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CLEANROOM TECHNIC SPECIAL

Not only the quality of garments but also the decision of buying or leasing and the logistics services are essential for the selection

THREE, TWO, ONE … – CLEAN!

P+F Trend: Cleanroom Garments

Special requirements apply to the manufacture of sterile products and pharmaceuticals, in order to eliminate the risk of contamination with micro-organisms and particles or cross-contamination with another product. Even if cleanroom technology is still a niche technology: the importance of controlling contamination in the pharmaceutical cleanroom is rapidly increasing.

In the manufacture of sterile products and pharmaceuticals, much depends on the expertise, training and behaviour of the personnel. The optimum and validated condition of the rooms, of the media supply systems employed and of other equipment such as sterilizers, autoclaves, insulators, filling and washing machines, must also be ensured. Also, the sterility of the production objects, the cleanroom garment, the primary package or the product utilized is of central importance.
This also results in higher standards for the cleaning and sterilization technology in the pharmaceutical industry. And the customers themselves in the pharmaceutical industry today also require top quality, reliability, service and innovative solutions for their systems. Yet competition is by no means determined by the price. What counts are the supplier's experience and innovative spirit in developing the products.

People are the primary source of contamination

People can still be considered the primary source of contamination in the cleanroom. Cleanroom clothing is therefore more than just clothing. And cleanroom clothing is not all the same, as Carsten Moschner of Dastex cleanroom accessories explains:
"In choosing the right cleanroom clothing, the concepts for the clothing and the cleanroom have to be well-coordinated. When we create a clothing concept together with the customer, we therefore look at the entire cleanroom as a separate system. The focus of our considerations is what the clothing has to be able to do and what not."
What makes more sense: to lease or buy clothing? Disposable or reusable clothing? "The answer is determined by the requirements of the user and the sensitivity of the products. But also by the conditions in the cleanroom itself and in the changing rooms," Carsten Moschner describes the expectations of his customers.

At the present time it is by no means standard practice to use antimicrobially treated cleanroom textiles, according to the cleanroom specialist from Muggensturm, in the vicinity of Baden-Baden. But the operators of microbiologically monitored areas in the pharmaceutical, food and cosmetics industries are relying more and more on a biocidal treatment of clothing. Antimicrobial agents prevent the colonization of micro-organisms in the fabric from the very start. State-of-the-art technology permanently bonds the biocidal substance with the polyester of the cleanroom textile. The biocide is polymerized with the textile, which makes emissions or migration from the fabric impossible.
The manufacturers of these textiles see clear advantages over the classical application of chemicals to textiles by means of “impregnation”. For example, the quality of the textile is not affected in any way, thus increasing its durability and wear resistance. The permanent bond also prevents the biocide from being dissolved or washed out. However, experts disagree as to whether such antimicrobial treatment is actually necessary. Carsten Moschner considers the treatment useful – but only in situations where it is really essential. “Of course, it seems reasonable at first glance to treat cleanroom clothing for sterile production areas to prevent increased microbial growth. In the GMP-compliant operation of production facilities, i.e. in Class A/B, this is frequently not necessary, since outer clothing for the cleanroom generally is worn no more than two to four hours, during which no significant microbial growth takes place in the fabrics.”
He also considers such fabrics superfluous in the C-zone, where cleanroom clothing is worn approximately eight hours a day. “For protection against mechanical penetration, as in the case of repeatedly sitting down on a chair, such a biocidal textile may be quite useful.” Wherever cleanroom clothing is worn several days in a row, such as in the microbiologically monitored areas of the food industry, Moschner advocates the use of such treatment for cleanroom clothing. “There, it is unquestionably necessary and desirable!”
Carsten Moschner considers a procedure known as double-gloving to be commonly practiced meanwhile. “First, you put on the first pair of gloves, before putting on the remaining protective clothing. This is followed by a second pair of gloves, thus ensuring that your hands are absolutely clean.” Where it is necessary, this procedure should be standard practice, according to Moschner.

Balance between technical performance, wearing comfort and economy

It would be fatal if the cleanroom clothing itself were to become a source of particles. Modern textiles and weaving processes achieve top results in the areas of particle retention capability, wear resistance and wearing comfort. Strong polyester threads made of continuous fibres have proven the test of time.
The dominant characteristic of modern cleanroom clothing is still the particle filtration of the fabric. This is what determines the garment’s suitability for a particular purity class. “The pore size of the fabric, the decisive factor here, can be affected nowadays by the woven construction of the fabrics and the use of special threads. Also, the processing of the seams or special processes used to treat the fabric after weaving have a direct effect on the particle retention capability of this special clothing,” *Christiane Schwittay of basan in Kriftel* explains. In the process known as calendering, for example, a fabric is inserted between two rollers heated to a high temperature, resulting in reduction or even closing of the pores.
In the field of cleanroom clothing, however, what is technically possible is not always ideal. Among the wearers of cleanroom clothing, there is a demand for comfortable cuts made of high-quality, lightweight and breathable materials. And fashion is also a factor of no small significance. “This balance between the optimum technical performance of cleanroom clothing and wearing comfort can be achieved only with high-quality threads and special fabric constructions. These are also responsible for the durability of the fabric, thus resulting in an optimum cost-effectiveness ratio,” *Christiane Schwittay* explains.

A well-thought-out clothing concept for the cleanroom also takes into account the intermediate clothing. On the one hand, this additional factor also means additional costs for the operator. According to Schwittay, however, the advantage is clear: “Cleanroom-suitable

intermediate clothing reduces the potential for particles beneath the cleanroom outer clothing by more than half!" The use of 100% polyester fabrics is again ideal here. "We use a breathable, high-quality micro fibre polyester material with a carbon content, which was specially developed for use in intermediate clothing in combination with a corresponding cleanroom overall," Schwittay explains.

Even if they do not manufacture the clothing themselves, cleanroom trading firms such as Basan have to be able to respond quickly and flexibly to very specific customer requirements. Christiane Schwittay: "Today, extreme flexibility is a must not only in the construction, but also in the furnishing of cleanrooms. When a cleanroom starts operation and the orders for equipment are late, the operator cannot wait weeks for his clothing on top of everything else. This means that all standard cuts and designs must be available within a matter of days or weeks." Since products for this sector are increasingly being manufactured abroad, fast delivery times are not to be taken for granted, if only due to the distances involved. Not to mention the fact that ever more customers also expect cleanroom clothing to be available in a choice of colours or even reflect the corporate design.

It is in the nature of things that the conditioning and decontamination of cleanroom clothing is an extremely complex process, which can hardly be managed by the operator of a cleanroom, also in terms of the documentation requirements. Specialized firms such as Initial Textile Service, with their Micronclean division, offer a comprehensive textile service for cleanroom clothing, supplying businesses and research facilities with cleanroom clothing based on a leasing system. The advantage for the lessee: no high initial costs and no need to establish a logistics department with transport, storage and collection containers. The customer also receives the necessary advice for the selection and manufacture of the cleanroom clothing and always receives the right quantity of clothing at the right time.

In such a model, the lessor is fully responsible for logistics and decontamination. "It is important that the effectiveness of the decontamination process be examined on a regular basis," according to Wilfried Sontheimer of Micronclean. Another aspect the customer no longer has to worry about is documentation: "Using a barcode system we can document the time and method used for decontamination of each individual garment. We can trace the number of processing cycles and the corresponding ambient conditions. Our validated processes guarantee the absolutely reliable supply of cleanroom clothing," Wilfried Sontheimer emphasizes. Such leasing agreements generally have a term of three years.

Disposable clothing as an alternative

That seems like a lot of trouble to go to for overalls, hoods, etc. Perhaps disposable clothing is an alternative, at least in individual, special areas of application?
"Protective clothing with limited duration of use" is less expensive in any case. After all, it eliminates the rather substantial costs for decontamination, in addition to the entire logistical expense, from inventory to transport and storage. "Of course, it always depends on what the clothing is needed for," according to Alexandra Kovacs, Field Market Manager at VWR International, a trading firm in Darmstadt. "Disposable clothing is often sufficient for visitors, cleaning and maintenance personnel or the operation of smaller cleanrooms." Depending on the model and design, such protective clothing could even be used in Class 100 cleanrooms, according to Alexandra Kovacs. However, she cautions, its use in higher classes frequently requires pre-cleaning. If necessary, disposable clothing can also be sterilized.
The cleanroom textiles – both disposable and reusable – are made up of more than just applied materials science and innovative know-how on wear resistance and particle retention capability. Because in addition to the inward and outward protective effect, good electrostatic conductivity of cleanroom clothing is also extremely important. It is common knowledge that synthetic materials easily build up an electrostatic charge, and to prevent a big bang in explosive areas – including many cleanrooms, not only due to the accumulation of dust, but

also due to cleaners and disinfectants containing solvents – modern cleanroom clothing is also designed with antistatic properties. For example, so-called bi-component fibres of carbon and polyester are woven into the polyester fabrics of reusable clothing. “Disposable clothing is also treated accordingly,” according to Alexandra Kovacs. “The Tyvek fibre for this protective clothing is provided on both sides with a full-surface antistatic coating during the manufacturing process.”

The choice of a disinfectant for the pharmaceutical cleanroom

What properties should a disinfectant for the pharmaceutical cleanroom have? In order to effectively prevent microbiological contamination, a disinfectant has to be effective and powerful – and it has to be sterile. This is also the requirement of the current GMP standards: “Disinfectants used in A and B cleanrooms must be sterile.”

The validation of disinfectants and disinfection logs in regulated areas can be extremely time-consuming and cost-intensive, according to Karen Rossington of Shield Medicare. If, in the event of an audit or a required change in the disinfection log, one first has to request all the batch documentation, product specifications, sterility and radiation certificates, validation data and effectiveness tests, this is certain to result in costly production downtimes. Rossington knows that the user is highly dependent on an efficient supplier with comprehensive technical support.

“In the certification process for a disinfection log for a pharmaceutical cleanroom, the auditor will probably request the validation results. In this case, much depends on the quality of the manufacturer and his ability to quickly adapt to constantly changing directives.” As a further criteria for selecting a suitable disinfectant and disinfection concept Rossington recommends to always first conduct extensive monitoring and also to precisely analyse the standard work processes. This is standard procedure nowadays and enables the timely creation of a suitable and effective concept in cooperation with the supplier. Effective trending is also necessary. Such a risk-based look toward the future can anticipate future challenges to be faced by the disinfection concept.

Generally, says the specialist for disinfection concepts, the disinfectant should be available in various formats. Only then can the disinfection concept be implemented in all areas of the respective cleanroom or even throughout the enterprise. In large environments, concentrates are frequently used with a mopping or atomization system; for critical areas, on the other hand, ready-to-use sprays or impregnated wipers are necessary. But the expert from Shield Medicare urges caution: some disinfectants, especially sporicides, can still cause corrosive damage to expensive cleanroom equipment. Other agents leave residue on work surfaces and equipment, requiring an additional cleaning step. A cleaning concept is economical if it can be implemented with a minimum number of steps, preferably in all cleanrooms throughout the enterprise and by all work teams. All of this, according to Rossington, must be considered in a modern disinfection concept and in a validation program.
“The cleaning method itself also affects the effectiveness of the disinfectant,” Dr. Howard Siegerman, Director Technology at ITW Texwipe, emphasizes. “For disinfecting surfaces or cleaning insulators, wiping is superior to simple spraying, because the contamination is mechanically removed, in addition. Also, intensive contact is established between the disinfectant and the surface.” Howard Siegerman recommends that modern wipers and mops used in cleanrooms and for cleaning insulators should be made completely of polyester. “Polyester is the only fabric with the necessary properties, such as purity, minimum number of particles and fibres, and maximum durability combined with minimum extractable residue,” Siegerman continues. “In addition, such a polyester fabric is autoclavable and can be sterilized with gamma rays to the Sterility Assurance Level of 10^{-6}.” This means that after sterilization, only one mop in a million may be non-sterile.

Summary: Cleanroom clothing is becoming more advanced, in terms of both technology and wearing comfort. Cleanroom-suitable intermediate clothing is making major progress in this respect. Individual service concepts provide comprehensive advice, rental clothing, decontamination and documentation so that the cleanroom personnel can concentrate on their actual work. Antimicrobial textiles are interesting especially for microbiologically monitored areas, such as the food, pharmaceutical and cosmetics industries.
Cleaning and disinfection concepts are becoming more streamlined and more efficient. Trending should help to recognize future challenges early on in order to overcome them. Competition is defined not by the price, but by the technical support of the supplier, his efficiency and experience.

Facts for decision-makers

For users

- Clothing and the cleanroom concept are well-coordinated.
- In choosing the optimum cleanroom clothing, the requirements are decisive, not what is technically possible.
- Antimicrobial cleanroom clothing is being used increasingly in microbiologically monitored areas.
- With respect to sterilization and cleaning in the cleanroom, much depends on the careful selection of the supplier.
- Modern sterilization and cleaning concepts follow a risk-based approach with trending.