EU GMP ANNEX 1 IMPLICATIONS FOR CLEANROOM GARMENTS

DUPONT Tyvek IsoClean

The EU GMP Annex 1 was published on the 25th of August, 2022.

WHOM DOES IT CONCERN?

It requires that **manufacturers of sterile products** will apply the principles of Quality Risk Management (QRM) to the design and control of facilities, equipment (such as cleanroom garments), systems and procedures used for the manufacture of all sterile products.

DEADLINE

The EU GMP Annex 1 will come into force on the **25th of August, 2023.**

WHAT IS REQUIRED TO BE COMPLIANT?

Manufacturers of sterile products need to provide **a proactive means of identifying, scientifically evaluating and controlling potential risks to quality** and to **ensure that microbial and particulate contamination is prevented in the final products.** They must also **implement a Contamination Control Strategy (CCS) across the facilities** in order to define all critical control points and assess the effectiveness of all the controls (design, procedural, technical and organisational) and monitoring measures employed to manage risks to medicinal product quality and safety.

WHAT SHOULD YOU DO TO ASCERTAIN THAT YOU REMAIN COMPLIANT?

If you are operating in GMP grade A/B cleanrooms, here are some **questions related to your cleanroom garment systems** you may ask yourself in order to ascertain that you remain compliant:

1 Test reports & Data sets

Do I have the necessary test reports & data sets needed to scientifically check if my cleanroom garments are meeting the new requirements on cleanroom garments set in the EU GMP Annex 1?

2 Particle Filtration Efficiency

How effective are my cleanroom garments at retaining the particles (skin flakes) shed by the operators? What is the particle filtration efficiency of my cleanroom garments?

3 Bacterial Filtration Efficiency

The EU GMP Annex 1 becomes more demanding on microbial contamination, what is the bacterial filtration efficiency of my cleanroom garments?

4 Body Box Test Reports

The EU GMP Annex 1 requires that the cleanroom garment retains human particles while the operators are moving. Do I have body box test reports for my cleanroom garments?

5 Validated Sterilisation Process

Are my cleanroom garments sterilised according to a validated sterilisation process? If yes, according to which standard and what is the sterility assurance level?

6 Frequency of changing cleanroom garments

For reusable cleanroom garments, how often are my garments being replaced? Do I have test reports to confirm this frequency?

E.g. the visual inspection with reusable garments will no longer suffice. You must have a technical solution to check whether the reusable garments are physically intact. Do you have a scientific method for the inspection of your cleanroom garments?

7 Cleanliness of cleanroom garments

For single-use cleanroom garments, are they clean processed? How do I evaluate the cleanliness of my garments? Do I have a Certificate of Compliance showing the Helmke Drum performance Category for each box of garments?

At DuPont, we have been manufacturing Tyvek® IsoClean® cleanroom garments for over 20 years and are proud to be the trusted solution partner for cleanroom garments.

For more information on the EU GMP Annex 1 implications for cleanroom garments or for assistance in addressing above questions **contact us**.