Cleanroom garments in the 21st century

Business as usual or are changes to be expected?

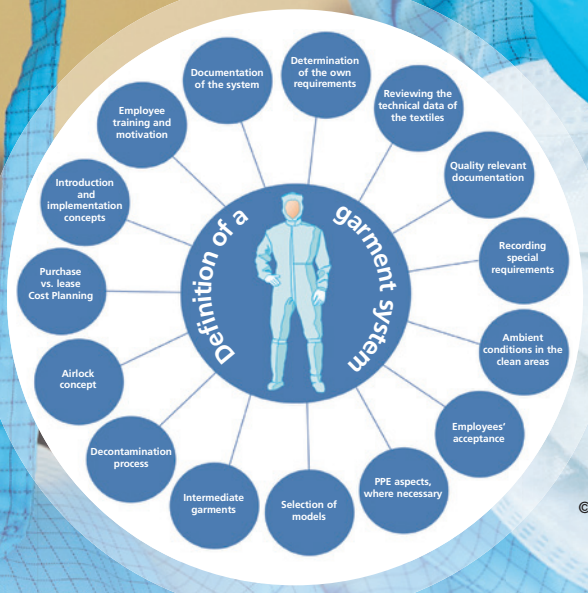

Fig. 1:
Different factors influencing the definition process: Cleanroom garment system
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Carsten Moschner

Humans are still one of the biggest sources of contamination in controlled areas, both in terms of particulate as in terms of microbial contaminations. The tables give an indication of the range – depending on the degree of movement and the garment system – that can be expected. Consequently, cleanroom garments as the only filters between man and product continue to play a significant protection function for the processes in the cleanroom.

Though, more and more stringent requirements have recently been made on a cleanroom garment concept. Especially with regard to qualification / validation or documentation of duration of wearing, wearing cycles, etc. The term „quality of a garment system" is increasingly being questioned and scrutinised by inspection authorities. In the following, these tendencies, among others, will be discussed in more detail.

General requirements

In the course of a definition process to determine a cleanroom garment system, it often surprises decision-makers that – contrary to original expectations – complex interrelationships emerge. Defining cleanroom garments solely in terms of filtration properties and the required cleanliness class (A, B, C or D areas) is too short-sighted.

Technical requirements, for example, have to be reconciled with employee concerns. Increasingly, requirements from the area of personal protective equipment (PPE) must also be taken into account in individual process steps. Changing processes, transition areas between the different hygiene zones and the respective airlock concepts must be coordinated. The decontamination process, the associated logistics and the costs must also be considered.

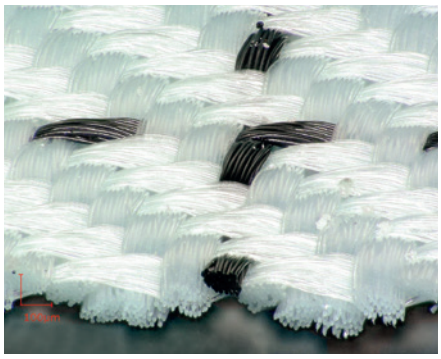
Fig. 1 gives a rough overview of which factors directly and indirectly influence the definition process towards a clothing concept.

After the most important aspects and requirements for a garment system have been gathered in a first step, it is necessary to review the technical data provided for the proposed textiles. At the same time, it is also necessary to weigh up which of these properties are relevant for one's own process and which can be neglected if necessary.

The most important criteria include:

- **Retention capacity against**
  - airborne particles (diffusion behaviour)
  - mechanically transported particles (migration behaviour)
  - microbial contamination
- **air permeability (taking into account the pump effect)**
- **wearing comfort (haptics and breathability)**
- **electrostatic behaviour**
- **abrasion resistance/roughening (ageing phenomena)**
  - especially in connection with the decontamination process and the resulting number of maximum wearing cycles
- **sterilisability, if applicable**

Cleanroom garments in daily use



Cleanroom fabric (3/2 twill weave) in new condition © Dastex

At the international level, there are still no binding regulations for the criteria listed above, so decision-makers must not only question the source of the respective data, but also the test method and its practical relevance. Certainly, from the user's point of view, it is also of interest to know whether the data describes the new condition of a cleanroom textile or (which would certainly be desirable) values that can be expected in the typical state of use – after, for example, 50 wearing cycles. From a quality perspective, the reproducibility or re-qualification of such data are further aspects that should not be neglected. Inspectors are increasingly focusing on this area.

Cleanroom garments with double protective function

In the opposite direction, cleanroom suitable garment systems are required increasingly to have protective functions. Both the product/process and, to the same extent, the people working in the process must be protected, for example in the production of highly potent active ingredients or HPAIs for short. In these cases, the cleanroom garments should also be certified with regard to the prescribed PPE properties. In the case of reusable garments that are regularly reprocessed (decontaminated), the PPE specifications cannot be implemented without further ado. The most important question here is how often a garment that has been cleaned several times can be used without hesitation is basically impossible to answer or to certify accordingly. Nevertheless, if a reusable solution is offered, it is advisable to clarify the question of „how often" in particular.

If a reusable garment system is ruled out due to the relevant PPE requirements, an appropriately certified disposable solution is recommended. In this case, however, users should be aware that not all garment variants based on a disposable material are suitable for use in controlled conditions. Even assuming that the filtration performance of the disposable material is sufficiently high, „self-contamination", i.e. the risk of contamination from the garment itself, is often a criterion for exclusion. Normally, disposable garments are produced in most cases in simple industrial environments. Thus, particulate and microbial contamination, which occurs in a wide range during the manufacturing process of the disposable material and during the production of the garment models, gets onto the respective disposable garments. Without proper post-cleaning (decontamination), these contaminants on the disposable garments can be introduced unhindered into the controlled areas. A study from 2006 impressively demonstrated, with the help of the „Body-Box method", the great risk of contamination that can emanate from disposable garments that have not been properly cleaned. At the same time, however, the study also showed that disposable garments decontaminated in accordance with cleanroom requirements can compete with reusable solutions.

Guidelines and directives

From the user's point of view, it is currently still very difficult to find binding specifications or guideline values in corresponding regulations. At ISO level (ISO 14644), there are only a few general formulations on the subject of cleanroom clothing in ISO 14644 – Part 5, and GMP guidelines also offer little concrete information on what „cleanroom garment" should fulfil.

Since 2016, at least in German-speaking countries, a reference work has been available in the form of VDI Guideline 2083, Part 9.2, which provides users with practical decision-making aids. Particularly in the annexes to the guideline, great importance is given to assigning concrete values to these properties as recommendations, in addition to the descriptions and explanations of the various characteristics of cleanroom textiles. What is a good retention capacity or what is a good wearing comfort are only two examples from the guideline. The fact that the required air cleanliness class (according to ISO 14644-1) can only be a component of the general requirement profile, that there can be no „ISO-5 garment" or similar or no „A/B overall", are further important core statements from the new VDI guideline.

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Qualification of cleanroom garments using the Body-Box method © Dastex

What is particularly important?

A key topic in many audits is the proof by the operator/user of the assurance that the defined cleanroom clothing meets the specified expectations accordingly. It is no longer sufficient to submit a simple manufacturer's data sheet with information on technical properties such as retention capacity, air permeability, surface resistance, etc., which in some cases does not even list the measurement methods used as a basis.

Even the information often provided by cleanroom laundries on so-called residual contamination (i.e. how many particles are still on the cleanroom garment after cleaning) is at best only a small part of the documentation required by the inspectors.

Rather, the current audits are about how the cleanroom operator ensures in his own daily operations that the garments fulfil their function. What relevant data was used to make a decision on a particular garment system? How were these verified and how are they continuously monitored? There is an increased emphasis on ensuring that the results and measurements presented relate to the user's particular processes.

Theoretical statements that are not directly related to the processes on site have recently been questioned in some audits. What is required is meaningful information on the relevant properties (first and foremost, of course, the protective function towards the product/process) of the defined garment system, taking into account the conditions of use at the user's site.

Presumably, the increased inspections and enquiries on the subject of „durability of the cleanroom clothing used" have their origin, among other things, in the fact that these garments were used in other sites for an excessively long time and without further thought. In some cases, users were unable to provide the inspection authorities with well-founded information on wearing cycles, i.e. how often the garments had already been worn, washed and, if necessary, sterilised. Or the garments were used much more often than recommended in the relevant literature.

However, cleanroom garments cannot be used indefinitely often. They are subject to mechanical wear and tear, especially when the garments are sterilised. The wearing time per use is also limited. Users should therefore define maximum wearing times and maximum wearing cycles and verify these specifications with appropriate validation documentation. Possible questions from inspectors on this can then be answered with appropriate justification.

The importance of cleanroom compatible undergarments

In recent years, there has been an increasing tendency to pay more and more attention to the garments worn directly under the cleanroom garments.

The most important reasons for this are certainly the following findings:

- With the help of cleanroom suitable undergarments or undergarments, the risk of contamination is considerably reduced in direct comparison to simple cotton-based undergarments.
  This applies to particulate contamination as well as microbial contamination. Studies show that the risk of contamination is reduced by more than 50% in some cases.
- The wearing comfort of an overall garment system can be improved with some models and materials, and with it the employees' acceptance. Compromise solutions, also in terms of cleanroom garments, are easier to implement through the use of appropriately optimised undergarments.
- Cleanroom suitable undergarments, that have proven antimicrobial, not only reduce unpleasant odours, but also reduce the risk that germs can penetrate due to increased perspiration from the inside through the garments to the outside.

Cleanroom compatible undergarments – functionality meets design!
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Garments	Particles ≥ 0.5 µm		Particles ≥ 1 µm		Particles ≥ 5 µm	
	standing	walking	standing	walking	standing	walking
Cotton jogging suit	873,304	34,955,780	657,312	25,114,780	17,077	448,638
Lab coat	331,742	6,304,946	130,901	2,506,495	9,795	101,172
Overall	28,827	106,328	10,396	32,135	331	851

Table 1: Measured (airborne) particles during different movement states. The test person wore different garment combinations.

Garments	Germs ≥ 1 µm		Germs ≥ 5 µm		Germs ≥ 10 µm	
	standing	walking	standing	walking	standing	walking
Cotton jogging suit	1,379	17,893	758	9,368	557	7,367
Lab coat	623	12,496	373	6,474	86	4,847
Overall	18	263	2	36	2	10

Table 2: Measured (airborne) germs during different movement states. The test person wore different garment combinations.

Designs in transition

Contrary to the general tendency to standardise everything if possible in order to save costs, process-adapted – and in some cases individualised – garment concepts proved to be the better and often also the more cost-effective solution in a large number of clothing projects. In some cases, dressing procedures could be simplified and thus deviations/inconsistencies in monitoring reduced, or different garment components, such as hood + face mask + protective goggles, were optimally matched to each other. Often it was sufficient to change only individual elements of a clothing system to meet new requirements. A special protective device in the chest – abdomen area, special sleeve protectors that are impermeable even to alcohol-based disinfectants, additional press-stud features that prevent the overboots from slipping down or specially placed press-studs that simplify the dressing procedure are typical examples.

Training and more

Finally, some general recommendations on how to handle a garment concept: When introducing or changing a garment concept, it is advisable to inform the employees at an early stage about what is being introduced or changed and why such a change is necessary.

Examples of a possible implementation, which have already proven successful in practice, are on-site information events with the employees concerned and with the help of external experts or posters, as well as other visualisation aids that explain the changes (and reinforce them with easily comprehensible facts).

Regular trainings that address „things on the site" in addition to general training content (such as hygiene behaviour and the like) are another important component of a good garment concept. Mistakes and anomalies can be discussed and debated in such training sessions, as can possible suggestions for improvement. The correct handling of the high-quality cleanroom garments as well as correct dressing should also be integrated into the regular trainings. Here, too, it is sometimes advisable to involve an external instructor into such a training event.

Article published (in German)
ReinRaumTechnik 1/2019

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