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UNDERGARMENTS

Arthur Lettinga
Product Manager West-Europe
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Introduction

Cleanrooms are being built to protect products from any form of contamination which could harm the product directly or indirectly, sooner as expected in its lifetime. When these batches become contaminated, then this would end up in a recall, business could be shutdown, potential claims could follow, and thus a total business could collapse.

Therefore, those are the reasons why particular companies whether you in pharmaceutical,
life sciences, microelectronics industry, have a cleanroom classification that fits to their operations in order to deliver an end product of outstanding quality meeting the requirements.
Especially within ISO 5/6 (Class A/B) classifications, undergarments is an important part of the choice of your cleanroom clothing.

Undergarments can be seen as a pre-filter that reduces particle dispersion by as much as 90% (source: Inner garments and filtration efficiency, Royal University of Stockholm, Sweden).
With the use of undergarments as an additional barrier, you form more security for your products and/or for your employees, which by definition makes your process even better secured.

If polyester garments are being compared to cotton clothing, a 1,000 times fewer particles of 0.3 µm than cotton is being noticed (source: IEST –RP-CC003.4). This is an enormous difference, which truly contributes to improved contamination control.

As the human is the biggest source of contamination inside a cleanroom, contamination prevention with most impact lies in the correct material, gowning, and behaviour.

This article will focus on undergarments as this has been outlined in the new Annex 1, implementation date August 2023, where the statement is to have dedicated undergarments in the facility.

Cleanroom undergarments

There are still a variety of companies who are operating in a cleanroom and their operators wear their own streetwear underneath the coverall.

This streetwear is usually made of cotton and it is a fabric which sheds a lot of particles which could negatively impact the cleanroom environment and the product(s) in the cleanroom.

As written in the introduction, it is about protecting the environment and the products that one is working with, and it has been established that people are the most crucial factor in exposing particles to the environment. The more filters you could apply, the more protection your environment will get and the less contamination risk you take. This is the overarching goal and the right set of undergarments will contribute to this massively.

Of course, this is one of the reasons why it is so firmly stated in the new Annex 1 that these undergarments are so critical.
Also, by not even be very precise on what to choose, they still put strong emphasizes onto ''garments that are not presenting a risk to processes …''.
This is in its generality, such a powerful sentence.

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The Annex 1 states the following:

> 7.13 i. Grade B (including access / interventions into grade A): appropriate garments that are dedicated for use under a sterilised suit should be worn before gowning (refer to paragraph 7.14). Appropriately sterilised, non-powdered, rubber or plastic gloves should be worn while donning the sterilised garments. Sterile headgear should enclose all hair (including facial hair) and where separate from the rest of the gown, it should be tucked into the neck of the sterile suit. .....

> 7.14 Cleanroom gowning should be performed in change rooms of an appropriate cleanliness grade to ensure gown cleanliness is maintained. Outdoor clothing including socks (other than personal underwear) should not be brought into changing rooms leading directly to grade B and C areas. Single or two-piece facility trouser suits, covering the full length of the arms and the legs, and facility socks covering the feet, should be worn before entry to change rooms for grades B and C. Facility suits and socks should not present a risk of contamination to the gowning area or processes.

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In essence, this would be the recommendation in terms of undergarments in order to be ready for the new implemented Annex 1:

- Cleanroom suitable garment which does not lint or shed particles.
- Cleanroom suitable garment that retains particles from the operator
- Comfort of employees is important to prevent errors during production.
- Ask your supplier to provide data-driven certificates to prove minimal particle shedding
- Test the chosen fabrics/models in your facility to get commitment from the team

A fair question to ask is how to know if a cleanroom garment is suitable for your cleanroom environment? Basically, it starts with documents of proving that the actual offered garment is doing what it promises. And would this solution be an overkill or a good fit for the environment?

It is important to know what requirements are needed in order to produce according the standards. If this means that you could wear a poly/cotton undergarment than this would be fine.

If we drill down undergarments on material into three sections and you would add the amount of particle shedding per minute to it, then this would be the overview:

	Cotton	Polyester/cotton	Micropolyester
Particles/min	1.000.000	350.000	10-200

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Cotton is a natural fibre which is short. It breaks easily and leaves the fabric potentially into your product. Moreover, the particle of 5µ is capable of carrying bacteria (CFU) and because of these reasons, cotton is often not used anymore in cleanrooms.

Synthetic fibres are long (endless) fibres which do not break and leave any fibres.

Microfibers are usually very fine fibres of less than 1 dtex (1g/10.000 m). Usually, these synthetic fabrics are very static (Polyester), but by adding carbon to it the garment become antistatic which improves the comfort of the garment.

The recommended material for undergarments consists of 100% synthetic fibres like polyester, which are usually microfibres with or without antistatic properties. These garments are worn under the cleanroom coveralls or cleanroom jackets to reduce particle emission during work. It is also becoming increasingly popular to wear undergarments as classic workwear. In almost all cases, these garments are also 100% synthetic fibre.

When companies have their operations in ISO 7, 8 and in so-called Controlled not Classified environments (CNC), then these two-piece suits are usually named outer garments as they are the only product category they wear and thus in order to be warm and not seeing the contours of the full body these garments are thicker.

On the other hand, undergarments are way thinner, because they are going underneath a coverall, which gives the operator more space to move and it creates comfort.

Polyester is a fiber which has a great track record on particle exposure, what are the main characteristics of this yarn:

- Continuous filament yarn | low particle emission
- Lightweight, soft, and breathable material
- Fabric wickers moisture away from the body, keeps the body dry and gives cooling effect
- Stain-resistant
- Colour-fastness
- Oeko-tex certified | no skin irritation

Conductive fibers:

- Reduced ESD effects by making use of all conductive yarns throughout the garment to ensure there is no potential difference between garment system and objects as long as the person is grounded.

Antistatic fibers:

- Improved comfort due to no build up on energy into the garment

Antibacterial finish options:

- No microbial or fungi growth

It is very important to weigh all the above mentioned factors and decide together with the operators, after testing, what is the best suitable option for your operations to protect the product and environment and to work comfortably.
Of course, this should be selected which fits the application area and the classification area but also taking comfort into consideration.

The right set of undergarments can reduce the particle emission by as much as 90% (source: Inner garments and filtration efficiency, Royal University of Stockholm, Sweden).
To have as indication what the particle emission is while executing the below mentioned activities:

Particle emission

Activity	Particles	Description
	100.000	Remain motionless (standing or sitting)
	500.000	Movement of hands, underarms, neck and head
	1.000.000	Movement of hand, arms, torso, neck, head and legs (not walking)
	2.500.000	From standing to sitting and vice versa
	5.000.000 7.500.000 10.000.000	Slowly walking Walking Running

This proves that particle emissions by human bodies are enormous and can impact your process massively.
Therefore, it is not a surprise that studies show that the right garments are decreasing
the particle emission tremendously. Elis Cleanroom has set up a test with several undergarments to check on particle emission and CFU.

Undergarments test

Scope

The goal of the undergarment test is to compare several undergarments with each other and the impact of street wear on particle emission inside a body box.

In this test the following eight combinations have been identified:

1. Street wear
2. Street wear + coverall
3. Undergarment
4. Undergarment + coverall
5. Undergarment
6. Undergarment + coverall
7. Antibacterial undergarment
8. Antibacterial undergarment + coverall

Methodology

To determine the particle emission a body box is been used according to the IEST-RP-CC-003.5 in which the following formula has been used to determine the actual particle emission:

Particles (D-value)

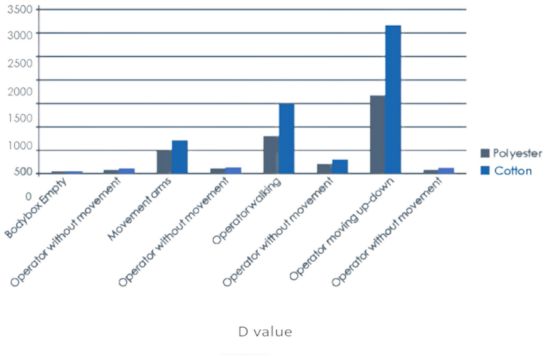
: Average dispersion rate, particles /min
: Sum of particle counts for same apparel set
: Total number of 1 min test period = 11

The motion of movement during the whole test run of a body box is specified in the IEST-RP-CC-003.5:

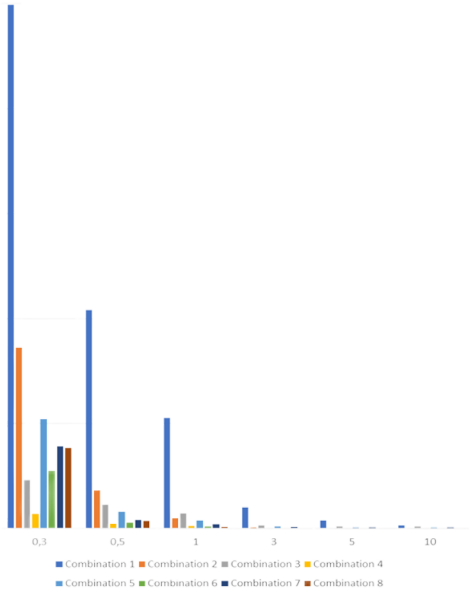
- Extend both arms in front of the shoulders at shoulder height for 5 min. to beat of a metronome at 60 beats/min.
- Stand still 1 min.
- Walk in place for 5 min. moving right hand to left shoulder and left hand to right shoulder
- Stand still 1 min.
- Perform three deep knee bends
- Stand still 1 min.

Hereunder an example of a body box test using the described methodology. The results are real data and compares polyester to cotton fabric.

Polyester and cotton undergarment body box test (particles 0,5 µm)



Results



Conclusion

The overall results of the body box testing (as seen on page 9) , shows directly a tremendous difference between combination 1 (full streetwear) , combination 2 (cleanroom coverall with underneath streetwear) and the rest of the cleanroom gowned test combinations.

Wearing streetwear in a cleanroom environment does have a significant negative impact on the particle emission in a cleanroom. Knowing that for a grade A or ISO 5 class cleanroom the maximum amount of particles per cubic meter is 3.520 of 0,5 µm. It seems that wearing a cleanroom coverall with streetwear underneath almost reaches this goal, considering the outcome of combination 2 (streetwear + cleanroom coverall).

A body box result is also been affected by the specific human being inside, which means that figures give different results when this test is been executed by another person. Moreover, having actual street wear in the gowning area before entering a cleanroom gives already so many particle emission (see combination 1), which will be ultimately brought into the cleanroom anyhow when utilizing garment combination 2.

The new revised Annex 1 wants to control contamination as much as possible and therefore forcing companies towards dedicated undergarments for changing rooms leading into grade C and B will give enough slack by staying within the actual permitted particles per cubic meter as stated in the ISO 14644-1, whether it be person A or person B.

From combination 3 and onwards it can be concluded that there is enough margin to stay within this permitted particle exposure and thus, dedicated undergarments makes a difference. The cleanroom undergarment made of polyester is acting as a pre-filter, whereas adding a cleanroom coverall, which can be considered as the main filter, brings even better results in terms of particle retention. This will ultimately lead to an improved level of contamination control.

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Important to understand is that all garments will release particles, but it should stay within specification as mentioned in the IEST-RP-CC-003.5. The body box test methodology explained on page 8 and 9 is basically also stipulating that behavior in cleanrooms, even though you wear the right set of cleanroom garments, is utterly important in relation to particle emission inside
a cleanroom environment. Thus, not only the right set of cleanroom garments gives you carte blanche inside cleanroom environments.

Considering the results of the test in terms of particle emission it is understandable that the revision of the Annex 1 is now requiring dedicated use of undergarments for cleanroom environments leading up to GMP class A and B, because it will give more control on contamination by adding an extra filter between the environment and the human body, which inevitably is considered as the most contaminated source inside a cleanroom, and therefore brings contamination control to a next and safe level.

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