

CLEANROOM

TECHNOLOGY

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**SUCCESSFUL SURFACE
CLEANING WITH WIPES
IS MORE OF A SCIENCE
THAN AN ART**



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- Calibration variability can affect particle counting performance
- UV light is an efficient means of disinfecting food packaging

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Successful wiping

Presaturated wipes are an efficient cleaning tool for cleanrooms, but if not used correctly the time and effort of sampling, testing and validating wipes can be wasted. **Karen Rossington** looks at the science behind effective wiping

Studies have shown that wiping is the most effective method of cleanroom surface cleaning. Presaturated wipes in particular 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 also 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. Wetting wipes significantly enhances particle entrapment and removal. Some manufacturers have also developed proprietary surface treatments for the dry wipes that enhance particle removal and retention.

Particle Attraction Technology (PAT) enhances the ability of the wipe to attract and retain fine particles of less than 10µm. This improves the wipe's ability to clean surfaces, thereby leaving them cleaner. It is a

permanent treatment that molecularly bonds to the fabric fibres and is enhanced in the presence of a solvent. It is most relevant in applications that are sensitive to fine particles (see Fig. 1).

Various studies demonstrate that wiping with saturated wipes is an effective way to control contamination on a hard surface.^{1,2} Studies of particle adhesion to surfaces have shown that the predominant force binding

particles to a surface is a capillary force.³ The use of a wipe presaturated with a low surface tension fluid, such as alcohol, helps to lower the surface tension of this binding force, facilitating the removal of the particle.

Wetting a wipe further enhances its ability to trap particles. A wetted wipe provides capillary hydroscopic forces via the moisture on the wipe that help to retain the particles removed from the surface on 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, simply moved around and not picked up into the wipe.⁴

A further question to be answered is whether it is more efficient to use a wipe that has been pre-wetted or a dry wipe that is wet at point of use from a squirt bottle, aerosol or trigger spray. (The terms presaturated, pre-wetted or pre-impregnated all refer to a wipe that is purchased already wet with a solvent or disinfectant, usually in a pouch or tub that can be resealed.)

Presaturated or dry wipes?

Presaturated wipes can offer many benefits over bottled IPA and dry wipes for cleanroom use. They were first introduced into cleanrooms by Contec in 1988 to reduce solvent utilisation and increase convenience in hand wiping for IBM. Because they provide exceptional solvent control presaturated wipes were soon adopted by the aerospace, semiconductor, automotive and other industries to meet increasingly stringent VOC emission and solvent reduction regulations. However, the medical device industry was one of the quickest adopters of these products as it saw the productivity and process control benefits that the technology offered.

Sterile presaturated wipes for the pharmaceutical industry were introduced in 1990 and are now one of the fastest growing consumable products used in pharma cleanrooms due to the benefits they provide.

Based on feedback from end users in

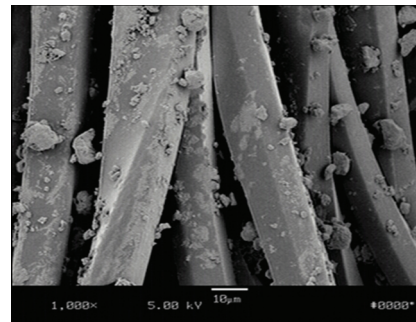
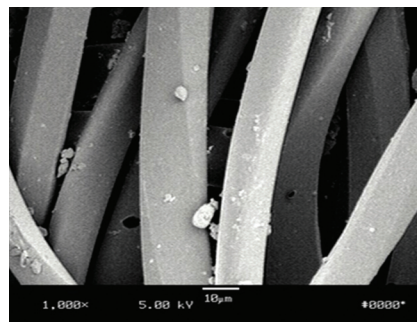


Fig. 1: (left) Without treatment; (right) with PAT treatment

multiple industries, a comparison of common methods of applying cleaning and other process solutions to wipes showed that solvent usage can be cut by between 15 and 50% depending on the method of saturation. This has been a significant benefit to companies looking to manage solvent usage and emissions but retain familiar work practices that involve hand wiping.

The majority of pharmaceutical and healthcare 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 400ppm 8hrs) 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.

A real example of the benefit of using presaturated wipes was shown at a major aircraft manufacturer that had reached the allowable limits for solvent emissions to atmosphere. Solvents were used in many operations and processes, including hand wiping with a wipe and separate solvent. The company took advantage of the greater process control that presaturated wipes provide and was able to reduce solvent usage and emissions enough to meet the allowed emissions limits.

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 the fact that the operator is probably wearing two pairs of gloves or in isolator gauntlets and the tendency is to over-wet the wipe as they cannot actually "feel" how saturated (or not) the wipe has become. Even the same operator on different days probably does not saturate a dry wipe in the same way.

Why is this a problem? 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 micro-organisms. 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. In a study by Mattina *et al.*,⁵ five different commonly used wipes were saturated at various volume

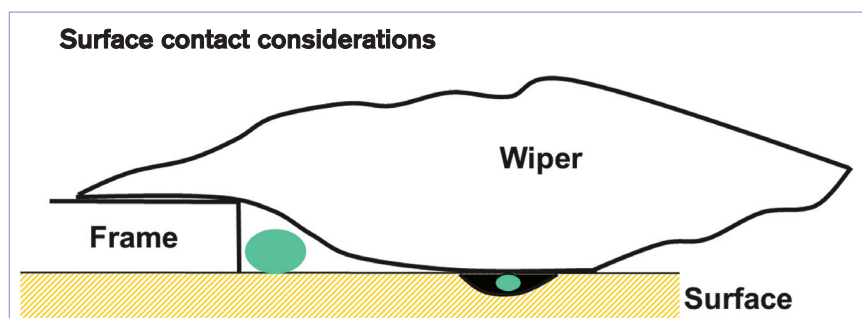


Fig. 2: Difficult to clean areas should always be cleaned first

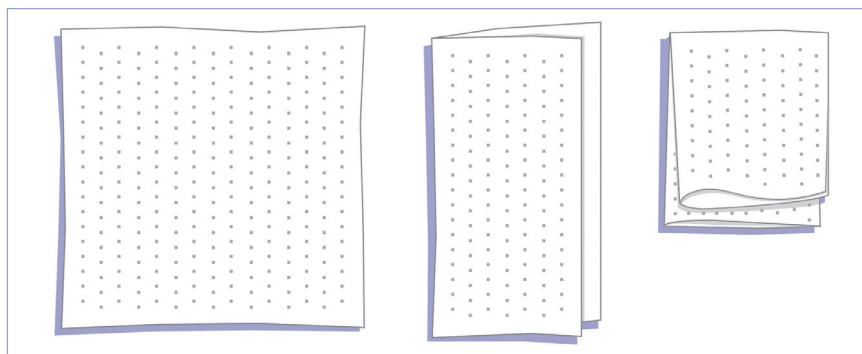


Fig. 3: The correct wipe folding method

levels above and below the full saturation limit of the wipe. The types of wipe tested included nonwoven polyester/cellulose, nonwoven polyester, melt blown polypropylene and both knife cut and sealed edge polyester. The performance of the wipes in cleaning a common surface was then compared by measuring the contaminants remaining on the surface after wiping.

The results clearly indicated 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. It is thought that the particles from the wiped surface and the wipe are distributed through the solution on the wipe. A wipe with excess solution will leave some solution behind on the wiped surface and with it any contamination within the solution.

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

Another more recent study published in *The Society for Applied Microbiology, Letters*

*in Applied Microbiology*⁶ 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."

It is worth noting that not all wipes are compatible with all disinfectants. Hypochlorite solutions are very adversely affected by organic materials such as cellulose, rendering the microbial efficacy negligible to non-existent.⁷ With a presaturated wipe this potential incompatibility will have been tested and verified or eliminated by the manufacturer.

Wiping techniques

For the wiping process to be successful the wipe must come into intimate contact with the unwanted contaminants and the process must be consistent and repeatable. There are many areas in a cleanroom where consideration needs to be given to whether the particles are being shielded (see Fig. 2). Areas that are difficult to clean should ►

consumables

◀ always be cleaned first, with particular attention to areas where particles may harbour or be difficult to reach.

Technique is also important to prevent the trapped contamination being re-deposited on a surface. Best practice rules include:

- Folding the wipe to ensure that even pressure can be applied across the wipe. It also means that a clean side of the wipe can be presented to the surface on every stroke, ensuring no contaminants are re-deposited on the surface. Folding the wipe in half and then in half again produces up to eight clean sides to be used (see Fig. 3).

- Pick up the quarter-folded wipe at the open edges. Grasp the unfolded edges between the thumb and forefinger. When wiping, place equal pressure across the edge of your hand, holding the fingers together and pull across the surface to be cleaned, ensuring that the open edges are lifted away from the surface. Angling the hand slightly allows the folded edge of the wipe to remain in consistent contact with the surface. This can be easily validated during training to ensure an operator is applying even pressure by using a coloured fluid and seeing if there are dense patches of colour where they have applied uneven pressure.

- Another example of best practice is the “pull and lift” technique, shown in Fig. 4. Lifting the wipe at the end of every stroke ensures that contamination is removed from the surface.

- At the end of every stroke, either flip or refold the wipe, exposing a clean surface. A general rule of thumb is that the wipe surface needs to be changed every 10 wipe lengths. Folding and refolding can get quite confusing for operators to ensure they always use a new clean side and needs to be validated during training. Alternatively, the wipe can be folded into halves only.

In addition to ensuring intimate contact is continually made between the wipe and the surface it is important to ensure that no area is missed. A best practice technique for this is wiping in straight lines with overlapping strokes. This ensures that every centimetre is covered. To prevent a miniscule gap between the strokes, each stroke should overlap the previous one by 10–25%. As well as ensuring no areas are missed, straight line wiping also means that contaminants are removed from the surface at the end of each stroke. Overlapping strokes also means no “contamination” trails are created by the edges of the wipe.

- Wiping should never be carried out in a circular motion as this causes the wipe in its dirtiest state to be passed over an area that has just been cleaned. This point needs to be reinforced with operators, as a circular wiping pattern is the most comfortable and convenient, according to studies.

- Wiping should be carried out from the



The pull and lift technique involves lifting the wipe at the end of every stroke to remove contamination from the surface



cleanest area to the dirtiest, most critical to least critical. This will usually be from top to bottom, from back to front, from driest to wettest. In cabinets and isolators work away from the filters; this ensures that the area “upstream” in the column of filtered air receives the most effective cleaning.

Contaminants that may be moved downward (less critical) will have the smallest impact on the cleanliness of the critical process areas. In areas that are difficult to reach, cleaning tools may help to maintain the correct wiping technique. Special tools are available that can be used with dry or pre-saturated covers in place of wiping by hand.

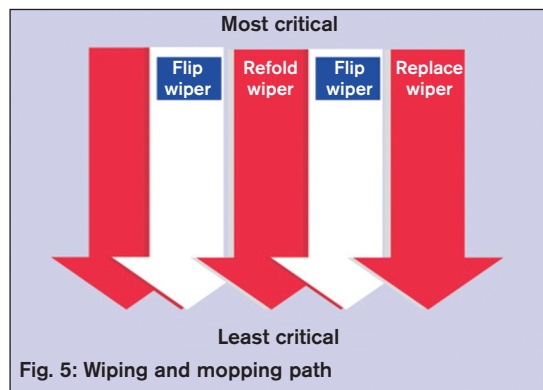
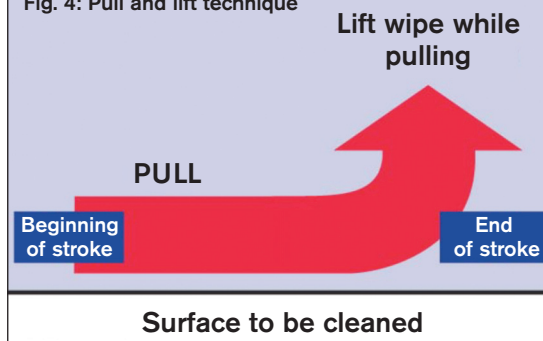
In conclusion, the hand-wiping of surfaces and equipment is an integral part of the manufacturing process in many cleanrooms. Cleaning and disinfection in a pharma cleanroom is a critical process to

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. **CT**

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Fig. 4: Pull and lift technique



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