



Superior quality. Pellet to pellet. Lot to lot.

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Clean rooms in the medical device marketplace are a requirement for device assembly. The environment provides for the quality control necessary to ensure a safe and clean process in all materials being assembled. Or does it? What if the most basic building blocks of your device are dirty and you don't even know it? What does the production area look like in which the most critical backbone of your device is being made? If you don't know for certain then you are running significant risk.

Simply bringing any given material or object into a clean room does not impart cleanliness to it. Items are often wiped down, rinsed, blown off or scrubbed thereby physically cleaning them in a range of methods. The environment in which any given material is produced prior to it arriving in a clean room is a topic that is rarely discussed. Small airlocks allow for the movement of parts into and out of a clean room environment but the clean status of the material prior to arriving at the airlock remains in question. A simple double bag does not mean it is clean.

Interventional devices and the parts associated with them are put under strict FDA review. Base materials, colorants, additives, secondary operations placing such things as ink or marker bands, braid/coil wires into and on the surface or internal walls are all given great scrutiny in filing reviews. In many cases these items are simply received in, put into the device and testing begins but was it clean when it arrived? Should you be testing or cleaning any given component more or less? The decision is yours but starting clean means you finish clean.

Compounding Solutions implemented the use of our White Room for all medical R&D and production materials in 2012. Our philosophy has been that starting with a clean product helps to ensure a clean final product. Pyrogen and Endotoxin studies on the inner or exterior surface of a part are major medical concerns. While gloved handling of finished products is a critical element in your assembly to help prevent excessive counts many issues are occurring before you have even received product for assembly.

Depending on how your vendor has built and operates their facility it may be adding risk to your raw materials. Ceiling drop downs for air, electrical wires or feed tubes can collect dust and other contaminants that can easily fall into open hoppers. Open water tanks capture the same environmental hazards as water baths do. Taking care to ensure it is all as clean as possible is a good first step.

Some history has been covered on the testing of pyrogens under FDA guidance and it may change again in the future however a focus on what can be done now starts with vendor selection. Companies either have the ability to help with cleanliness issues or they do not. Most compounders do not run products under anything close to white room conditions.

Our White Room operates under conditions similar to a clean room via laminar air flow conditions to ensure that no contamination enters the feeders of the compounding line. The walls and floors are all sealed so that in the event of some kind of contamination we can wash from the ceiling to the floor. We also took the extra precaution during construction to bring all of our electrical and water lines in from the ground up rather than using drop downs which can collect dust and other contamination.



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Our feeders for items like radiopacifiers and colorants or additives are all covered and sealed under nitrogen to ensure that nothing is getting into the compound other than what you have specified. Waterbaths can be areas in which pyrogens collect easily so our processes call out for cleaning after each run. In our processing strings of molten polymer enter the waterbath for cooling and then cutting. Changing the water and scrubbing the tanks is standard practice to ensure that a minimal amount of pyrogens may be in contact with the resin string post extrusion and prior to cutting and bagging.

The only real differences between our White Room and a Clean Room are the certifications associated with the label. Due to the extremely fine particle sizes of most colorants and even some radiopacifiers the ability to obtain and then maintain the certification is extraordinarily challenging. We have and do conduct our own air quality reviews and have found that we meet Class 100,000 standards. Due to the costs involved in maintaining that level we have chosen to not take a certification and our customers appreciate the savings it passes along as well as the cleanliness of their products without undue extra costs.

Main objectives of the White Room are to provide a controlled environment. Temperature and humidity control offer substantial benefits to processing conditions based on the time of year. Urethane materials always appreciate the venue due to its low water vapor content. Similar hygroscopic materials are always a challenge to process under high humidity conditions. The White Room provides a step far above typical environmental conditions to further assist with effective processing.

Further assistance from our team is available if any customers ever require us to effectively dry and package off materials with a nitrogen blanket so they are usable directly from our plant to your molding or extrusion line. Whatever drying technology you choose to use is also a critical element of processing our materials once they arrive assuming they are shipped via our standard packaging methods. Recently we have upgraded all of our shipping containers from fiberboard (cardboard) to plastic pails with sealed lids in an effort to both ensure our areas remain clean and clear of particulates. This major benefit is passed along to you directly by allowing for introduction immediately into your Clean Room or White Room environment without concern for extra particulate contamination.

White Room compounding is not an industry standard by any means. Unlike other compounding companies we built our company from the ground up as a medical supplier rather than backing into the market as a side thought. Why work with an industrial company that makes medical materials as a side project? Work with Compounding Solutions today and ensure that you are running clean materials in your clean room!