

Leland has prepared packaged gas cartridges for more than 50 years. During that time, the US FDA has participated in the testing and approval process of hundreds of devices which utilize a gas cartridge.

Not surprisingly, the FDA left much of 21CFR grey when it comes to gases so that, based on the current administration in the FDA and their guidance policies, they pretty much decide on the fly how to classify and direct as to the need for a specific grade of gas.

We must caution anyone who requires to utilize a gas cartridge and specifies the gas grade as the initial standard/specification, usually aimed too high. We say this because the cartridges are sealed closed, sampling the gas destroys the cartridge. But more importantly perhaps, is that the general population in the FDA and many of our clients, do not know how to differentiate between a gas cartridge and a traditional refillable gas cylinder.

There are several ways to better understand what is needed to properly classify which type of gas cartridge is required. There may be others, but this list is based on our experience and the application of our gas cartridges over many decades.

- The Pneumatic pusher. The energy from the gas is used to pneumatically drive a piston (typical). This includes drug delivery.
- The Inflator. The expanded gas inflates a balloon.
- The Insider. The gas is delivered to a cavity within a human or animal for the purpose of providing positive pressure. Usually, so other work can be performed inside the inflated space.
- The Inhaler. Gas is used to deliver a therapeutic medium such as a powder or atomized liquid, typically orally.
- The Physio. Gases can affect the physiological function of the human body. And when intentional, typically, the FDA classifies this as a drug gas.

While we are delighted that a gas cartridge is being thought of for its' role in your product, we always suggest to start, to select the lower grades of gas, like industrial or beverage grade. Downplaying the role of the gas with the FDA has ultimately been the most successful approach. Certainly, there are instances of the FDA making a case for a higher level of purity or cleaning. But those are things that can be upgraded. If we start with the highest levels first, the time and expense have been known to bring down projects.

Our goal is to provide you with guidance as you would expect from a partner; Straight and to the point.

Providing gases and their application so as to enrich life and further science

- Disposable Gas Filled Cylinders
- Gas Handling Equipment

ISO9001:2015