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6 Tips for Selecting Cleanroom Apparel

By Roberto Greselin, Kimberly-Clark Professional™ Global Scientific Business

To avoid contamination in the cleanroom, you have to manage its primary source: the presence of people.

Did you know that 70 to 80 percent of contamination events are linked to the presence of people?[1]

That's a pretty stark statistic. But there are ways to minimise the risk. One of the most effective is to purchase sterile cleanroom apparel that protects the environment from viable particles and non-viable particles.

The right apparel is critical to reducing contamination risk. When choosing apparel for your cleanroom, be sure to take the recently published EU GMP Annex I updates[2] into account. These more stringent guidelines can be addressed by selecting well-designed, sterile single-use cleanroom apparel.

Here are six tips to keep in mind before selecting cleanroom apparel:

1. Understand the advantages of single-use garments.

Sterile single-use garments, such as Kimtech™ A5 Apparel, are engineered to reduce contamination risk and offer significantly higher Bacterial Filtration Efficiency (BFE) ratings and Particle Filtration Efficiency (PFE) ratings.

2. Look for sterility and packaging integrity.

(Annex I – 7.11) Kimtech™ A5 Sterile Cleanroom Apparel is the only solution on the market that is vacuum-packed. This not only ensures the sterility of the apparel but also acts as a visual sterility breach indicator, so you can be assured that Kimtech™ A5 Apparel is sterile when you use it.

3. Select apparel that is appropriate for the process and protects the product from contamination.

(ANNEX I – 7.13i) Kimtech™ A5 Sterile Cleanroom Apparel is certified as Class 1 for particle release (Helmke Drum Test) with 96% BFE and 94% Particle Filtration Efficiency (PFE).
(ANNEX 1 - 7.10) Proprietary CLEAN-DON™ technology makes it easy to adopt proper gowning procedures and minimises the risk of contamination during the donning process.

4. Select garments for Grades A/B that are folded and packed to minimise contact with the outer surface when gowning.

(ANNEX I – 7.13i) Kimtech™ A5 Apparel is uniquely configured with inside-out folding and built-in snaps that automatically release as the garment is put on, lowering the risk of it touching the floor. A blue line indicator along the inside of the garment guides the operator throughout the donning process and helps them avoid touching the outside of the garment.

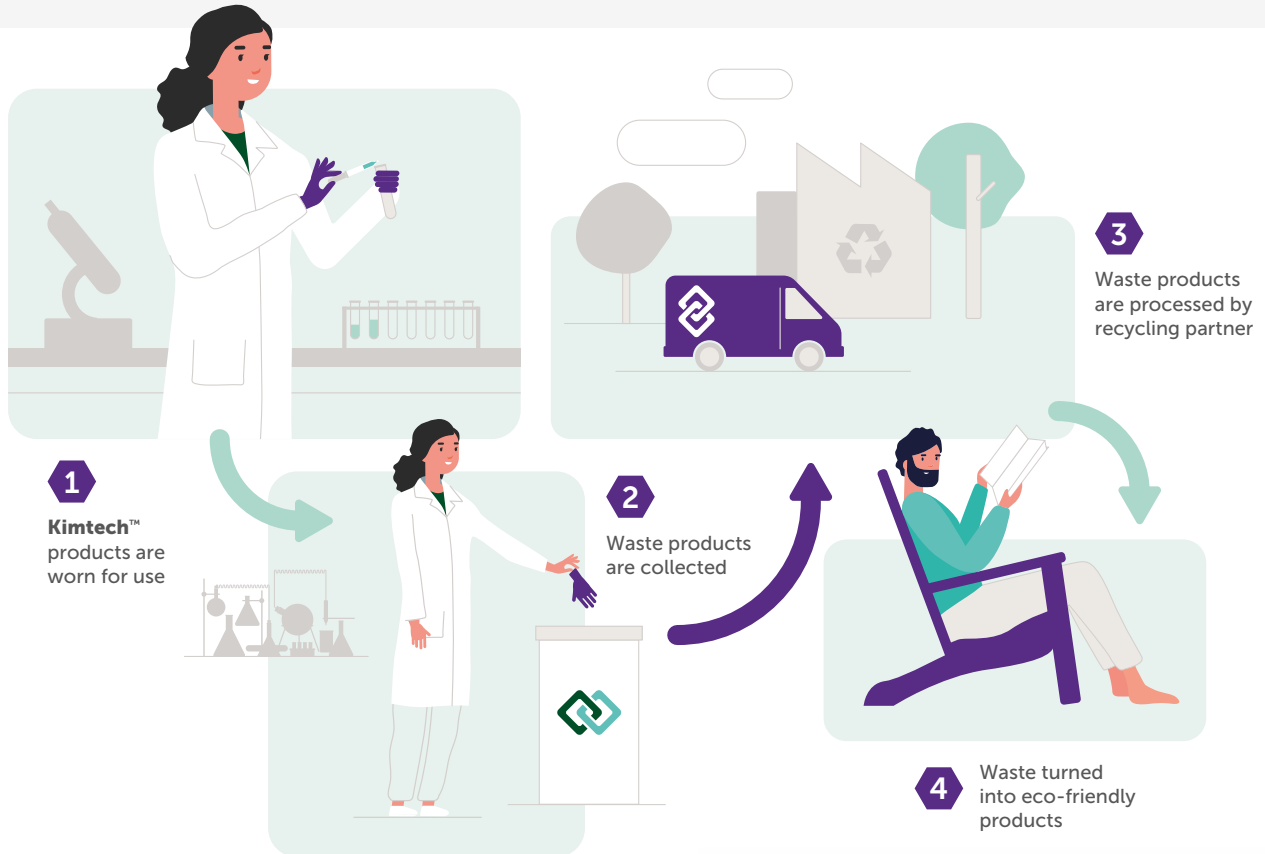[1] Ginette Collazo. "Reducing Human Error on the Manufacturing Floor." MasterControl, 2010.
[2] Based on the final revision of the EU GMP Annex 1, Manufacture of Sterile Medicinal Products, published by the European Commission on 22nd August 2022. Annex 1 is coming into operation in August 2023.

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5. Look for a base construction material that maintains ideal body conditions.

(ANNEX I – 7.13i) Kimtech™ A5 Apparel features a Spunbond/Meltblown/ Spunbond (SMS) fabric that provides strength, cloth-like comfort, and a strong barrier against both fine particles and bacteria while maximising airflow to keep the wearer cool and comfortable.

6. Take end-of-life considerations into account.

Kimtech™ Apparel is recyclable through The Right-Cycle™ Programme, a groundbreaking service that gives used single-use apparel and nitrile gloves a second life as flowerpots, lawn furniture, plastic shelving, and other products. The programme helps to divert waste from the landfill, providing cleanrooms with a sustainable apparel solution.

1 Kimtech™ products are worn for use

2 Waste products are collected

3 Waste products are processed by recycling partner

4 Waste turned into eco-friendly products

For the cleanroom industry contamination control is paramount. Performance failure of cleanroom garments can be a primary cause of alerts. To protect your process, you need to use the most reliable protective apparel available. The risks of contamination are simply too great. Not all garments perform equally when it comes to holding in particles and bacteria. That's why it's essential to choose a garment that offers consistent performance.

Roberto Greselin is EMEA Sales Manager with the Kimberly-Clark Professional™ Global Scientific Business.

For more information, visit **www.kimtech.eu**

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