Dycem®

Floor-level Contamination in Pharmaceutical Manufacturing

Alun Jones

CONTENTS

INTRODUCTION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

It can be concluded that much of the contamination control efforts in the pharmaceutical industry tend to address eye-level or hand or operation levels. There is concentration on what is in front of personnel and what is seen at that eye or hand level; environmental monitoring efforts reflect such. The range of the filling or packaging lines and what is more easily cleaned are frequently considered.

A major misunderstanding lies in believing that a routinely cleaned and maintained floor harbors no microbiological or particulate contaminants.

Floor-level contamination and its causes cannot be neglected. It cannot be the hidden or least considered area of concern. Addressing aspects of floor-level contamination in this chapter by giving thought to its causes and types, and the simple, yet effective remedies that may be implemented are presented.

SOURCES AND TYPES OF CONTAMINATION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

The potential sources of floor-level contamination entering critical environments are shown in Table 1.

While all of these may not be initially generated at the floor-level, they may be passed down to the floor from above. In those cases, they can then be returned to the operations level in a riskier state. For example, fibers may be crushed and reduced in size by wheeled traffic, which may much more easily get into the product.

Table 1. Potential Source of Contaminants

Source	Potential Contaminants
Air System/Air Handling	Microbiological, dust
Building/Room	Plastics, oils, paints
Disinfectant cloths	Cellulose fibers
Flooring	Dust, resins
Manufacturing line	Metal, plastic, rubber, silicone fluid
Packaging materials	Cellulose fibers, plastics
Personal Protective Equipment	Particulates, fibers
Personnel	Skin cells, fluids, microbiological, hair
Shoe covers	Fibers
Shoes	Soil, microbiological
Trolley wheels	Soil, microbiological

Poorly designed or poorly functioning air handling systems, fill or packaging lines may exacerbate contaminants being introduced into the environment. Those contaminants may fall to the floor-level, and they may be a source of nutrients for microorganisms.

SOURCES AND TYPES OF CONTAMINATION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

Product or personnel and their movement patterns should be examined. Those potential issues should be addressed with operations, maintenance and facilities teams and within the organization and are not directly addressed here. However, in training it is beneficial to offer pictorials such as 'Potential Source of Contaminants', Table 1. This will help those involved take ownership and better grasp the complexities of floor-level contamination and the impacts on the products manufactured by their behaviors.

DON'T IGNORE THE FLOOR...

80% of Contamination Enters a Critical Space at floor-level.

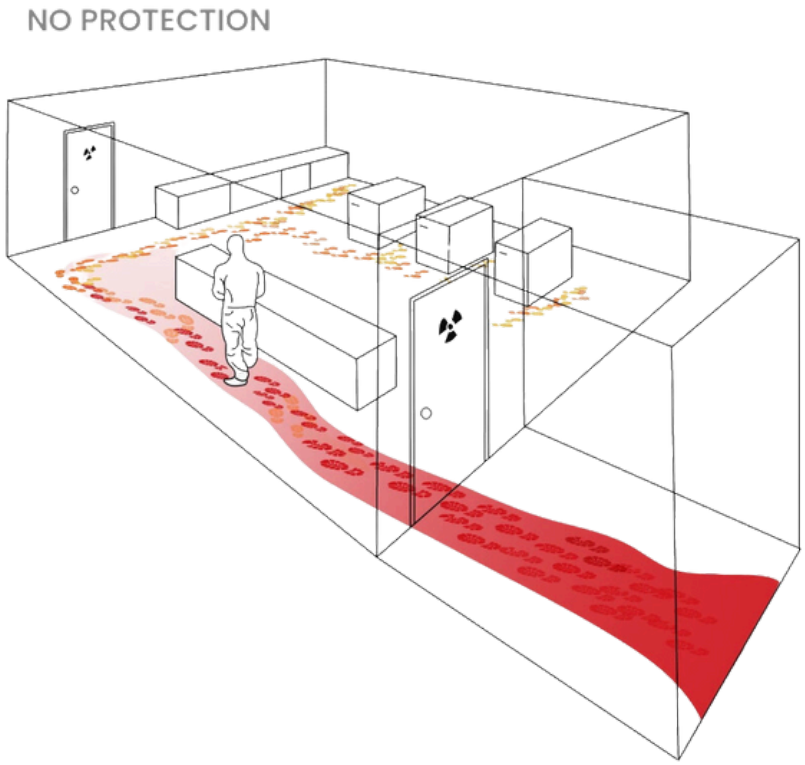
ABOUT CONTAMINATION

In a study, it has been shown that 80% of contamination entering critical environments is via feet or wheels (1). This is significant and should be a focal point for pharmaceutical companies to place their efforts in contamination control. If a contamination event occurs, studying foot-borne and wheel-borne patterns may be the first place to begin an investigation.

SOURCES AND TYPES OF CONTAMINATION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

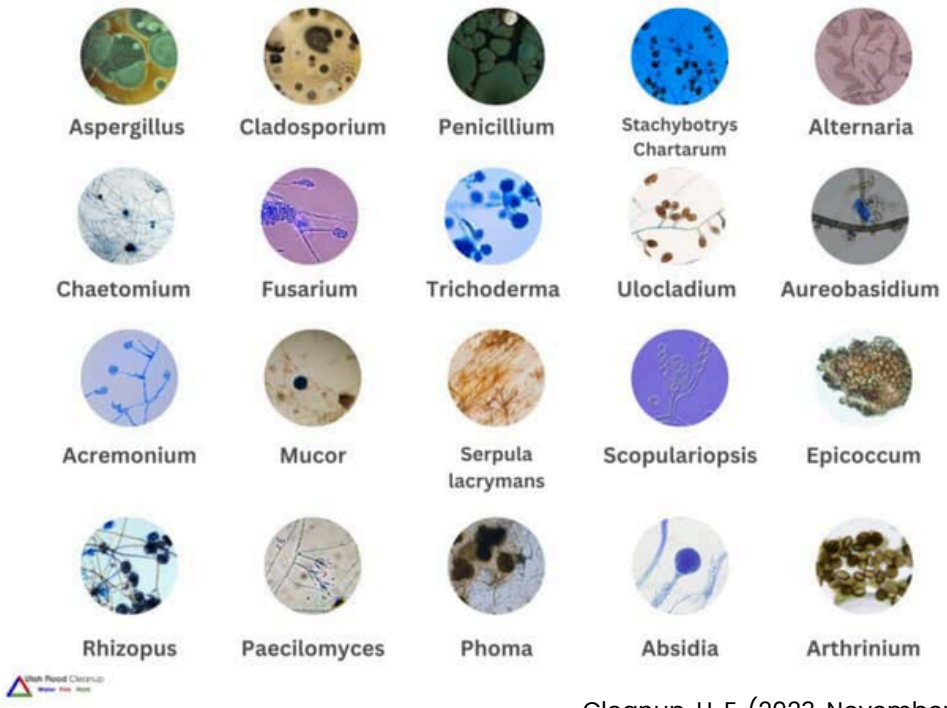
Viable microbiological contaminants include bacteria, yeast, mold, or viruses. Their sources are numerous and identifying the microbiological contaminant can give clues to its source. Knowing the microbiological identification, at a minimum genus-level identification, can direct the sanitation teams on how to treat or eliminate the particular organism source. Without microbiological identification, sanitation teams may employ improper treatments, possibly not eliminating a problem organism. Or, just as likely, use a treatment that is too costly when a “simpler” treatment could be used.



SOURCES AND TYPES OF CONTAMINATION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

MOLD IDENTIFICATION CHART



Cleanup, U. F. (2023, November 17).

Biofilms may be of particular concern. If these are allowed to be established, usually through improper or infrequent cleaning, they can be extremely difficult to eliminate. They also may resist treatments or release or transfer the organisms post-disinfection (4).

Mold growth warrants specific mentioning. Mold is extremely fastidious and, once established, can be challenging to eliminate. Often, floor-level mold contamination occurs when there may be moisture and nutritional sources that do not exist in other areas of the critical environment. Visual elimination of mold contamination is insufficient. And again, an identification is helpful.

SOURCES AND TYPES OF CONTAMINATION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

Mold spores are of concern as they are extremely prolific and can become widespread in the environment. Spores being so small in size and their ability to become airborne can cause them to lodge in cracks and crevices that are nearly impossible for routine cleaning to reach. If established on the floor-level, foot and wheel traffic can move this contaminant throughout the whole facility.

Particulate contaminants can be generated from cellulose fibers of disinfecting cloths, poor quality gowns, human origins, metals, rubbers, plastics, etc. as shown earlier. Sizes can be from visible (>100µm) to sub-visible throughout various industries (Figure 2). Particulates that settle onto floors can be further deteriorated and transferred through wheel and foot borne modes.

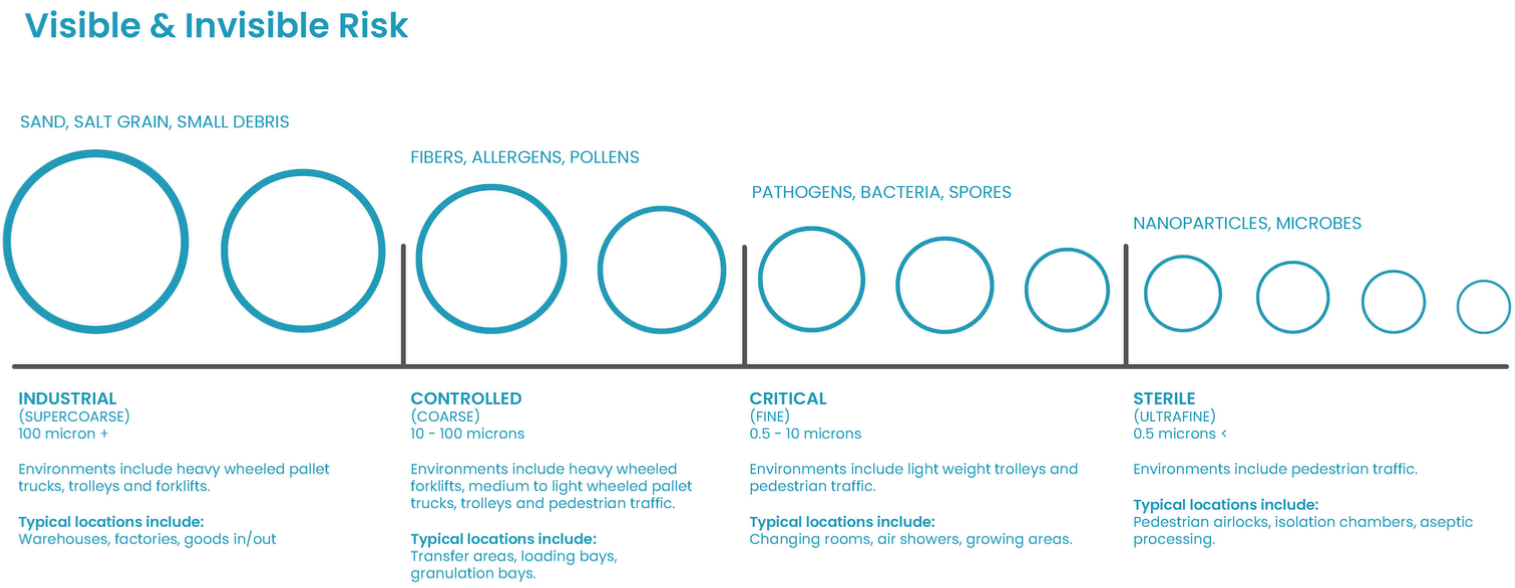


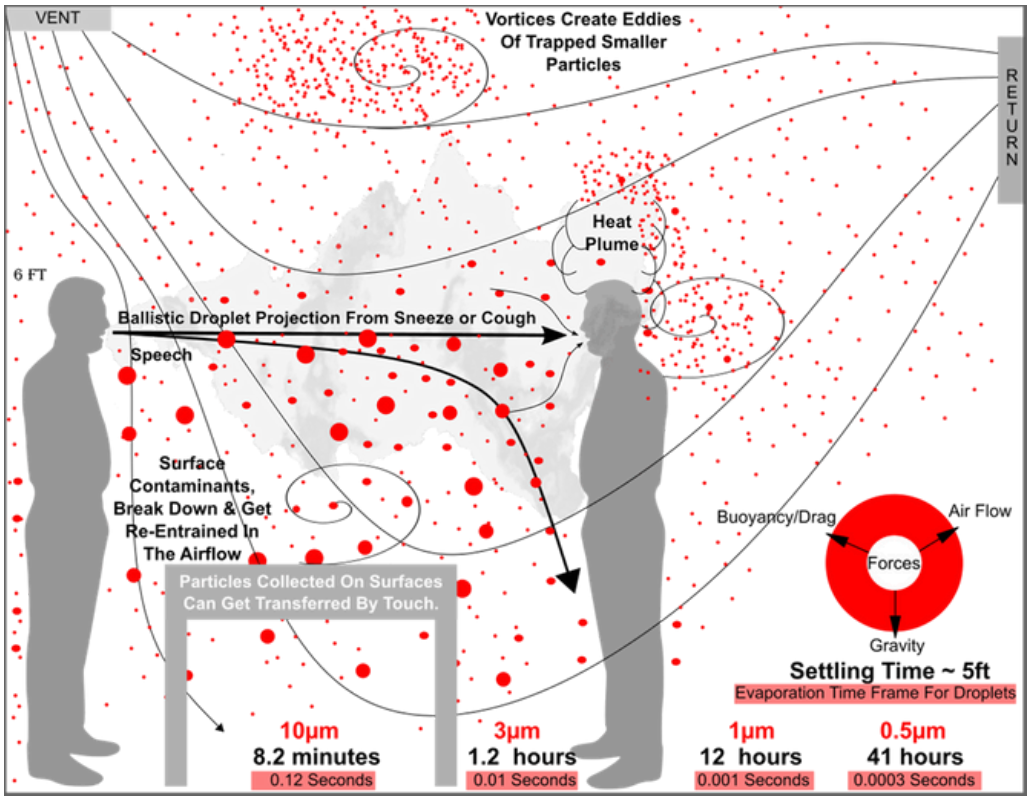
Figure 2. Particulate Sizes

PARTICLE SETTLING

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

PARTICLE SETTLING:

The rate at which particles settle from the air plays a crucial role in contamination control. In a room with an eight-foot ceiling, the settling time can vary significantly. Only about 5%-10% of particles are heavy enough to fall to the floor. When these particles are stepped on, they can break into smaller, finer particles, often less than 1 micron in size. Particles smaller than 1 micron are so light that gravity has little effect on them, causing them to remain airborne for extended periods and making them difficult to control.



BROWNIAN MOTION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

BROWNIAN MOTION

Once particles have settled on the floor and broken into smaller particles, they can become subject to Brownian motion, causing erratic movement through the air. This poses a serious concern as it becomes difficult to predict where the particles may eventually settle. In a cleanroom without an effective contamination control system, personnel movement can disturb these particles, allowing them to be reintroduced into the air and potentially contaminate surfaces at operator level or come into contact with products.

Particles smaller than 1 micron have extremely low settling velocities and are easily influenced by air movement, such as that generated by hot machinery or equipment. For particles smaller than 0.3 microns, Brownian effects dominate, causing random motion that keeps them almost indefinitely suspended in the air. This unpredictable movement increases the risk of contamination in critical environments.

BROWNIAN MOTION...

DESCRIBES THE RANDOM MOTION OF PARTICLES SUSPENDED IN AIR

SOURCES AND TYPES OF CONTAMINATION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

Both particulate and microbiological contaminants carried on trolley wheels are a noteworthy source of risk. The rough texture seen on trolley wheels can easily hold these contaminants.

The motion of wheel movement can be significantly greater than human foot traffic. While a person may stand in a particular spot with little movement while operating, they often move a trolley quite frequently in a space around them.

Trolley wheels can subsequently have numerous rotations in a small area and, if contaminated, can release particles, which will be deposited into the air stream.

Lets revisit Table 1 from page 4.

Source	Potential Contaminants
Air System/Air Handling	Microbiological, dust
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Shoe covers	Fibers
Shoes	Soil, microbiological
Trolley wheels	Soil, microbiological

Table 1. Potential Source of Contaminants

REDUCING RISKS CONTROLLING AND MITIGATION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

To achieve the highest standards of cleanliness in a cleanroom, it's crucial to stop particles and microorganisms from entering critical areas from the surrounding environment.

GMP guidelines and quality assurance measures require that contamination, both particulate and microbial, be kept to a minimum to protect products from any potential exposure.

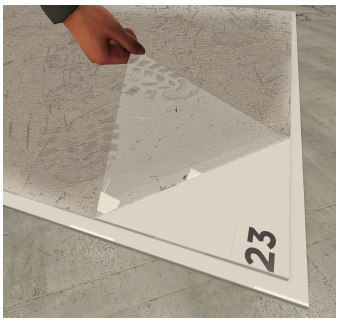
In the case of potential floor-level microbiological contamination, prior to reducing the risk, it is important to understand the potential floor flora beforehand. A few questions must be asked:

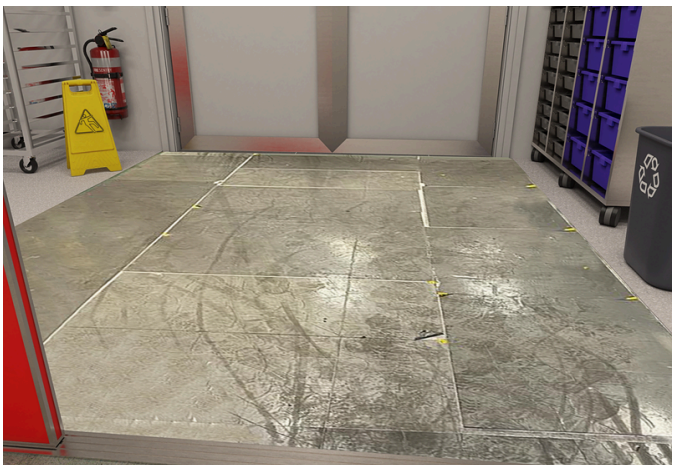
1. Are pharmaceutical environmental monitoring programs currently testing surfaces like floors and trolley wheels for contaminants?
2. Should swabs or contact plates be used for this testing? If so, when and how should they be applied?
3. Is there a clear justification for conducting or not conducting these tests?
4. Could trolley wheels carry contaminants such as mold, mold spores, or soil?
5. If trolley wheels are disinfected, are there protocols in place to address potential contamination between cleanings, in case the cleaning process is insufficient or incomplete?
6. Would it be beneficial to occasionally include trolley wheels in environmental monitoring programs, particularly if the trolleys move between different rooms?

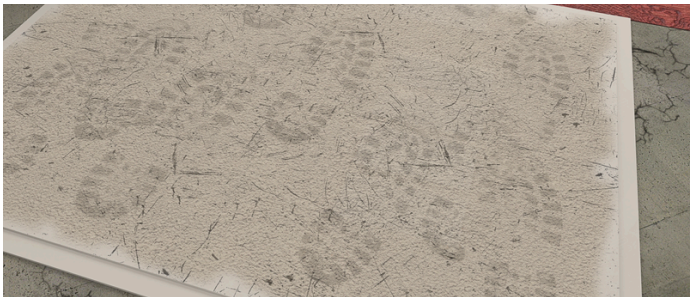
PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

The most common form of floor-level contamination control in a pharmaceutical manufacturing environment is peel-off ‘tacky-mats’ or ‘sticky mats’. The estimated annual global spend, in the healthcare industry (which includes pharmaceutical manufacturing), on peel-off mats is thought to be $350m, which is the second largest consumable spend after gloves.







PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

Peel-off mats are layers of plastic sheeting, usually 30-60 layers coated in adhesive. The mats rely on adhesive strength to remove particulate from feet and wheels. Once the adhesive strength has diminished through saturation and/or transfer of adhesive material, the top layer of plastic is peeled to expose a fresh layer of adhesive. They are available in range of sizes from 18" x 36" to 36"x 60", although typically they are 24" x 36".

Peel-off mats are typically placed outside of a critical area, at the entrances to a cleanroom/controlled environment, in personal airlocks, or in materials airlocks.

SIZE:

Put simply, peel-off mats are too small to effectively decontaminate feet and wheels. It has been established that in order to effectively control foot-borne contamination at least 6 footfalls (3 on each foot) need to meet the contamination control surface. For wheel-borne contamination, a minimum of three wheel rotations need to be achieved on the contamination control surface (3).

Figure 3. Stepping Around the Peel-off Mat

PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

A single peel-off mat will only allow for 1 or 2 footfalls (as displayed in Figure 3) on the adhesive surface and in some cases can be avoided all together. With such a small surface area, it is incumbent on the operators to step on the mat several times with each foot to achieve 6 footfalls. This practice is inconvenient and could be overlooked during day to day operations.

For wheeled traffic, it is not possible to achieve three wheel rotations without 'ganging' several peel off mats together to make a larger surface area. This 'ganging' practice is problematic as it creates 'gaps' where contaminants can gather.

PARTICLE TRANSFER:

Numerous studies have shown that peel-off mats are ineffective at containing particulate matter and, in some cases, can result in an increase in particulate matter on the foot or wheel (6). It is thought that this is due to the adhesive quality of the mat quickly diminishing after one footstep. Therefore, when another operator steps in the same place (overstrikes) on the peel-off mat, more particles are deposited onto the shoe than are removed.

Figure 3A. Particle Transfer on Peel-off Mat

> "We had 'suffered' the classic sticky mats for many years..."
>
> *- Nigel Disney, Ontic*

PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

PARTICLE TRANSFER:

Sandle (6) also showed that the act of peeling an adhesive mat generates a relatively high number of airborne particles and this number of particles is highest when the mat is heavily soiled. The level of airborne particles increases when the top surface of the mat was peeled quickly. So again, it is incumbent on the cleanroom operator to peel the top layer in a controlled manner to minimize airborne particle transfer. This can exasperate any floor-level contamination into the cleanroom or critical space.

WHEELED TRAFFIC:

As already discussed, most peel-off mats are too small to allow three full wheel rotations of any cart or pallet jack that is being driven over them. Another issue with wheeled traffic is the plastic sheets wrapping around the wheels of the cart/pallet jack and jamming the wheels. This is not only inconvenient but poses a health and safety risk.

Peel-off mats are not designed to handle heavy wheeled traffic, such as motorized palate jacks or forklift trucks. A pallet jack could easily tear through multiple layers of plastic, rendering them useless and in need of replacement, leading to increased cost.

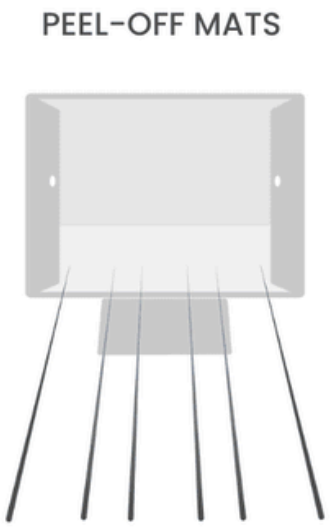


Figure 3B. Wheels marks on Peel-off Mat

PEEL-OFF MATS

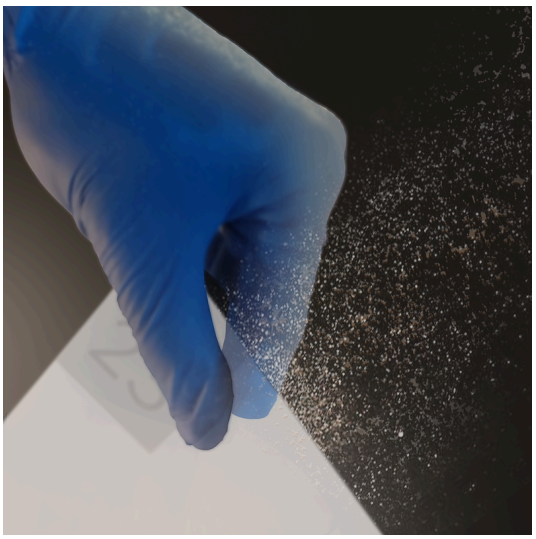
FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

HEALTH AND SAFETY:

In pharmaceutical manufacturing environments, peel-off mats pose several health and safety risks that should be carefully considered.

First, peel-off mats can present a tripping hazard. There have been numerous reports of operators tripping due to the mats being overly adhesive, causing them to lose balance, or because the mats delaminate from the subfloor, with raised edges or corners creating a tripping risk. Additionally, shoes or shoe covers may stick to the mat, increasing the likelihood of falls.

Another concern is the strain placed on cleanroom operators. Peeling off a layer of the mat requires bending and significant physical effort, which can lead to back strain or injury if not performed properly.



Lastly, peel-off mats can release particles into the air during the peeling process. Since operators are often in close proximity to the mat when peeling, there is a risk of inhaling contaminants that are dislodged into the environment. This reintroduction of particles can compromise the sterile conditions of the cleanroom.

These risks highlight the need for safer, more effective contamination control solutions in sensitive environments like pharmaceutical manufacturing.

PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

CONVENIENCE:

Peel-off mats are often regarded as a convenient and easy solution for floor-level contamination control. They can be ordered as needed, quickly self-installed, and require no cleaning to maintain their adhesive surface—simply peel away the soiled top layer and dispose of it.

However, peel-off mats need to be replaced frequently. With most mats consisting of 30 layers, daily peeling requires replacement roughly once a month. Replacing a mat can be time-consuming, as any adhesive residue left on the floor must be cleaned, and the new mat must be carefully placed to avoid air bubbles. Additionally, the subfloor must be thoroughly sterilized to eliminate any microbial contaminants before installation. This process may require temporarily closing the area to ensure proper mat placement and contamination control.

Storage is another challenge. Peel-off mats must be stored correctly to prevent damage or warping before use, which can consume significant shelf space depending on the facility's usage volume. These factors complicate what may initially seem like a simple solution, highlighting the need for more efficient and reliable contamination control alternatives.

DID YOU KNOW...

Scientific testing shows that sticky mats are only 27% effective in preventing contamination from foot and wheel traffic

READ THE STUDY

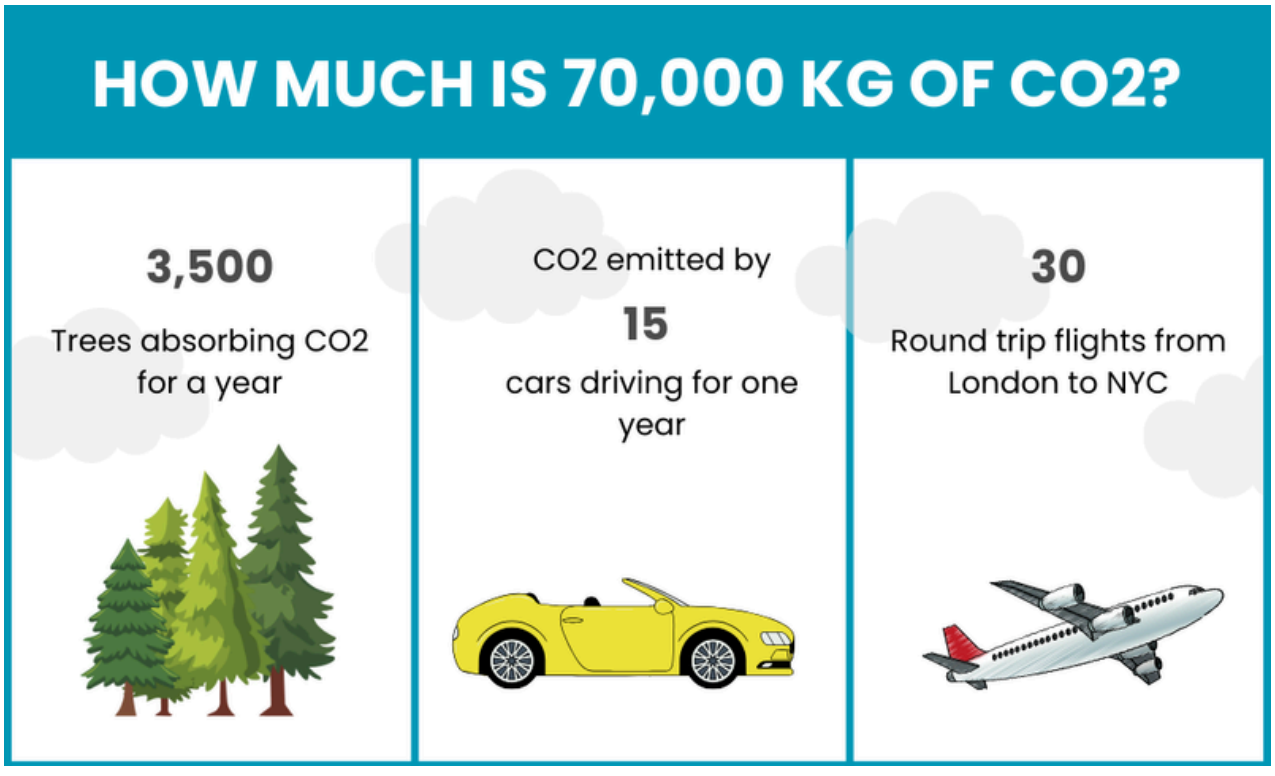
PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

ENVIRONMENTAL:

Peel-off mats are made up of multiple layers of plastic and adhesive, both of which are non-recyclable. After use, these layers are typically disposed of in general waste (following decontamination) or in contaminated waste drums for incineration. Research indicates that peel-off mats are less environmentally sustainable compared to other floor-level contamination control methods.

One study found that a pharmaceutical manufacturing facility using peel-off mats in 10 locations could generate up to 70,000 kg of CO2 from the production process, with an additional 55,000 kg of CO2 emitted during disposal, assuming incineration is used. (4)



PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

ENVIRONMENTAL:

If the mats are not incinerated, disposal presents further environmental challenges. Many peel-off mats are made with acrylic adhesives and polyethylene film, which require costly removal of the adhesive before the remaining materials can be landfilled. Additionally, contaminated mats from healthcare settings must undergo decontamination prior to landfill disposal.

Because these mats are non-recyclable, any that are not incinerated contribute to landfill waste, exacerbating the global plastic waste crisis. This highlights the significant environmental impact of peel-off mats compared to more sustainable alternatives.

COSTS:

Peel-off mats are often considered an immediate cheaper option for floor-level contamination control; however, the costs vary significantly depending on size and the manufacturer/supplier. When analyzed over a three to five year period, the cost of using peel-off mats is considerable.

On average, the cost per peel of a peel-off mat is around $0.50 before the cost of disposal is added. If the peel-off mats need to be de-contaminated prior to disposal, the cost per peel can as much as double. A 24/7 facility peeling mats 5 times per shift, 3 shifts per day, will spend as much as around $9,000 per annum per peel-off mat location.

These costs can increase through poor operator behavior, peeling more than one mat at a time, or taking heavy loads across the peel-off mat, causing damage.

PEEL-OFF MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

COSTS:

The average cost per peel is approximately $1.00, and in a 24/7 facility, a single area could require up to 5 peels per shift, with 3 shifts per day, leading to significant usage. Additionally, disposal costs, if applicable, can double the overall cost per peel. Poor operator behavior, such as mishandling, can contribute to increased waste, damaged mats, and additional sunk costs, further impacting overall efficiency and expense.

SHOE COVERS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

There are various options for preventing floor-level contamination from entering controlled spaces, with shoe covers being one of the most commonly used forms of personal protective equipment (PPE) in pharmaceutical manufacturing environments. These disposable, slip-on garments fit snugly over the operator's shoes to prevent potentially hazardous contaminants from being introduced into the controlled environment and tracked to other areas of the facility or beyond.

While shoe covers provide a simple solution to contamination control, several challenges need to be considered. They pose a significant slip-and-fall hazard, particularly when crossing demarcation lines. Additionally, a single pair generates substantial waste, especially when multiple layers are used to prevent contamination between cleanroom grades. Variations in material and manufacturing quality can lead to issues like particle shedding, rips, and tears that can actually increase contamination risks. Improper donning can also result in bacteria transfer from shoes to hands.

Although automatic dispensers and removers can mitigate some of these challenges, they introduce added costs and time constraints. Furthermore, shoe covers are not compatible with tacky mats, complicating contamination control efforts even more.

9 TIPS TO IMPROVE YOUR CONTAMINATION CONTROL STRATEGY (CCS)

BY DR TIM SANDLE

A Contamination Control Strategy (CCS) is critical for industries like biotechnology, food production, healthcare, and pharmaceuticals to minimize contamination risks. Based on scientific principles and a risk-based approach, a CCS must cover the entire product lifecycle and be regularly updated.

Regulatory compliance, like EudraLex Annex 1, requires a CCS to ensure sterile product manufacturing. Beyond compliance, a CCS prevents quality issues and costly recalls, while supporting audits and inspections.

Effective CCS implementation focuses on these 9 key tips:

1. **Contamination Control Ambassadors:** Promote best practices and raise awareness.
2. **Continuous Training:** Ongoing, engaging training for staff.
3. **Rapid Microbiological Methods:** Use fast, precise contamination detection.
4. **Preventative Maintenance:** Routine upkeep to reduce contamination risk.
5. **Environmental Feng Shui:** Apply risk management to facility design.
6. **Dycem Mats:** Use polymeric mats to control floor-level contamination.
7. **Surprise Audits:** Regular, unexpected checks for protocol adherence.
8. **Gap Analysis:** Identify and address weaknesses with continuous improvement.
9. **Strategize and Improve:** Evolve the CCS using data and root cause analysis.

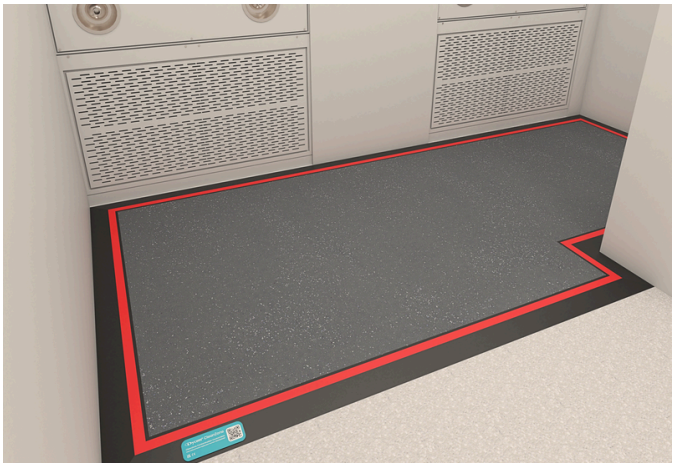
By addressing contamination risks proactively, a well-maintained CCS ensures product safety and cleanroom management excellence.

WATCH THE RECORDING

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

The most common form of floor-level contamination control in pharmaceutical manufacturing environments is peel-off “tacky mats.” However, the estimated annual global spend on these disposable mats in the healthcare industry, including pharmaceutical manufacturing, is around $350 million, making it the second-largest consumable expense after gloves. Polymeric mats offer a more sustainable, long-term alternative by trapping contaminants efficiently without the need for frequent replacement, significantly reducing waste and overall costs while maintaining high levels of contamination control.



POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

Polymeric mats consist of a polymeric surface manufactured from a non-toxic, plasticized material, which is extruded onto a non-permeable substrate. The polymeric surface is optically smooth, soft, and supple, with a natural tack and a high level of short-range electromagnetic forces (Van der Walls). Combined, these properties enable the material to retain particulate contamination (viable and non-viable) that comes into contact with its surface. The function of polymeric mats is to attract particles to their surface and retain them until they can be removed through cleaning and disinfection.

Most polymeric mats require professional installation and are fixed to the existing subfloor using adhesive tapes. They are usually fitted with a tapered edge, which is sealed to the subfloor to prevent the ingress of water and the growth of mold or other microbial contamination beneath the polymeric mat.

Polymeric mat manufacturers advertise a lifespan of 3-5 years - this is the length of time that the polymeric floor remains tacky and can effectively trap and retain particulate.

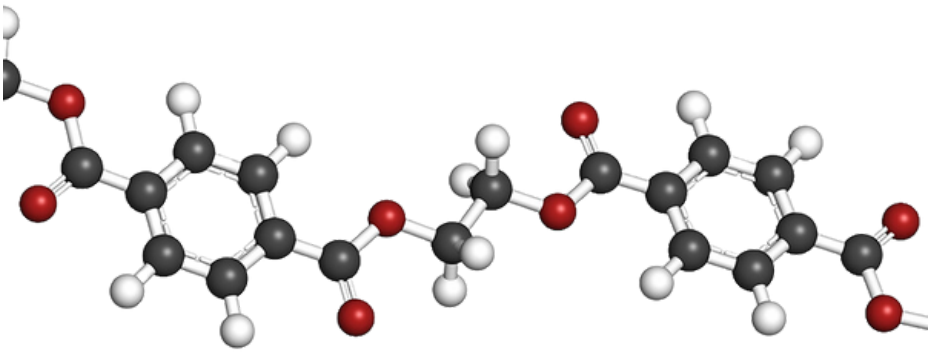


Figure 4A. Polymer Chain (8)

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

SIZE:

Polymeric mats are typically provided in rolls, with most manufacturers producing rolls that measure 6'6" wide and 40' long. The recommended minimum length is 10 feet, which allows for six footfalls or three full wheel rotations. However, the mats can be customized to accommodate any room size or layout.

For optimal performance, polymeric mats should be installed in a way that it cannot be bypassed—either wall-to-wall or spanning the entire doorway. This maximizes footfall contact during normal walking patterns, helping to reduce floor-level contaminants from entering critical areas (Figure 4).

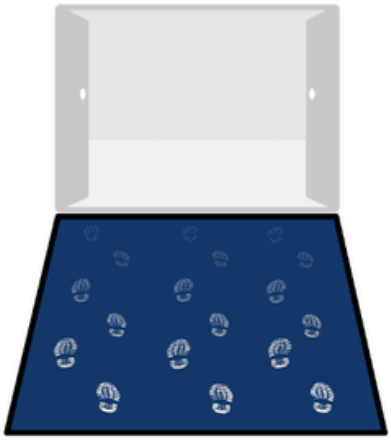


Figure 4. Footfalls on Polymeric mats

When installing polymeric mats, the volume of traffic should also be considered. High-traffic areas may require larger surface areas to prevent the mats from becoming saturated with contaminants between cleaning cycles.

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

PARTICULATE REDUCTION:

Research suggests that polymeric mats are a superior method of floor-level contamination control compared to peel-off mats.

Clibbon (3) swabbed cleanroom operators' footwear before and after walking across a peel-off mat and a polymeric mat (after making 4 footfalls on each surface). She also took swabs from trolley wheels before and after being pushed across both types of mats.

The results showed a reduction of 25.2% and just 11% in wheel and foot-borne contamination, respectively, after contacting a peel-off mat, compared to 99.8% and 99.9% after contacting a polymeric mat.

Sandle (6) analyzed the surface particle count of shoes and overshoes before and after walking across 6 different brands of peel-off mats and 2 polymeric mats mats (one new and one 2 years old).

The results showed a reduction in particles from shoes of between 20% and 52% after stepping on a peel-off mat, compared to a 77% reduction after stepping on an 'old' polymeric mat and an 82.1% reduction after stepping on a new polymeric mat.

READ THE STUDY

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

PARTICULATE REDUCTION:

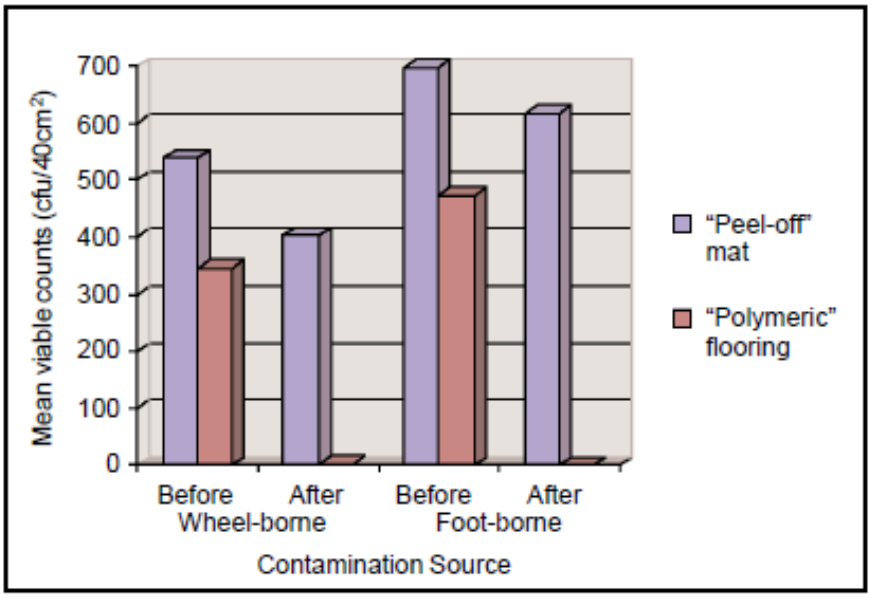


Figure 1. Graphical representation of mean viable counts for wheel- and foot-borne contamination, using Tryptone Soya Agar.

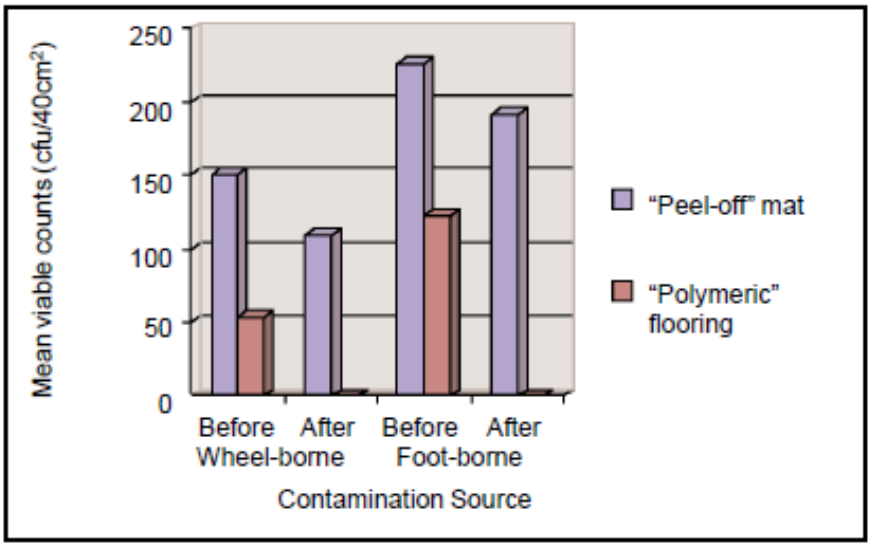


Figure 2. Graphical representation of mean viable counts for wheel- and foot-borne contamination, using Sabouraud's Dextrose Agar

Table 2: Results, Clibbon 2002 (3)

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

PARTICULATE REDUCTION:

When compared against peel-off mats, polymeric mats have been shown to be much more effective at reducing particulates of 10 microns and below. In his 2009 paper, Prout (4) examined studies carried out by the University of Bath and the University of Strasbourg. Both studies examined particle reduction from feet and wheels of particles of different sizes. For polymeric mats and peel-off mats above 25 microns, the performance is mainly similar; however, for particulates of 10 microns or smaller, the results are radically different:

See Table 2 & 3.

Reduction in particle count (%)			
	2 microns	5 microns	10 microns
Polymeric flooring	71.1	64.9	68.4
Peel-off mat	15.2	43.1	38.1

Table 3. Particulate Reduction Data

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

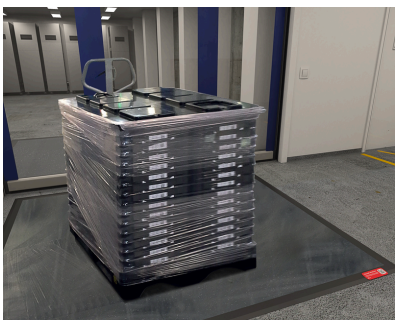
WHEELED TRAFFIC:

As stated above, polymeric mats are the superior system for removing particulates from wheeled traffic. The primary reason for this is likely due to the size of the contamination control area and the ability of the wheels to achieve multiple rotations on the mats.

Other practical considerations that further support the use of polymeric mats in areas where wheeled traffic will be present include;

- Polymeric mats are 'tacky', not 'sticky', and most manufacturers install the mats with a diminishing edge strip that allows a smooth transition onto the mats. Therefore, carts and trolleys can pass easily across the surface without interrupting the cargo.
- Manufacturers of Polymeric mats advertise a load capacity of up to 1200 pounds per square inch, meaning that very heavy loads can pass across the mats without causing damage to the material.
- The only other method of effectively cleaning wheels of carts is to spray down and wash them with anti-microbial disinfectants. This is a time-consuming method and will have varying results depending on the diligence of the cleanroom operator. Polymeric mats have been shown to be 99.9% effective in some studies, so it might be considered a more efficient and 'fail-safe' way of ensuring the cleanliness of wheels than the washing method.



POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

HEALTH AND SAFETY:

Polymeric mats offer significant advantages in environments like pharmaceutical manufacturing, where cleanliness and safety are paramount. Its smooth, non-porous surface allows for easy and effective cleaning with industry-standard antimicrobial disinfectants, reducing the risk of contamination without posing health hazards to humans or the environment. Unlike peel-off mats, polymeric mats provide a more permanent, low-maintenance solution that minimizes waste and labor.

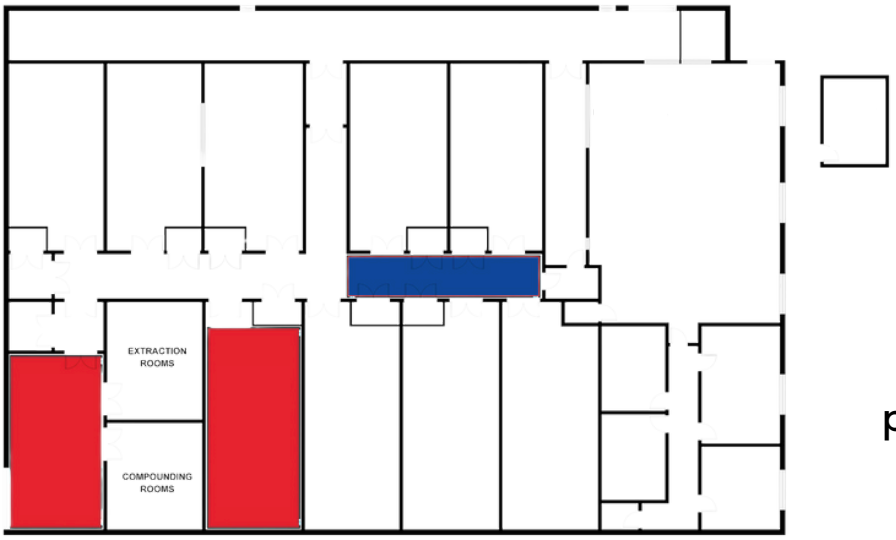


Figure 4: Potential placement of polymeric mats

Additionally, polymeric mats contribute to a safer work environment by offering a non-slip surface that reduces the likelihood of slips and falls. However, it's crucial to understand that while it maintains slip resistance under dry conditions, the surface can become slippery when wet. Therefore, its installation should be limited to areas where water exposure or standing water is not a frequent issue. In environments prone to moisture, careful planning is required to ensure optimal safety and functionality, such as incorporating proper drainage systems or pairing the mats with other safety measures.

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

ENVIRONMENTAL:

Polymeric mats are not subject to the same environmental concerns as peel-off mats. Polymeric mat products avoid the waste of resources associated with the manufacture and disposal of adhesive peel-off mats.

In a facility using polymeric mats in 10 locations, totaling 2,800 ft2, the kg of CO2 produced for the manufacture and disposal (incineration) of the mats is just 4,620kg (5).

Should the polymeric mats be used in environments where hazardous substances are present, they can be easily cleaned using antimicrobial disinfectants, eliminating the costs associated with decontamination before disposal.

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

CONVENIENCE:

Polymeric mats are overall easier to use for reasons listed previously; however, adding this solution to floor-level contaminations can involve several teams within an organization.

As stated, the mat does need to be professionally installed, and this may require, in some cases, for the area to be closed for several hours to allow for the installation to be completed. Once the polymeric mats are installed, very little maintenance is required, and as noted above, the floor has a life span of 3-5 years, so it does not require constant replacement.

Polymeric mats do need to be cleaned in order to remain effective; however, the cleaning schedule can usually be incorporated into the Standard Operating Procedures for floor cleaning.

While it may take longer to implement than peel-off mats, and the process of cleaning may take longer than the process of peeling a layer from a peel-off mat, the benefits outweigh the time invested in implementing and maintaining.

POLYMERIC MATS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

COSTS:

At first glance, polymeric contamination control mats may seem to have a higher upfront cost when compared to traditional peel-off mats. However, when analyzing the mats' typical lifespan of 3-5 years, most facilities will experience significant cost savings. This long-term value becomes particularly clear when considering the recurring expenses associated with peel-off mats, which require constant replacement and disposal.

For example, in a facility spending approximately $9,000 annually on peel-off mats for each location, switching to polymeric mats offers a much quicker return on investment. By installing polymeric mats, the facility would offset the initial expense within the first year of use, as the one-time installation cost eliminates the need for ongoing mat replacement and waste management. Over the full lifespan of the mats, these savings would accumulate even further, reducing operational costs and lowering the environmental footprint due to reduced waste.

SANITATION METHODS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

SANITATION METHODS:

Whatever approaches are taken to control or mitigate microbiological floor-level contaminations, a good checklist to use includes the following:

- Is the method able to kill the organism in question?
- When applied, will the method achieve good and complete distribution on the floor?
- When applied, will the method achieve thorough and total penetration into cracks, crevices, and other difficult-to-clean areas?
- When applied, will the method be able to achieve sufficient contact time at a concentration to kill but not destroy equipment?

Options to decontaminate a microbial-contaminated floor need to include sterilants to fully eliminate bacteria, yeast, viruses, molds, and spores (which are the most difficult to eliminate).

SANITATION METHODS

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

STERILANTS:

Chlorine dioxide in its gaseous phase and properly administered has proven highly effective and less problematic than other methods (2). Because it is a gas at room temperature, the gas can fully penetrate a space where fogging, vapors, foams, or fluids cannot. Vaporized Hydrogen Peroxide and other chemicals and combinations can be effective in limited capacities such as smaller spaces.

UV-C LIGHT:

UV-C light is an effective decontamination method for the floor-level. Devices that contain UV-C light can be angled or directed, or swept across a floor and decontaminated. UV-C Light is an inexpensive, safe, and effective option. However, anything not in the direct path of the light will not be killed.

UV Robots have become very popular in the fight against SARS COV2

Portable Hydrogen Peroxide unit by Bioquell

CONCLUSION

FLOOR-LEVEL CONTAMINATION IN PHARMACEUTICAL MANUFACTURING

CONCLUSION:

Floor-level contamination in pharmaceutical manufacturing environments is a critical concern that must not be overlooked. Unlike contamination from operators, the sources at floor-level are often less visible but just as significant. Effective cleaning and sanitization methods need to be paired with comprehensive environmental monitoring to maintain awareness and control of contamination risks within these sensitive areas.

Adopting company-wide mat solutions designed to minimize contamination from wheeled and foot traffic has shown to be highly effective. While developing and implementing such a strategy may require a considerable investment of company resources, the benefits to both product integrity and personnel safety are invaluable. A well-thought-out mat strategy not only enhances contamination control but also strengthens overall operational efficiency in critical environments.

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Disclaimers:
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