

# Successful Wiping



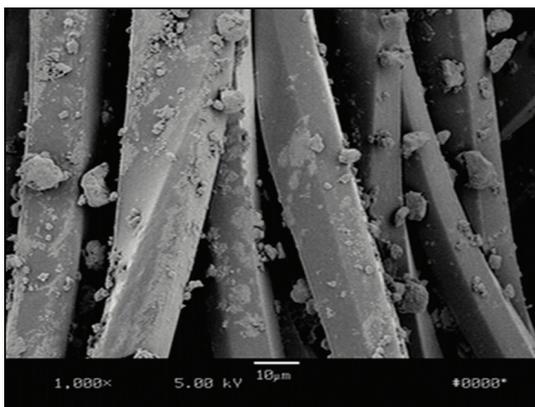
Studies have shown that wiping is the most effective method of cleanroom cleaning. Presaturated wipes especially, are highly suitable for capturing and removing particles and dirt, disturbing biofilms and removing residues. The removal of particles is especially key, not only to pick up dirt and particles, but to trap them in the wipe and physically remove them from the cleanroom. The ability of a wipe to retain and remove a particle or fibre depends on the structure of the wipe and the size of the contaminant.

## Dry or wetted wipes for cleaning?

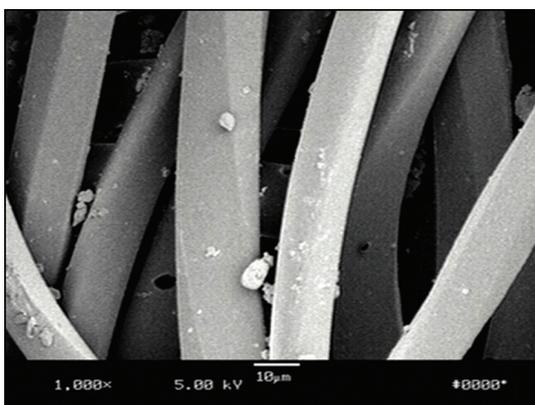
Some manufacturers have developed proprietary surface treatments to dry wipes in order to enhance particle removal and retention. Particle Attraction Technology (PAT) enhances the ability of the wipe to attract and retain fine particles, less than 10 microns. This improves the wipes ability to clean surfaces, thereby leaving surfaces cleaner. It is a permanent treatment that molecularly bonds to the fabric fibres and is in fact actually enhanced in the presence of a solvent.

Wetting the wipe significantly enhances particle entrapment and removal. Using a wetted wiper provides an overpowering bias for the particles to remain with the wipe, since capillary hydroscopic forces from the moisture on the wipe provide the mechanism for the particles removed from the surface to remain with the wipe. Once the wipe is removed from the environment, the particles go with it, resulting in the most effective method for removing particles from a cleanroom surface.

The amount of fluid used to pre-wet the wipe is critical: if the wipe is over saturated then particles are re-deposited on the surface and simply moved around, not picked up into the wipe<sup>1</sup>.



Wipe with PAT



Wipe without PAT

## Advantages of presaturated wipes

Presaturated wipes can offer many benefits over bottled IPA and dry wipes for cleanroom use. Presats were first introduced to cleanrooms in IBM in 1988 by Contec Inc, to reduce solvent utilisation and increase convenience in hand wiping. Because they provide exceptional solvent control, presaturated wipes were soon adopted by the aerospace, semiconductor, automotive and other industries in order to meet increasingly stringent VOC emission and solvent reduction regulations. However, one of the quickest adopters of these products was the medical device industry, which saw the productivity improvements and process controls the technology offered. Sterile presats for the pharmaceutical industry were introduced in 1990 and are now one of the fastest growing consumable products used in pharmaceutical cleanrooms due to the benefits they provide.

## Solvent reduction and lowering of VOCs

Based on feedback from end-users, a comparison of common methods of applying cleaning solutions to wipes showed that solvent usage can be reduced between 15 and 50% depending on the method of saturation. The majority of pharmaceutical cleanrooms use 70% alcohol solutions for transfer disinfection as it is fast acting and leaves no residue. For instance, if IPA is the alcohol of choice, it has a low work exposure limit (UK TWA 400 ppm eight hours) and this limit can be very easily breached when spraying for long periods of time during transfer disinfection. The use of presaturated wipes can eliminate the need for costly remedial work to install ventilated transfer hatches.

## Process control and repeatability

In all cleanrooms there is a need for repeatable and validated processes. The spraying of a dry wipe with a solvent to a predefined saturation level is not a repeatable process. Each operator has a different view on when a wipe feels wet. Add to this that the operator is probably wearing two pairs of gloves and the tendency is to over wet the wipe as they cannot actually feel how saturated (or not) the wipe is. Even the same operator on different days probably does not saturate a dry wipe in the same way.

In the case of disinfection, the objective is to leave a visible film of disinfectant on a surface for a defined contact time. The wipe needs to be saturated enough to leave behind enough disinfectant, but not be so wet that the benefits of controlled application of the fluid are lost. Also, the validated process of disinfection relies on the correct amount of disinfectant being applied by each operator to get the expected log reduction in microorganisms. If insufficient disinfectant is applied, the disinfectant may dry before the validated contact time is reached.

In the case of cleaning, the saturation levels are even more crucial. A groundbreaking study by Mattina et al<sup>2</sup> showed that a wipe saturated beyond its ability to hold solution, left a surface with more contaminants than with any other level of saturation. Indeed, saturation levels below the saturation limit (i.e. a less wetted wipe) consistently resulted in fewer particulate contaminants remaining on the wiped surface. A wipe with excess solution will leave some solution behind on the wiped surface and with it any contamination within the solution.

## Validation

Having a validated cleaning process requires documentation of both the process and the products

used in the process. The use of a presaturated wipe reduces time and costs as only one product, the presaturated wipe, needs to be qualified and validated as opposed to two products, the wipe and the spray. Using presaturated wipes simplifies the writing of SOPs as the process of validating the spraying of the wipe is removed. This saves time, but more importantly provides a process that is more easily audited by internal and external agencies.

## Disinfection

Another more recent study also came to a groundbreaking conclusion. A study published in Letters in Applied Microbiology<sup>3</sup> compared the spread of microbial contamination on surfaces cleaned with dry wipes that were sprayed with alcohol with those cleaned with presaturated wipes. This independent study concluded that wiping with presaturated wipes minimised the spread of contamination: "The dry wipes sprayed with alcohol demonstrated minimal effect at reducing the bacterial bioburden on a surface and were able to transfer viable micro-organisms between surfaces... However, the continuous transfer of bacteria following the use of the dry wipes sprayed with alcohol is of concern. ...our results clearly demonstrated, in a quantitative manner, that alcohol pre-impregnated wipes are more effective at reducing surface bioburden than dry wipes sprayed with alcohol."

## Conclusion

Cleaning and disinfection in a pharmaceutical cleanroom is a critical process to protect patient safety and product quality. More effective and consistent hand cleaning and disinfection will result in greater consistency, quality and safety in the overall process and the resulting product. Damp wiping to a validated procedure is a proven method of effective surface cleaning versus other techniques. The use of presaturated wipes brings additional benefits in improved productivity, reduced validation, increased process control and repeatability, improved safety and VOC reduction. For life science cleanrooms, the use of alcohol presaturated wipes versus wipes wet at point of use is even more beneficial as it has been proven that they are more effective at reducing surface bioburden.

## References

1. *Wiping Surfaces Clean* Vicon Publishing 2004: H Siegeman Ph.D.
2. *The cleanliness of wiped surfaces: particles left behind as a function of wiper and volume of solvent used.* C F Mattina, J McBride, D Nobile *Cleanroom East Proceedings* 1996.
3. *Evaluation of alcohol wipes used during aseptic manufacturing.* The Society for Applied Microbiology, *Letters in Applied Microbiology* 48 648-651. M.N. Panousi, G.J. Williams, S. Girdlestone, S.J. Hiom and J.-Y. Maillard (2009).  
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