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CLEAN
FACTS
Cleanroom Hygiene

PRACTICAL CONCEPTS FOR CLEANROOM CLEANING

A CLEAN CASE FOR A SYSTEMATIC APPROACH

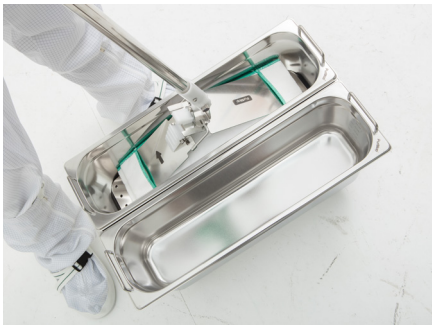
Careful thought must be given to a cleanroom cleaning concept. Besides the various norms, guidelines and standards, a number of practical aspects must also be taken into consideration. This especially applies to the use of mops, wipes, cleaning agents, and disinfectants as well as staff training.

When choosing a cleaning system and tools for cleanroom cleaning, the first thing to consider is the suitability of the products and materials: They should be easy to clean (hygienic design), durable, abrasion-resistant, and, in some cases, autoclavable.

Compared to stainless steel equipment, plastic materials are much lighter, making it easier to clean walls and ceilings in particular. On the other hand, plastic surfaces often become rough over time, making them more difficult to clean and turning them into potential sources of contamination. This is particularly the case for products that are not specifically designed for the use in cleanrooms. Accordingly, it is recommended that plastic buckets and accessories are replaced in good time and at regular intervals, approximately once a year. Since most plastics are not autoclavable over a longer time period, they should not be used in GMP A / B areas.

DIFFERENT MOP SYSTEMS

Mop systems provide the basis for the cleaning of walls, ceilings, and floors. These can be wetted and used in conjunction with various systems. Pre-saturation systems (boxes) are a useful aid in small, confined spaces where few mops are needed. However, users should be aware that the mops are generally highly saturated and consume a large quantity of disinfectant in this method – reusable mops need 300–500 ml, for example. A simple way of discarding the mop (while avoiding hand contact) should also be considered beforehand.

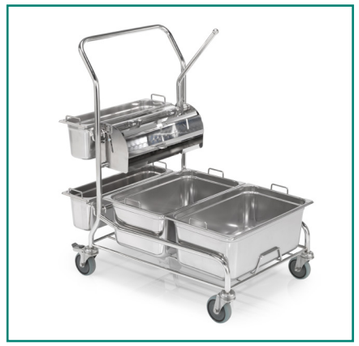


PurMop® PREPARE Presaturation System

Wringer systems were often used in the past, but the disadvantage here is the difficulty in validating the process. How the mop is wrung at each use depends on the operator – in other words, the amount of liquid in the mop can vary considerably. In order to avoid contaminating fresh mops, care must be taken to ensure that the mops do not come

Hydroflex

into contact with the wrung out liquid. Wringer systems also require a fairly high user exertion due to the repeated manual wringing process.



PurMop® DUO Wringer System

Innovative concepts such as the PurMop® ERGO system on the other hand, guarantee a highly ergonomic and safe option for the user because any form of hand contact with the mop or mop frame during use is eliminated. This system is especially advantageous in medium to larger cleanroom areas (from 100 m²). Presaturated mops or ready-to-use products are ideal for small, sterile cleanroom areas.

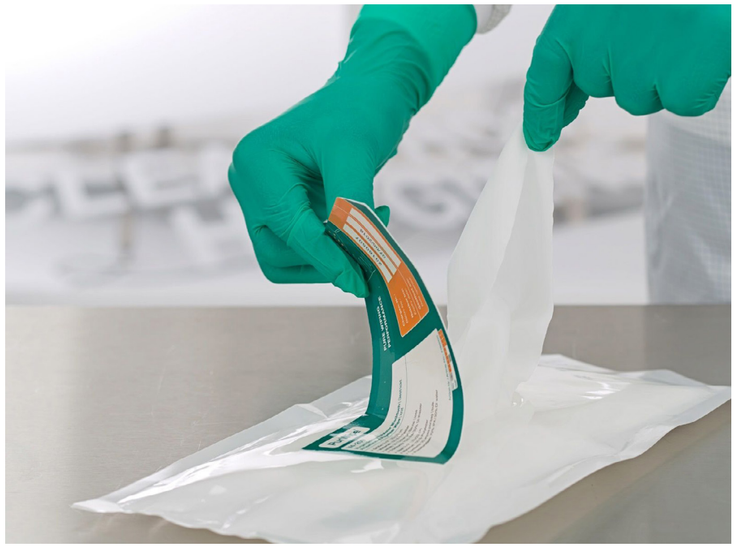
PurMop® ERGO: the intelligent discarding mechanism enables a touchless discarding

DISPOSABLE MOPS VS. REUSABLE MOP CONCEPTS

The key factor when using reusable mops in the cleanroom is the method and quality of the laundry and preparation process – in other words, how they have been decontaminated and, if necessary, sterilized. Cleanroom mops must not only be washed in special cleanroom washing machines within a cleanroom, but also dried, inspected and packed in line with the cleanroom class in which they will be used for cleaning. Furthermore, the number of washing cycles must be tracked using a suitable system (RFID or bar code) and the mops must be discarded after a set number of cycles. Mops will naturally wear with use, and factors such as autoclaving, aggressive chemicals, rough surfaces, and contact with glass breakages will often accelerate this process.

Disposable mops offer a number of advantages in the cleanroom. It is important to make sure that mops are certified for cleanroom use, made of 100% polyester, and only emit a certain amount of particles and fibers. Ready-to-use saturated mops have the capacity to cover large areas and are proven to provide high cleaning performance. The theory of supposedly higher costs for disposable systems can often be disproved by means of a realistic comparison of costs. Disposable systems are now economically comparable to a reusable concept, because there are no costs to lease and wash / sterilize the mops, while simplifying internal quality checks and processes.

In many cases, it is even possible to save on cleaning chemicals thanks to the highly efficient cleaning performance of single-use mops. If no critical agents such as hormones or cytostatic residues have come into contact with the mops and they are only being used for disinfection and particle collection, they can easily be re-used outside the cleanroom after the initial usage.



THE RIGHT WIPES WITH THE RIGHT PACKAGING

It is a general necessity to check the compatibility of wipes that are used in the cleanroom. As a rule, nonwoven wipes are not prewashed and thus contain a certain amount of particulate and nonvolatile residues. These should only be used on smooth surfaces due to their tendency to roughen up and pill, and are generally not recommended for sterile cleanroom applications. Non-sterile wipes are never free of microbial contamination, as microorganisms that find their way onto the wipe during the manufacturing process are not inactivated. However, they can be killed by subsequent sterilization, for instance by gamma irradiation.

The use of pre-laundered wipes which guarantee a low particle level is recommended in critical cleanroom areas – such as GMP A / B or ISO 5 and above. These are also available as a microfiber version. Furthermore, the right packaging concept is important. It is essential to consider aspects such as how the wipes can be safely brought into the cleanroom in a multipack and whether the right amount of wipes – neither too many nor too few – is in a pack.

Reusable wipes in the cleanroom are very uncommon for various reasons: Since they are used on surfaces which, compared to the floor, are much closer to the product or production process, there is a greater risk of contamination caused by damaged or imperfectly laundered wipes. It is also essential to check the condition of the wipes and track the wash cycles, which is complicated and oftentimes obstructive for a delicate product such as a wipe.

Presaturated, ready-to-use wipes are available with a wide range of cleaning agents and disinfectants. It is important to make sure that they are suitable for use in the cleanroom / GMP areas.

CLEANING AGENTS AND DISINFECTANTS NEED TO BE CAREFULLY CHOSEN

Every surface should be clean prior to disinfection, which means free of production residues, biofilms, or the residue of previous disinfectants. A wipe material with high cleaning efficiency and possibly also a surfactant should be used for this. However, the cleaning agents must not interact. Only then can the entirely clean surface be disinfected. Neutral cleaning agents (pH value approx. 7) that are harmless to the operator and gentle on the surface are commonly used, and / or alkaline cleaning agents (pH value approx. 10–12) that are primarily used to inactivate cytostatics or organic substances such

as proteins or blood plasma. In any case, it is recommended to set fixed cleaning cycles in the hygiene plan – always before a sporicidal disinfection, for example.

Surfaces should be disinfected daily or after every use. Wall and ceiling surfaces should also be cleaned and disinfected at regular intervals. The GMP Guidelines set out the rotation system – i.e., the use of more than one kind of disinfectant. An agent that is effective against bacteria spores should also be used. The rotation system can thus ideally be covered with two agents: A regular biocide for routine use, and a suitable sporicidal agent.

Be mindful of residue formation with the disinfectants used. Many cleaning agents leave residues on the surface once they have dried and may even attack materials such as stainless steel. Due to their strong oxidizing properties, most sporicidal agents must be wiped away in an additional work step at the end of the recommended contact time – using WFI or isopropanol, for example.

Accordingly, the contact time for sporicidal agents must be taken into consideration. If a multiple shift system is in operation or production comes to a halt during the contact time, cleaning agents with the shortest possible contact time, optimally less than 15 minutes, are ideal. The general rule is that sporicidal agents should be used as often as necessary, but as seldom as possible – based on an internal risk assessment conducted by the user.

Ready-to-use agents offer a number of advantages over concentrates. Dosing errors are avoided, the right amount of liquid can be poured out based on specific need, and only one product has to be validated and stored. When using concentrates in GMP A / B areas, care must be taken to ensure that the packaging is sterile until the point of use.

Practical demonstration in a mobile cleanroom during a training

TRAINING IS EVERYTHING

When using any kind of cleaning system, it is important to give the cleaning staff clear instructions and practical training to ensure that equipment and cleaning materials are used correctly and potential errors are avoided. Staff training courses should be run by qualified trainers who possess practical experience of working and cleaning in the cleanroom. Good training is practical and not just based on theory. Targeted training courses tailored to the SOPs and processes of the individual user are generally the most successful. With cleanroom training, care must be taken to ensure that the training provider is neutral and not holding a covert product sales event. The trainer should ideally have a broad overview of products commonly available on the market and should also be able to recommend products made by a wide range of manufacturers if there is room for optimization.

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