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 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 and protection must be assured 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 cleanoom: cleanroom garments. They are a barrier between the operator and the production environment.

The 2020 draft of the Good Manufacturing Practice guidelines (GMP) 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 DuPont™ Tyvek® fabric

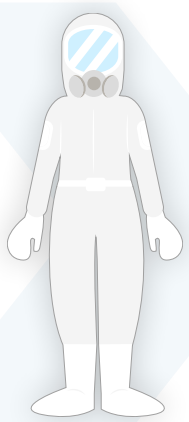
Tyvek® is made from high-density polyethylene filaments that are thermally bonded into a tight, homogeneous and soft fabric that is breathable, with low-linting and strong barrier properties. This unique combination of barrier protection and breathability makes Tyvek® suitable for cleanroom environment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

Protection of the cleanroom and production

- Suitable for different cleanroom types (GMP A/B,C/D and ISO Class 4-9)
- 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



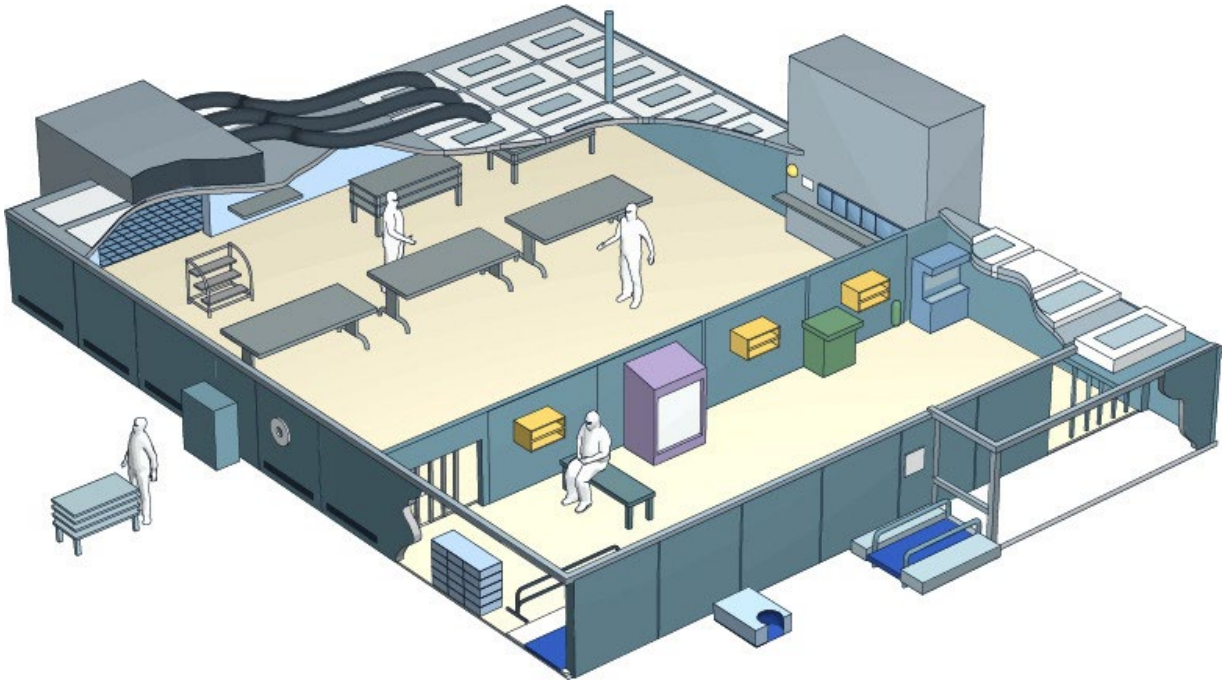
Comfort of the operator

- 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 nowadays 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.



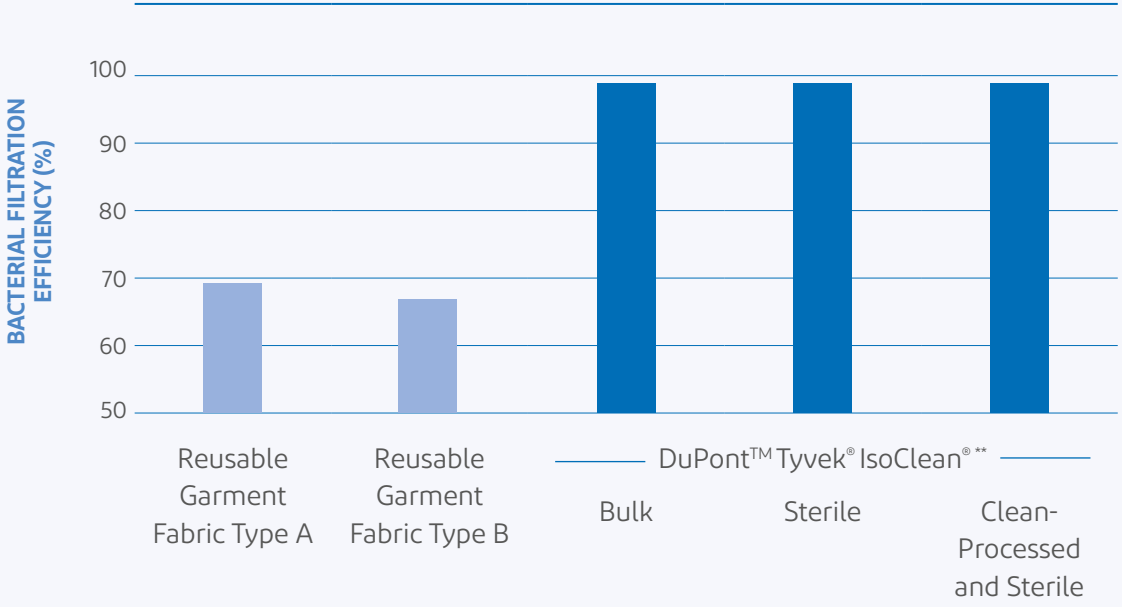
Consistent performance

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%** whereas **Tyvek® 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, desinfecting 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 garment offer maximum flexibility with maximum of process protection and are ideal for production tailored to smaller group of patients, start ups, production with single use reactor or production requiring frequent adaptation and changes. Additionally, non-contaminated Tyvek® garments can be recycled.

DuPont Personal Protection your trusted partner

DuPont understands your need to do everything possible to reduce contamination risks when manufacturing and handling vaccines.

One of the companies who collaborated with DuPont is the Butantan Institute in Brazil one of the largest biomedical research centers started replacing reusable solutions used in the manufacturing processes of vaccines, with disposable garments (made of Tyvek®), to address the Good Manufacturing Practices of Anvisa, the Brazilian public health agency. Another example of successfully implementing DuPont products in the manufacturing is represented by the Sinovac company, a China-based biopharmaceutical company that focuses on the research, development, manufacturing, and commercialization of vaccines that protect against human infectious diseases including coronavirus vaccine.

Furthermore, DuPont uses strict quality systems for cleanroom garments such as:

- The DuPont Controlled Environments quality management system is ISO 9001:2008 registered.
- DuPont™ Tyvek® IsoClean® sterile garments have a sterility assurance level (SAL) of 10^{-6}.
- DuPont™ Tyvek® IsoClean® sterile garments are gamma irradiated in a facility that is registered by ISO 13485 quality standard and adheres to the requirements of ANSI/AAMI/ISO 11137.
- A Certificate of Sterility and a Certificate of Compliance come with every shipment of sterile Tyvek® IsoClean® single-use garments.
- Dose audits are conducted quarterly to maintain dose validation.
- Customers are invited to audit our manufacturing and sterilization facilities.
- Quality documentation is readily available and accurate when requested to help meet customer requirements.

We have collaborated with many partners to help them develop and handle their products and processes safely and reduce the risks of contamination originating from operators.

DuPont cleanroom clothing in vaccine manufacturing

STERILE ENVIRONMENTS GMP GRADE A/B (VACCINE MANUFACTURING STEPS)

CLICK ON THE PRODUCT TO LEARN MORE

VACCINE MANUFACTURING STEPS

Cleanroom Type	Cleanroom clothing properties	Standards	Antigen Production	Purification	Formulation	Fill and finish	Recomended DuPont solutions
STERILE ENVIRONMENTS GMP GRADE A/B	Sterility Assurance Level	ANSI/AAMI/ISO 11137 and AAMI TIR 33			All ingredients are melt together: active substance + adjuvant, preservatives, anti-biotics etc.	The vaccines is filled into a vial or syringe.	**Tyvek® IsoClean® clean-processed and sterile range of coveralls and accessories** • Clean-processed and sterilised by gamma-irradiation to SAL of 10^{-6} (ISO 11137-1) Helmke Drum Category I. • Aseptically folded. • Dual barrier packaging system • EN 14126 (barrier to infective agents), EN 1073-2* (protection against radioactive contamination) • CE-certified. Chemical protective clothing, Category III, coveralls: Type 5-B and 6-B; accessories: Type PB [6-B]
	Cleanliness (Helmke Drum, Body Box)	IEST-RP-CC003.4 Category I particle cleanliness (particles > 0.5 µm/ minute)					
	Garment filtration efficiency (BFE,PFE)	Difference between cleanliness and Barrier Filtration					
	Aseptic folding	To support aseptic gowning procedures in EU-GMP grade A/B environments					
	Packaging system	Aseptic presentation of garments (multiple layers) to prevent contamination of the cleanroom					
	CE certification	(EU) 2016/425 Chemical protective clothing Cat. III, type 5 & 6					

TYVEK® ISOCLEAN® COVERALL IC 183 B DS

TYVEK® ISOCLEAN® BOOT COVER MODEL IC 458 B WH MS

TYVEK® ISOCLEAN® SLEEVE MODEL IC 501 B WH MS

TYVEK® ISOCLEAN® HOOD WITH TIES MODEL IC 668 B WH MS.

TYVEK® ISOCLEAN® LABCOAT WITH BOUND NECK MODEL IC 270 B WH MS

TYVEK® ISOCLEAN® COVERALL IC 193 DS WITH HOOD AND OVERBOOTS

FOR MORE PRODUCT DETAILS VISIT WWW.SAFESPEC.DUPONT.CO.UK

*Not applicable to accessories.

DuPont cleanroom clothing in vaccine manufacturing

NON-STERILE ENVIRONMENTS GMP GRADE C/D (VACCINE MANUFACTURING STEPS)

CLICK ON THE PRODUCT TO LEARN MORE

VACCINE MANUFACTURING STEPS

Cleanroom Type	Cleanroom clothing properties	Standards	Antigen Production	Purification	Formulation	Fill and finish	Recomended DuPont solutions
NON-STERILE ENVIRONMENTS GMP GRADE C/D	CE certification	(EU) 2016/425 Chemical protective clothing Cat. III, type 5 & 6	Antigen are developped using raw materials (cells) such as Protein, virus, bacteria, toxins, sugar, DNA or RNA	Impurities are removed and concentrated through physical and chemical processes			**Tyvek® IsoClean® non-sterile range of accessories** • Non-sterile Helmke Drum Category III. • Packed in a controlled environment • EN 14126 (barrier to infective agents) • CE-certified. Chemical protective clothing, Category III, Type PB [6-B]
	Cleanliness (linting data)	BS 6909 (dry linting propensity)					
	Chemical protections	(EU) 2016/425 Chemical protective clothing Cat. III, type 5 & 6					
	Biological protection	EN 14126					**Tyvek® garments non-sterile**
	Antistatic properties	EN 1149-5					

TYVEK® ISOCLEAN® HOOD WITH TIES MODEL IC 668 B WH 00.

TYVEK® ISOCLEAN® BOOT COVER MODEL IC 458 B WH 00

TYVEK® ISOCLEAN® SLEEVE MODEL IC 501 B WH 00

TYVEK® ISOCLEAN® LABCOAT WITH BOUND NECK MODEL IC 270 B WH 00

TYVEK® 500 LABO

TYVEK® 600 PLUS

TYVEK® 500 XPERT

FOR MORE PRODUCT DETAILS VISIT WWW.SAFESPEC.DUPONT.CO.UK

DuPont Personal Protection
DuPont de Nemours (Luxembourg) S.à r.l.
Contern - L-2984 Luxembourg

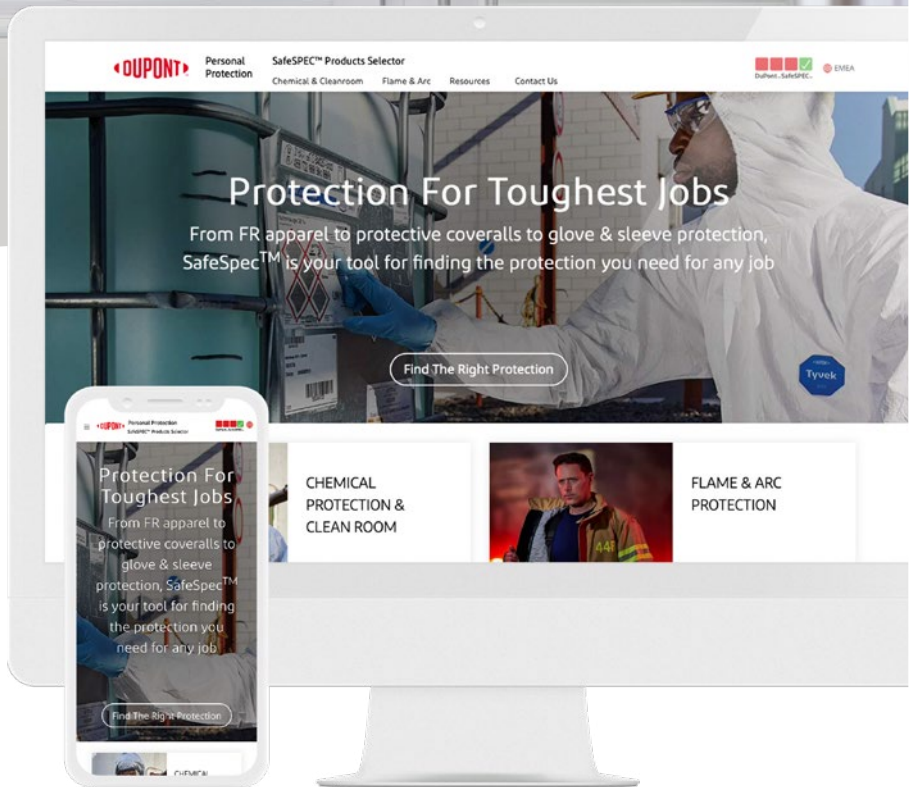
Customer Service
T. +352 3666 5111
mycustomerservice.emea@dupont.com

DuPont™ SafeSPEC™

DuPont™ SafeSPEC™ - We're here to help

Our powerful web-based tool can
assist you with finding the appropriate
DuPont garment for chemical or cleanroom environment.

safespec.dupont.co.uk



dpp.dupont.com

Connect with us: