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Cleanroom Molding vs Traditional Molding is it worth the money?

Many times there are misconceptions surrounding cleanroom molding. The biggest misconception is cleanroom molding generates “sterile” parts. While considered “clean,” parts molded and packaged in a cleanroom still are not sterile.

The purpose of a proper cleanroom is to minimize the amount of particulate and bioburden which can find its way onto the surface of the part. Particulate is controlled by HEPA air filtration and by specific industrial hygiene protocols – surface cleaning and personal gowning procedures. In addition to the particulate controls, a proper cleanroom system will also include a microbial (bioburden) testing and monitoring system.

A cleanroom facility addresses air cleanliness at the design stage. This is done by surface selections, pre HEPA and HEPA filtration, air lock rooms and the selection of appropriate equipment suitable for operation in a cleanroom.

Surfaces selected for walls, ceilings, floors and work surfaces must be easy to clean and be made of materials that will withstand the cleaning materials that alternate between sanitizer and alcohol based cleaning agents.

HEPA filtration must be sized for the appropriate air flow which will generate the number of air turns within the room to achieve the designed particulate levels in the room. If a “non-recycling” filtration system is used, pre-filters will greatly extend the life of the HEPA filtration media which is much more expensive to replace when air flow performance decreases past an acceptable level.

Gowning rooms and appropriate air locks – including proper procedures – must be incorporated to minimize contaminating the cleanroom while bringing product and personnel in and out of the room.

The equipment and tooling used within the cleanroom must have the appropriate abatements in place to minimize the generation of contaminants by the equipment. With the injection molding equipment and processes, some potential areas of concern are: barrel heater band dust, drive belt residue, hydraulic oil vapor, resin dust, hose particles, metal (wear) dust, rust, lubricants, etc. These are contamination sources that should be considered as you specify the various equipment and auxiliary supplies used in the cleanroom. Particle count testing must be done with calibrated equipment to ensure the systems in place are performing as expected.

Bioburden testing can be done on the room air, work surfaces, the actual produced part surfaces or a combination of all of the above. Bioburden is the measure of organisms found on the surfaces or in the air that can make their way onto the product surfaces. This is done by exposing agar plates to either the air or by contacting them to surfaces. They are then sealed up and sent to a certified lab to be cultured. After culturing, the colony forming units, or CFU,s are counted to arrive at a bioburden level. The labs use a similar process by culturing the CFUs on the actual product produced. The bioburden level determines the appropriate type and level of sterilization of the product once it is packaged.

The personal hygiene protocols (hair nets, face masks, shoe covers, frocks, gloves, etc.) all are in place to reduce bioburden and particle contamination. Additionally, appropriate cleaning processes should be in place and followed. These are typically a rotation of sanitizing all surfaces with a sanitizer solution followed by cleaning with alcohol based solutions. Like the manufacturing processes, these schedules must be followed and documented to ensure they are meeting the system requirements.

While a general purpose molder may produce parts that meet all of the requirements of a cleanroom produced product, they typically do not have the controls or documentation in place to ensure all products being produced can meet the requirements of the device manufacturer. Unfortunately without physical systems in place, particle counts, and bioburden testing; it is impossible to prove to a device manufacturer your products meet their expectations for cleanliness and are ready, if needed, for sterilization.

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