Cleanroom Clothing: Factors to Consider

Advances in reusable garments and the availability of hi-tech specialist cleanroom laundries are making non-disposable clothing a more cost-effective option.

In any pharmaceutical production environment, high standards of cleanliness are paramount. A failure to address this issue properly can lead to product wastage and have potentially fatal consequences. This article will look at the latest advances in cleanroom garments and laundry operations in preventing contamination.

Cleanroom garments are designed to prevent foreign particles and bacteria from operatives contaminating the production process. Particular attention must be paid, therefore, to the selection, design, preparation and cleaning of these garments to ensure they are providing an optimal service.

In the past, pharmaceutical companies have chosen disposable garments but this thinking is now changing, and advances in reusable garments and the availability of hi-tech specialist cleanroom laundries are making non-disposable clothing a more cost-effective option.

STERILISATION

To remove any potentially harmful microbes, garments must undergo a sterilisation process. This is usually carried out by subjecting the garments to gamma radiation, which kills off any bacteria. However, use of this method can cause items such as zips and elastic cuffs to deteriorate rapidly – drastically reducing the useful life of the garment. At Origin, we have developed a special process, which removes the need for radiation yet provides the same standards of sterilisation. This process not only ensures that garments last for longer, but it also offers more scope in terms of garment design. It allows the use of zips and stud fastenings instead of elastic, and features such as penholders can also be incorporated. Another benefit of this approach is that the fit of garments can be improved, further reducing the potential for contamination. Regular testing for microorganisms on garments is essential; garments need to be swabbed and the samples then cultivated on a petrie dish.

Garments are normally cleaned at a specialist cleanroom laundry to international cleanroom standards. Key criteria to consider here:

- Garments for pharmaceutical use should be cleaned under ISO 14644-1, ISO Class 4 and tested to AST 51-00 standards
- The supplier should carry out regular independent audits of the air and water quality standards within the cleanroom laundry
- Water used to clean garments should be 18 mega-ohm ultra-pure de-ionised to eliminate the risks of contamination through impurities found in normal water
- Garments should be double-bagged at the laundry
- Sets of garments should be individually packaged and uniquely identified to employees
Three key methods are employed to test garments once they have been through the cleaning process:

- Garments are put into a Helme drum where an airborne particle counter is used to determine the number of particles over 0.3 microns in size per cubic foot of air.
- The ASTM 51-00 test involves drawing air through a filter on certain parts of the garment; this tests for loose particles and fibres in and on the surface of the garment.
- Static dissipation tests are used to check how well the garment can resist static charges.

**GARMENT SELECTION**

In selecting garments, operator comfort is very important. Garments should integrate seamlessly with other items such as hats, gloves and footwear. A good fit is essential to ensure operator comfort and the operational efficiency of the garment. Carrying out a measuring exercise will ensure that each employee feels comfortable wearing the garment, and the lifespan of the garment is maximised. Poorly fitting garments will wear out more quickly, adding to the total cost of ownership. When sourcing garments from overseas, especially the US and Asia, it should be borne in mind that these countries have specific body characteristics. Choice of footwear is particularly important, as overshoes tend to suffer the worst wear and tear. Skimping in this area can be a false economy.

The fabric from which the garments are constructed is also important. There are a number of well-established brands – but new fabrics emerging from the Far East offer comparable performance and functionality at a reduced cost.

**MONITORING**

Careful monitoring and management of the stock of garments is vital. Each garment should be barcoded so it can be tracked and also traced should any contamination issues arise. Key factors to consider include the following:

- How many sets of garments will be required for each employee? It is essential that contingency stock is held at the site for emergencies, and that spare garments are ready to hand should existing garments be contaminated or damaged.
- Each garment should be thoroughly inspected for any damage when returned to the supplier; the stage at which a garment should be replaced rather than repaired should be agreed in the contract.
- What service level agreements are in place to ensure that response times, collections and deliveries are in line with operational and commercial objectives?
Does the supplier have sophisticated Management Resource Planning systems in place to manage the flow of garments and to make sure that the right garments are in the right place at the right time?

Are coats, hats, gloves and overshoes packaged together and assigned to each individual?

Traceability is vital if anything goes wrong – can the supplier provide a detailed audit trail so that cleaned garments can be identified by batch number?

What policies and procedures are in place to enforce frequency of garment changes? Detailed management reports should be supplied to show employee compliance and monitoring of the garment lifecycle.

CONCLUSION

The importance of cleanroom garments to the safe and efficient operation of a pharmaceutical manufacturing plant cannot be overestimated. How garments are sourced, designed and cleaned can have a significant impact on operational efficiency and operator comfort.