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Reducing Particle Contamination via Ionization in Medical Device Manufacturing Gown-Up and Product Transfer Rooms

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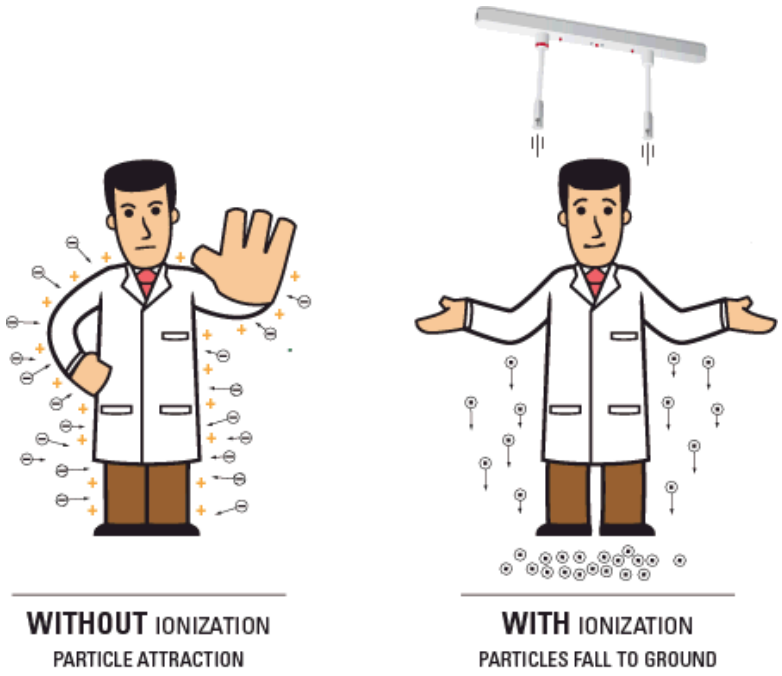
Ionization systems, installed in medical device manufacturing facilities *gown up rooms* and product *transfer areas*, have proven to be critical components in reducing particle counts in the associated clean room production and assembly areas. These reduced particle counts translate into substantial reductions in yield losses and rework.

Particle Contamination Issues During Gown Up Procedures: We begin by discussing the particle contamination issues in gown up rooms. Operating personnel enter gown up rooms to prepare for entry into the final clean room environment where the medical devices are processed. Without any static mitigating techniques, the operators and their clothing are statically charged causing substantial particle attraction. If these particles are not eliminated at this point, they remain statically attached to them and are carried into the clean room and can wind up eventually on the products being manufactured, causing yield losses and/or rework.

For lowest possible particle counts in a clean room, it is critical to remove as many particles as possible in the gown up room areas so that they are not carried into the clean rooms. Simple air showers or blowers have proven to be *not* very effective in this regard, as the particle attraction forces are typically greater than the blow off operation (with regular air). When ionization is used to eliminate the static attraction root causes, particles are "loosened" and can be eliminated all together from entering the clean room.



Similar static attraction issues can of course exist inside the clean room as well. When plastics or other insulative devices are contacted, rubbed, handled, etc., they generate tremendous static charges. When these products are charged, they attract drastically more particles to their surface than their non-charged counterparts.

What is Ionization? Air ionization is the most effective method of eliminating static charges on non-conductive materials and isolated conductors. Air ionizers generate large quantities of positive and negative ions in the surrounding atmosphere, which serve as mobile carriers of charge into the air. As ions flow through the air, they are attracted to oppositely charged particles and surfaces. Neutralization of electro statically charged surfaces can be rapidly achieved through the process.

Air ionization may be performed using electrical ionizers, which generate ions in a process known as corona discharge. Electrical ionizers generate air ions through this process by intensifying an electric field around a sharp point until it overcomes the dielectric strength of the surrounding air. Negative corona occurs when electrons are flowing from the electrode into the surrounding air. Positive corona occurs as a result of the flow of electrons from the air molecules into the electrode.

It is noted here that insulative materials such as plastics, glass, rubber, ceramic, etc. will ***not dissipate their charge when grounded***. Only bringing air ions close to their surface via ionization equipment removes the charge (which resides on the surface of the insulator).

How Does Ionization Help? Ionization equipment employed in a gown up room "loosens" the particles on personnel by eliminating the attraction force and a great majority of the previously adhered particles will literally fall off of the person and their clothes due to gravity - even in the absence of any additional airflow. Incorporating additional ***ionized*** air flows (ionizing air showers, ionizing blowers, etc.) is effective at eliminating even more of the unwanted particles from entering the clean room.

Ionization Techniques in Gown Up Rooms: Many different types of ionizers exist in the marketplace. As with most technologies, certain types are better for certain applications. For gown up room applications, to remove particles from people and their clothing, we discuss the following:

- ***Room System Ionization Equipment***: A common and quite effective technique is to outfit the gown up room with a complete room ionization approach. Ionizing "pods" attached to the ceiling in a grid formation generate the ionization and all areas in the gown up room are covered with ions, removing static charges on all objects, people, and on the particles as well. There is no additional air flow associated with such ceiling pod systems. Waves of positive and negative ions are generated, and can go long distances in this arrangement. (A typical ceiling configuration for room ionization systems is shown below.)

Ceiling Mounted Room Ionization System in Gowning Room

The ionization pods should be located intelligently in the room to bathe personnel for the maximum amount of their time during the gown up process. Pods above hand washing sinks and above the benches where footwear is installed are areas where personnel spend more time in a stationary position, and are key areas of implementation.

- ***Overhead Ionizing Blowers***: In addition to the room system ceiling pod approach described above, it is possible to remove even more particles by installing overhead ionizing blowers at the ideal positions in the gown up room. Specifically, a strong ionizing blower should be located just inside the street entrance to the gown up room, and another similar ionizing blower just before the entrance to the clean room. In this way, particles are removed from personnel as they enter into the gown up room in their street clothes, and also when they are subsequently gowned and are ready to enter into the clean room. (A typical 4-fan overhead ionizing blower is shown below.)

4-Fan Overhead Ionizing Blower

- ***Vacuum Systems to Collect Particles***: Once particles have been eliminated from personnel via the ionization techniques, it is desirable to remove them *entirely* from the gown up room so that they are not available to relocate on personnel at a later point in time. Underneath the overhead ionizing blowers described above, at the very least, an industry standard blue tacky mat located on the floor can be utilized to "catch" and retain the particles that have fallen off of the personnel. A much more effective approach, although costlier, is to implement a floor mounted vacuum vent that personnel will stand on underneath the ionizing blower. Very good results from a number of facilities have

been observed with such a floor vacuum vent underneath the ionizing blower. The additional effectiveness of the floor vent vacuum system (versus the tacky mat approach) can be measured via clean room particle counts.

Similar Issues in Transfer Rooms: In typical medical device clean room manufacturing facilities, there are dedicated "transfer rooms" where product is staged before entering the clean room. These transfer areas are not typically a part of the clean room and can be less than clean. If this area is not ionized as well, substantial amounts of particles once again find their way into the clean room. The basic issues are reviewed below in a typical example of transfer room process steps that don't include ionization:

- Most manufacturers use a "double bag" packaging technique to keep incoming product clean. In principle, this is the correct approach. However, care must be taken to avoid static attraction issues. Widely across the industry, no precautions are taken (unfortunately).
- First, the double bagged product typically comes from a warehouse area into a transfer room for staging. There are typically enormous amounts of particles on the outside of the outer bag due to it being highly charged in the warehouse, attracting particles continuously while charged. The outer bag is then removed and discarded. Without ionization in place here, the inner bag is highly charged as well and attracts particles found in the transfer room and also from the outside bag that is removed.
- Then, the "single bagged" product is transferred into the clean room with substantial particle contamination on the outside of that inner bag, due to its highly charged exposure in the less than clean transfer room. Thus, all sorts of unwanted particles enter the clean room on the outside of these single bagged products. *It can be common for the single bagged product to sit in the transfer room for hours and hours; continually attracting particles to the outside of the bag the entire time that it remains charged.*
- Inside the clean room, the single bag is opened and the product inside is then exposed. Charge redistribution takes place, and particles on the outside of the bag can rush inside the bag and end up all over the product (and also all throughout the clean room).
- To avoid these **incoming issues**, ionization should be in place in the transfer room to bathe and blow off the double bag first before its removal and also to bathe the inner bag as soon as it is exposed so that it does not attract massive amounts of particles while it sits in the transfer room. Room ionization, overhead ionizing blowers, and ionizing guns (or a combination of all of them) can all be used effectively here. The bottom line for particle control is to insure the static charges are always removed during the bag removal processes and to keep the single bag free of charge during the entire length of time it sits in the transfer room.

Similar issues exist as well when ***packaging final product for shipment*** to customers as follows:

- In the final stage of manufacturing, finished product is sealed in its packaging and then placed into its inner bag in the clean room.
- Many facilities then move the single bagged product out of the clean room to the (non clean room) transfer area to cover with the outer bag. As the inner bag is charged typically, it attracts particles in the transfer area on the outside of the inner bag before the outer bag is applied.
- Now, when the product reaches the customer and the moment the inner bag is opened, charge redistributes and the particles on the outside of the inner bag find their way onto the product itself. This has been a common occurrence in our past experience at many customer facilities. The product leaves the manufacturing site perfectly clean, but attracts contamination from the outside of the inner bag when it is opened initially at the customer site. Customers then reject the product as particle contamination is observed on it, assuming that the particle contamination took place during manufacturing.

The attraction of particles to charged product also is a worry in the clean room. Ionizing the gown up and transfer rooms is only a piece of the puzzle. Ionizing the clean room as well is needed for full elimination of *static-related contamination issues* (which are historically the biggest root cause of particle contamination in the medical plastics industry[1]). However, the cost for addressing the gown up room and the transfer area is relatively **very** small while providing a ***huge*** benefit, both in terms of reducing particle counts overall in the clean room and also reducing subsequent yield losses and rework attributed to particle contamination. In addition, by implementing these small first *affordable* steps, the facility can acquire in-house data immediately on the effectiveness of ionization for particle control. Good future decisions on the expansion of ionization into other areas in the facility, without risk, can be made on the basis of the documented internal improvements observed with these initial small implementations.

Particle Count and Yield Loss Reductions: I have worked with over 100 medical device manufacturers since 2006. My involvement and goal as a consultant in each of these facilities was to reduce particle contamination yield losses. As non-disclosure agreements prevent the publishing of their data and results, I will summarize here anecdotally:

- Each and every facility (100%) that has done the testing has measured substantially reduced particle counts in the clean room when ionization has been implemented in the gown up room. Many facilities conducted experiments where they would turn the ionization systems on and off in the gown up room and observe the correlated rise and fall of their clean room particle counts. Almost all facilities in this industry have particle count measurement equipment, so this is an easily verifiable experiment to conduct.
- Yield improvements were observed in ALL cases when ***only*** gown up room ionization was implemented. The **typical** reduction in yield losses due to particle contamination was 25%. That reduction was totally due to just the gown up room ionization. That is a huge return on a very small investment!
- When room ionization is implemented throughout all areas in the facility (i.e., the gown up rooms, transfer areas, and clean rooms), a very large majority of the contamination losses previously experienced on an ongoing basis were eliminated (80-90% typically). To date, the *lowest* reduction in losses observed in any of the facilities was 50%. The *highest* reduction was over 95%.

Summary: Implementing ionization solutions in medical device manufacturers' gown up rooms and transfer rooms is a significant first step in the process of reducing particle contamination. From these two low cost implementations, particle counts are reduced in the clean rooms and yield improvements result. Implementing total ionization coverage throughout all areas in the facility provides the maximum benefit for particle contamination reduction. But by implementing these small first *affordable* steps, the facility can acquire in-house data on the immediate effectiveness of ionization enabling good future decisions for the implementation of additional ionization for the clean room and other areas.

References:

1. R.J.Peirce, *"**Confronting Static Attraction in Medical Plastics Manufacturing**,"* MD&DI, August, 2011.

About the Author:

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