Vaccine manufacturing

Protecting processes, products and operators with cleanroom clothing

Most vaccine manufacturing processes depend on quality control at every step. Failures can not only be costly and dangerous, they may also compromise compliance. Cleanroom garments are necessary to protect both processes and products from contamination, while also protecting operators from the hazardous substances involved in manufacturing. Find out how DuPont™ Tyvek® and Tyvek® IsoClean® coveralls and accessories can be beneficial in ensuring clean vaccine manufacture.

Vaccine manufacturing is of paramount importance during the COVID-19 pandemic, and it remains a fast-growing market sector. The manufacturing processes are complex and consist of many steps. To ensure the highest quality of the finished products, there are strict quality assurance procedures in place and protection must be ensured throughout all processes.

Operators represent the biggest source of contamination inside cleanrooms

Operator contamination can be reduced through training and impeccable hygiene, but it cannot be eliminated. An effective way of preventing particle contamination generated by operators in the cleanroom is the use of cleanroom garments. They are a barrier between the operator and the production environment.

The 2020 draft of the Good Manufacturing Practice (GMP) guidelines Annex 1 states that *'cleanroom garments should retain particulates shed by the body'.* Sufficient cleanroom clothing is therefore required at most steps of the vaccine manufacturing process to prevent contamination and ensure patient safety, as well as protect operators from hazardous substances.

For over 20 years, Tyvek® and Tyvek® IsoClean® garments have been an excellent choice for a variety of processes in vaccine manufacturing because of the outstanding fabric design and performance.

Advantages of Tyvek® fabric

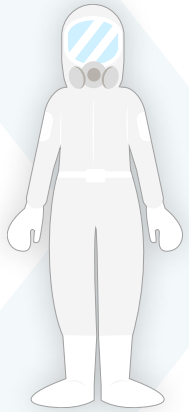
Tyvek® is made from high-density polyethylene filaments that are thermally bonded into a tight, homogeneous and soft fabric that is breathable and has low-linting and strong barrier properties. This unique combination of barrier protection and breathability makes Tyvek® suitable for the cleanroom environment and is GMP compliant. Additionally, Tyvek® fabric offers the operator protection against chemicals and biological substances.

Protection of the cleanroom and production

- Suitable for different cleanroom types (ISO Class 4-9 and GMP A/B, C/D)
- Barrier against contamination generated by the operators (bacterial filtration efficiency and particle filtration efficiency)
- Low particle release
- Also available in clean-processed & sterile options

Protection of the operator

- Repels aqueous liquids and liquid aerosols
- Provides biological protection
- Two-way barrier against particles
- Tear and abrasion resistant



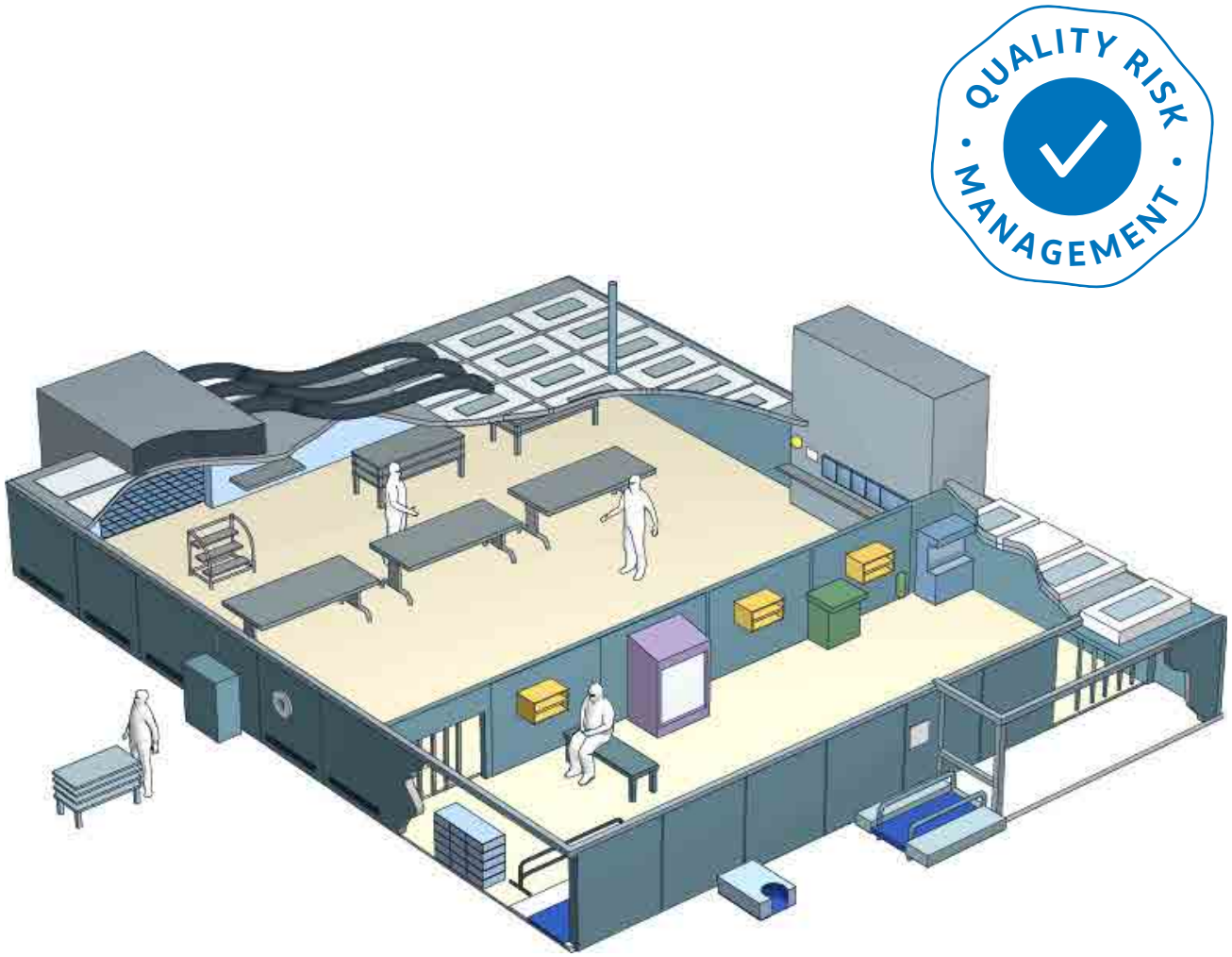
Comfort of the operator

- Lightweight and soft
- Breathable
- Coveralls designed for operator comfort
- Clear donning and doffing procedures

Compliance with QRM procedures and GMP Annex 1

GMP Annex 1 (2020 draft) anticipates that all pharmaceutical manufacturing activities will be governed by quality risk management (QRM) principles and documented in the contamination control strategy (CCS). This is a proactive approach and simply reacting to and correcting detected contamination will no longer be enough. Manufacturers will be expected to identify potential risks to quality, put in place technical and procedural means to control these risks and aim for continuous improvements.

Cleanroom garment systems are a critical part of sterile and aseptic manufacturing and must also be managed under QRM principles to ensure GMP compliance and, ultimately, patient safety. Vaccine manufacturing involves a lot of manual interventions and there may be some risk to operators. It is a legal requirement to equip operators with appropriate PPE whenever there is a risk to their health and safety.



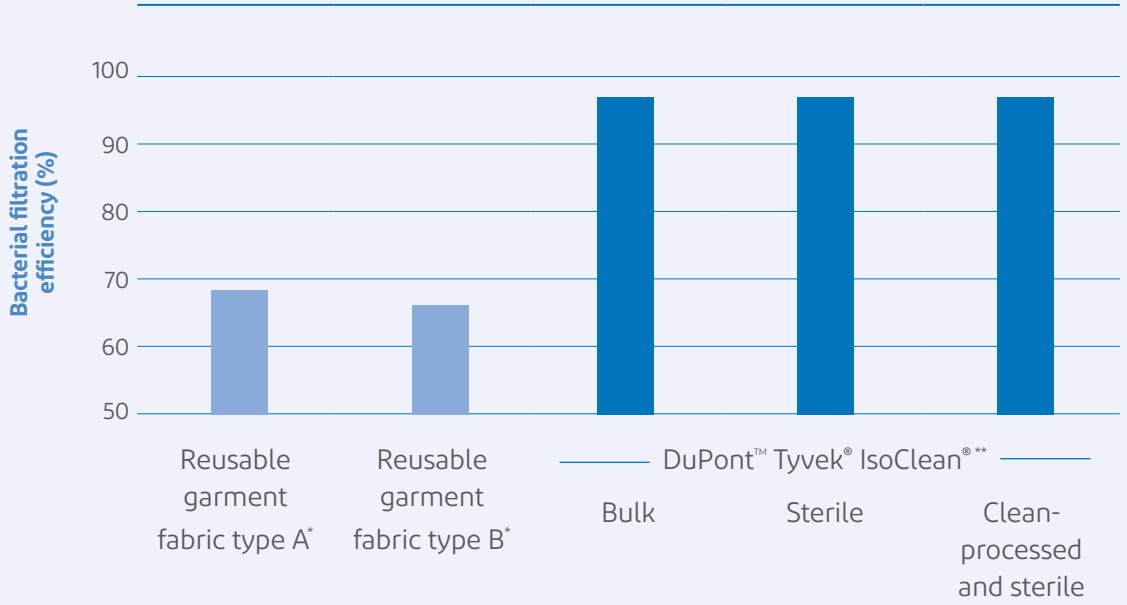
Consistent performance

Regulators expect vaccine manufacturers to keep their vaccines free from contaminants at all times. Control of the contamination risk linked to operators will rely on the barrier performance of cleanroom garments. Tyvek® IsoClean® sterile cleanroom garments make this control easier. Since garments are only used once, their Helmke drum, particle filtration efficiency and bacterial filtration efficiency performances are constant. This is not the case for reusable cleanroom garments that are used, washed, dried and sterilized multiple times. We have demonstrated in our study that the performance of reusable garments is significantly reduced by repeated laundering cycles. Please read the study here.

CHART 1

Average bacterial filtration efficiency (%)

Higher numbers indicate better filtration efficiency



For single-use garments, the impact of gamma radiation on the polymer only occurs one time, so the properties are consistent.

Average bacterial filtration efficiency of **reusable garments** is in a range of **64% to 69%** while average bacterial filtration efficiency of **Tyvek® IsoClean® single-use garments** is in a range of **98% to 99%**.

*Results average of 10 measurements per fabric type from "as-received" garments **Results as reported in SafeSPEC™

Peace of mind

Producing high-quality innovative vaccines is a difficult and complicated task, and the anticipated need for a QRM-based approach with a documented contamination control strategy will not make it any easier. As DuPont is the manufacturer of both the Tyvek® material and the finished clean and sterile Tyvek® IsoClean® cleanroom garments, we control the value chain and can provide test data and certificates (such as lot-based certificates of sterility, irradiation and compliance). This makes qualification and subsequent quality audits easier than with reusable cleanroom garments involving several value chain partners (PET filament manufacturer, fabric weaver, garment manufacturer, laundry, etc.). Also, the stock management of a single-use Tyvek® IsoClean® garment system is much easier than managing a reusable garment system (due to washing, sterilizing, disinfecting cycles, garment replacement or repairs, complex invoice checking, etc.).

Flexible single-use solution

The vaccine manufacturing companies are growing fast, and manufacturing contracts are rarely synchronized with the five-year leasing contracts of most laundries. Single-use coveralls made from Tyvek® can offer more production flexibility, speed up production, and do not require infrastructure or laundry processes. Inventories can be adjusted to meet production needs. Single-use garments offer maximum flexibility and process protection, and they are ideal for start-ups, small-batch production, single-use reactor production and production requiring frequent adaptation and changes. Additionally, Tyvek® & Tyvek® IsoClean® garments that have not been exposed to hazardous substances can be recycled in our Tyvek® Protective Apparel Recycling Program.

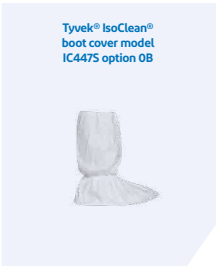
DuPont cleanroom clothing in vaccine manufacturing

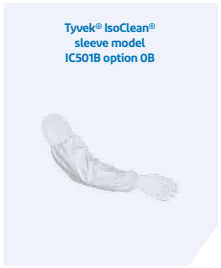
Non-sterile environments (vaccine manufacturing steps)

Click on the product to learn more

Vaccine manufacturing steps

Cleanroom type	Cleanroom clothing properties	Standards & features	Antigen production	Purification	Formulation	Fill and finish	DuPont solutions
Non-sterile environments	Cleanliness (Helmke Drum)	IEST-RP-CC003.4 Category I particle cleanliness (particles > 0.5 µm/minute)	Antigens are developed using raw materials such as proteins, viruses, bacteria, toxins, sugar, and nucleic acids.	Impurities are removed and concentrated through physical and chemical processes.			**Tyvek® IsoClean® and Tyvek® non-sterile garments and accessories** • Non-sterile • Helmke Drum Class I • Packed in a controlled environment (Tyvek® IsoClean® products) • Bacterial filtration efficiency (3.0 micron) of ~99% (typical result using ASTM F2101) (Tyvek® IsoClean® products)
	Chemical protection	(EU) 2016/425 Chemical protective clothing Cat. III, type 4, 5, and 6 (Tyvek® 600 and Tyvek® 800 products)					
	Biological protection	EN 14126 (Tyvek® 600 & Tyvek® 800 products)					





For more product details, visit **safespec.dupont.com**

DuPont cleanroom clothing in vaccine manufacturing

Sterile environments (vaccine manufacturing steps)

Click on the product to learn more

Vaccine manufacturing steps

Cleanroom type	Cleanroom clothing properties	Standards & features	Antigen production	Purification	Formulation	Fill and finish	DuPont solutions
Sterile environments	Sterility assurance level	ANSI/AAMI/ISO 11137 and AAMI TIR 33			Ingredients are combined, including active substance, adjuvant, preservatives, antibiotic, etc.	The vaccine is filled into a vial or syringe.	**Tyvek® IsoClean® clean-processed and sterile garments and accessories** • Clean-processed and sterilized by gamma irradiation to SAL of 10^{-6} (ISO 11137-1) • Helmke Drum Class 1 • Aseptically folded • Packed in a controlled environment • Bacterial filtration efficiency (3.0 micron) of ~98% (typical result using ASTM F2101)
	Cleanliness (Helmke Drum)	IEST-RP-CC003.4 Category I particle cleanliness (particles > 0.5 µm/ minute)					
	Bacterial filtration efficiency (3.0 micron)	ASTM F2101					
	Aseptic folding	To support aseptic gowning procedures in ISO Class 5 environments					
	Packaging system	Multilevel interior packaging features one or two polyethylene carton liners					

Tyvek® IsoClean® model IC253B option CS

Tyvek® IsoClean® boot cover model IC458B option CS

Tyvek® IsoClean® sleeve model IC501B option CS

Tyvek® IsoClean® hood with ties model IC668B option CS

Tyvek® IsoClean® frock with bound neck model IC264S option CS

Tyvek® IsoClean® coverall IC105S option CS with hood and overboots

For more product details, visit **safespec.dupont.com**

DuPont™ SafeSPEC™—we're here to help

Our powerful web-based tool can assist you with finding the appropriate DuPont garments for chemical, controlled environment, thermal and mechanical hazards.

Certified Industrial Hygienist team

A DuPont Certified Industrial Hygienist can conduct a job hazard assessment to help you determine the best DuPont garment for a specific hazard.

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