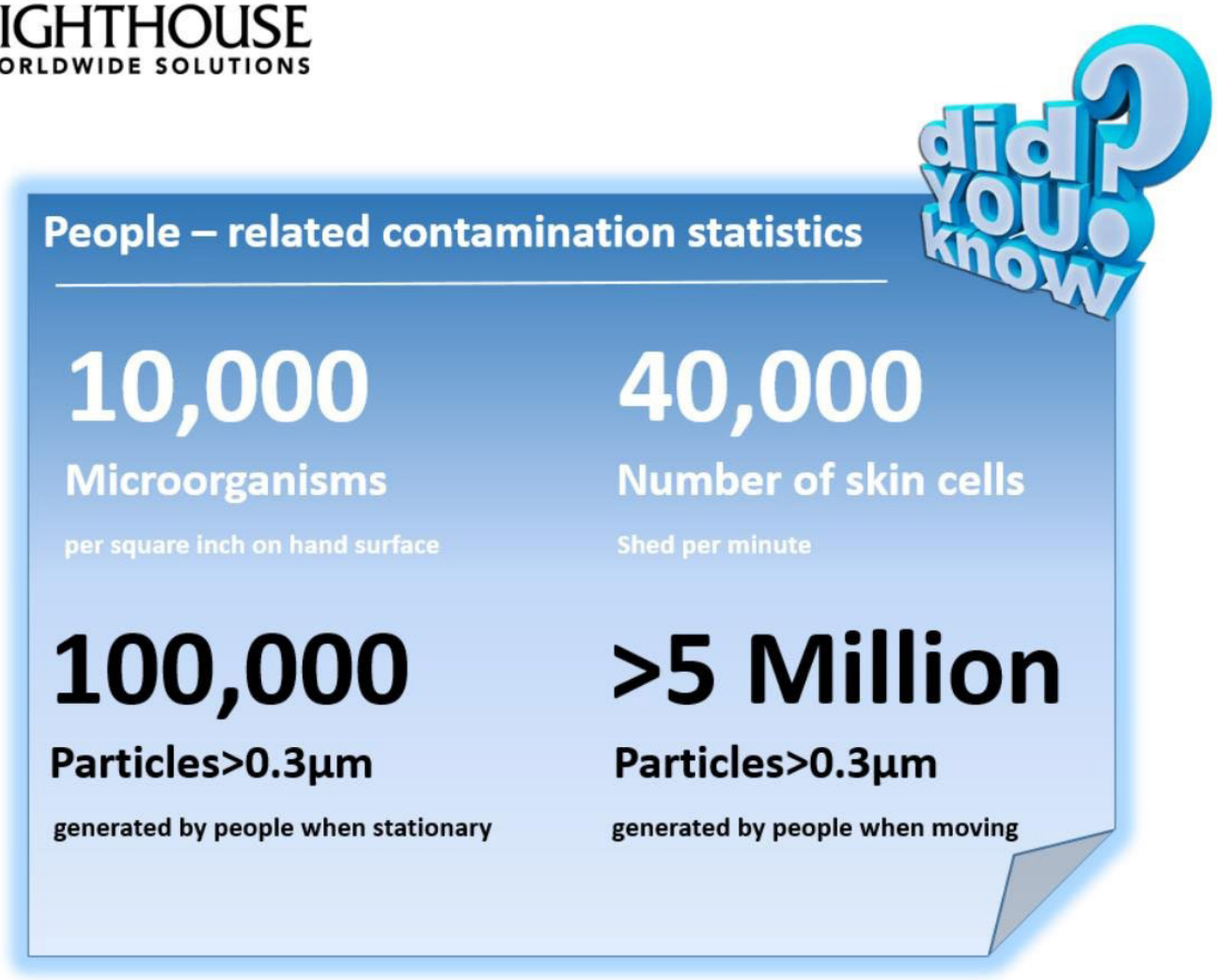

The Human Impact

The biggest source of contaminants, by far, is human personnel. Unlike inanimate objects, human beings cannot be sterilised. Even when sitting perfectly still, they continuously spread around dead skin, hairs, microbes, and other pollutants.

Therefore, it is necessary for cleanroom personnel to wear specially designed clothing that can serve two functions:

1. preventing natural human contaminants from infecting the environment
2. protecting the wearer from hazards in the immediate area

Gowning Considerations

Like so many beneficial accessories, cleanroom apparel must be used correctly to obtain its full range of benefits. It requires a precise sequence of actions to ensure that the clothes do not become contaminated. Exactly how this sequence goes depends on the needs of the particular facility, including its ISO cleanroom classification. There is no standardized gowning procedure that applies to every environment.

In general, though, the gowning procedure involves thoroughly cleaning exposed skin (including the removal of cosmetics) and any clothing that will be worn underneath the cleanroom apparel. Jewelry must be removed or at least completely covered. Personnel must be able to don their clothing while preventing it from touching the ground, where it can pick up contaminants, at any time during the process. Many cleanrooms place a sticky mat before the entrance to remove dirt and other contaminants from the shoes of personnel.

While cleanroom garments can either be disposable or reusable, according to industry analysts, most sterile facilities will opt for disposable garments due to contamination concerns relating to reusable garments returned from laundering facilities. In some companies, disposables may be used at some locations and reusables at others. This can depend on the classes of the various cleanrooms at different locations.

Most operators in a sterile cleanroom environment in the pharmaceutical industry will wear three to four disposable suits in a day, each suit being worn for two to three hours at a time. Often, cleanroom protocol dictates that garment changes must be made each time the cleanroom is

re-entered. Once discarded, these suits can be incinerated, or they can be re-purposed through a garment recovery service that will take the used garments and sell them back into non-sterile applications.

When a cleanroom operator is due to start any aseptic gowning process, it is paramount that the correct size garment (coverall, hood and overboot) is available on each occasion. This removes any potential for the user to take a poorly fitting garment that could increase the risk of contaminating the clean environment. The management and control of all aseptic gowning inventories, therefore, must commence well before the operator dons a cleanroom garment. Among the aspects to be considered and managed are:

- The supply, storage and rotation of stock
- The availability of the correct size and type of gowns at all times, at all storage locations
- Effective and 'in date' operator training, i.e. operatives must be assessed regularly
- A defined process of how to handle damaged garments and a documented maximum number of washing cycles and repairs.

Gowning Training

Training should be provided using visual means, i.e. via video technology, as this not only demonstrates and standardises the correct aseptic gowning technique, but a recording of the operator's gowning technique (particularly for higher classification areas) can also be used to offer particular feedback. Beer6 states that the use of video replay enables operators and the trainer to identify improper or subtle flaws in technique. This can have particular impact when used in conjunction with microbial monitoring – for example, when a trainee has their aseptic gowning technique assessed using contact plates. If a count on these plates comes back high it is useful to review this data in conjunction with the videotape to see if it corresponds to poor gowning technique, enabling the trainee to see exactly what aspects of the technique they need to work on.

Cleanroom Gowning Best Practices

Cleanroom gowning protocols differs depending on cleanroom class and application. In ISO Class 7 or ISO Class 8 cleanrooms, frocks are often acceptable. A cleanroom classified as ISO Class 5 or ISO Class 6 (or cleaner) requires cleanroom coveralls, along with hoods, gloves, and booties (shoe covers). For sterile processing, additional precaution is needed to assure that no sterile surfaces contact non-sterile surfaces during gowning, processing, or cleaning.

Cleanroom Gowning Procedure Checklist

1. Before entering gowning room taking at least three small steps with each foot; remove dirty sticky mat layer if needed.
2. Use a shoe brush cleaner
3. Don shoe cover booties
4. Don cleanroom bouffant
5. Wash hands thoroughly (use waterless alcohol solution for USP 797)
6. Put on cleanroom glove liners
7. Apply alcohol solution to outside of liners
8. Put on cleanroom gloves
9. Wash or apply alcohol solution to cleanroom gloves
10. Apply cleanroom bouffant (beard covers for those with facial hair)
11. Apply a freshly laundered cleanroom hood
12. Attach facemask
13. Apply coveralls, only touch the floor on the clean side of a gowning bench
14. Hoods are tucked inside of coveralls
15. Put on cleanroom booties
16. Put on cleanroom gloves
17. Ensure that booties and gloves overlap the coveralls
18. Wipedown the gowning bench with a clean, sterile wiper
19. Use cleanroom mirror for self-check