Tech Article

Vapor Degreasers: The Optimal Cleaning Process for Medical Device Cleaning Validation

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Medical device manufacturers are looking for reliable, cost-effective cleaning options, especially processes which facilitate FDA medical device cleaning validation. Many companies are considering exiting from pyrogenic aqueous cleaning systems and migrating instead to fast, reliable, consistent vapor degreasing processes. Perfecting and validating a cleaning method that works effectively on intricate parts is vital to ensure patient safety and to a reliable cleaning validation. Vapor degreasing offer a simple, proven, reliable answer.

New advances in solvent technology also mean that modern vapor degreasing processes are an environmentally sound option. They are more effective than aqueous systems, they are smaller with equivalent throughput, they do a better job on bioburden and they are nonpyrogenic. Compared to aqueous cleaning systems, vapor degreasers are simpler to use and cheaper to run. It's a win-win, many times over.

Finding a Process that Works

Nearly all medical devices require cleaning during manufacturing to remove particulate, oils or inorganic contamination resulting from the manufacturing process. The challenge is to identify a process that is suitable for critical cleaning processes that include complex assemblies, intricate shapes and delicate parts.

In decades past, vapor degreasing was the cleaning method of choice for medical device components. The solvent-based cleaners were easy to use and very effective. They consistently achieved the high levels of cleanliness required by medical devices to ensure patient safety and product performance. This changed in the 1990s when environmental concerns of solvents were raised. Because there were few alternative solvents, device manufacturers were forced to switch to water-based cleaning systems. Many quality vapor degreasers were literally pushed into dumpsters simply from a lack of cleaning solvents.

Cleaning Fluids That Are Better For The Planet

Today, there are many solvent options available and they are highly effective, safe, environmentally friendly and affordable. In response, medical device manufacturers are realizing again that vapor degreasing is becoming the most effective method for critical cleaning.

Advances in solvent technology are leading to environmentally acceptable cleaning options that also greatly minimize bioburden issues. In fact, many manufacturers and engineers are discovering that a properly designed and maintained vapor degreaser is more environmentally friendly than an aqueous-based cleaning system. As well as the most effective cleaning process and overall the lower-cost option.

The Bioburden Risk

Medical device components are getting smaller, more capable, more complex and more precise. This complexity brings with it the problem of cleaning well enough to satisfy regulatory requirements needed in medical component manufacture. A well-engineered process is easy to validate and will reduce costs associated with device sterilization by removing sources of bioburden from the manufacturing process.

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Removing water from the manufacturing process removes a major source of bioburden.

There are many factors that can cause bioburden in a manufacturing process but one of the biggest is cleaning with water. Water is the primary growth medium for bacteria; it is the pyrogenic environment. Therefore, removing water from the manufacturing process removes a major source of bioburden. This is one of the main reasons solvent cleaning is becoming the preferred choice. Solvents are hostile to pyrogens, so vapor degreasing greatly simplifies process control requirements for eliminating bioburden. Since they are inherently hostile to the bacterial growth vapor degreasing offers an easy way to validate bioburden issues out of the manufacturing process.

If bioburden is not properly addressed it can result in increased difficulty in the validation of subsequent product sterilization processes. A solvent-based cleaning process with submicron filtration can run at very high production volumes while significantly reducing bioburden. Other benefits include substantially lower energy consumption, a smaller footprint on the clean-room floor, and minimal capital outlay when compared with a water system.

The Vapor Degreasing Option

Vapor degreasing accomplishes this magic with unique “low boiling” synthetic chemistries. These are usually in the halogen family on the periodic table of the elements (the fluorine found in toothpaste, the chlorine found in bleach and the iodine in your medicine cabinet are three common halogens). Typically these chemistries have very high densities, very low surface tension and very low viscosity in comparison to water. Together, these factors contribute to the excellent cleaning results achieved by vapor degreasing systems.

These solvents offer other benefits that mystify users of water-cleaning systems. First, the solvents dry extremely quickly. They are very, very pure: they leave no moisture or residues on parts after they exit the vapor degreaser. The solvents are immiscible with water — they simply don’t mix, and water literally floats off the surface of these solvents just as oil refuses to mix with water. Lastly, these cleaning fluids are constantly recycled through the vapor degreaser. They are literally used hundreds or thousands of times; the solvent never “wears out.” These are significant differences from water-based cleaning systems, especially when compared to expensive surfactants and saponifiers used in aqueous systems which are never recycled.

The Aqueous System Option

With aqueous systems, relatively complex processes must be established to ensure the cleaning water does not harbor bioburden. Water cleaning machines can be huge — sometimes 15 or 20 meters in length — because the machinery has to fight against the inherent chemical characteristics of water. The rinsing and drying processes also are more complex because it takes a great deal of energy to heat water and then evaporate water. Blowers or heated dryers are often used to reach all crevices, and even then, spotting or corrosion of parts can be a problem if any steps in that process are not properly engineered.

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Programmable vapor degreaser controls allow for excellent process control and repeatability.

It is a general rule in cleaning that "you cannot clean if you cannot wet." Better wetting means better cleaning. The relative ability of a fluid to wet a surface is measured by a composite, scaleless value called "the wetting index." The wetting index combines the relevant chemical characteristics to predict the quality of the cleaning. The wetting index of water is 14 while the wetting index of modern, non-flammable cleaning fluid is 100 or higher. It should be no surprise that solvent cleaning will be faster, better, more consistent and easier to manage than aqueous cleaning results.

Preventing Bioburden

These molecular characteristics significantly increase the process validation and process control costs with aqueous systems. Of course, air knives and heating systems are large users of additional energy and expensive to operate. These characteristics are inherent in the nature of the water molecule. No amount of pumping, heating, filtration and treatment is going to change the water from becoming a growth medium for bacteria. Hence, managing the bioburden issue will always be a problem with aqueous cleaning.

In short, the benefit for vapor degreasing is the pyrogenic issue. Even trace amounts of moisture can allow the growth of bacteria and create related bioburden issues, compromising the ability to properly sterilize the device. The liability risks alone justify the expense of investigating in vapor degreasing.

Vapor Degreasing – the Ins and Outs

Since many younger engineers have never seen a vapor degreaser, it might be useful to spend a moment explaining the technology. Vapor degreasers come is many sizes and shapes. The smallest one I have ever seen was a benchtop unit carried by one man. The biggest one I ever saw took two trucks to move it and a third truck of solvent to fill it. But amazingly, they all work the same way and deliver very similar results because the chemistry is doing the cleaning, not the machine. This means vapor degreasers are highly scalable.

Vapor degreasing systems usually consist of a top-loading machine composed of two chambers, both filled with the non-flammable solvent. It is closed-loop system, has few moving parts, and ensures that the solvent is reliably clean for ongoing cleaning needs.

The cleaning fluid is heated to a boil in the first chamber or sump which then generates a vapor cloud that rises to meet two sets of cooling coils. This refrigeration causes the vapors to condense back to their liquid state. This liquid is then channeled back to the second chamber, the rinse chamber. When the rinse chamber is full, the fluid flows back into the boil sump and the recycling loop is completed.

There are a number of options engineers might specify to enhance cleaning. The use of ultrasonics can further ensure residue-free, clean parts. "Super heat" will reduce solvent losses. Programmable computer controls allow for excellent process control and repeatability. An automatic hoist frees up workers and reduces solvent losses. Any vapor degreasing expert can help companies engineer a system that is optimal for their requirements.

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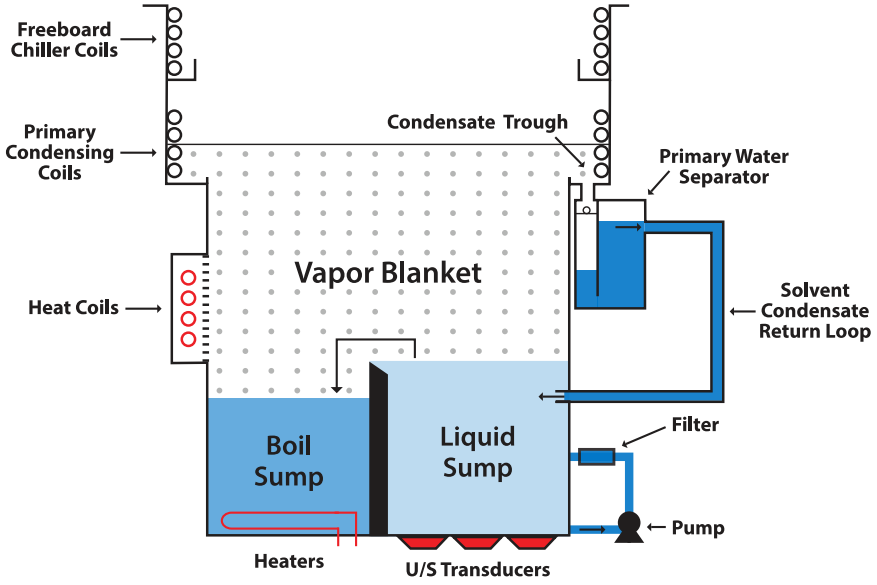

A vapor degreaser is a closed-loop system that cleans, rinses and dries parts.

The New "Greener" Cleaner

It would be perfectly understandable to assume aqueous cleaning would be the environmentally preferred method of cleaning. What can be greener than water? However, compared to solvent cleaning this is a mistake.

Aqueous cleaning systems generate a waste water stream that requires treatment before discharge. Many aqueous detergents contain non-biodegradable ingredients, which can make discharge to sewer systems or surface waters problematic. For example, some cleaners are biodegradable when new, but become contaminated during use. It is rare to find an aqueous surfactant or saponifier that is ever re-used; the systems recycle the water but not the detergents.

Water used in aqueous systems does not come straight from the tap. Water always needs pre-cleaning to be viable as a cleaning agent. This is necessary to ensure there are no trace materials, minerals or preexisting bioburden that would compromise the effectiveness of the process. In contrast, solvents come ready-to-use and require no mixing.

Global Warming

The biggest source of global warming carbon emissions are the burning fossil fuels to make electricity. Aqueous systems need high temperatures for effective cleaning. Drying after aqueous cleaning uses large quantities of energy with heaters and air knives, and the waste water treatment system also is energy-intensive. Surprisingly, having a large machine emitting large quantities of warm water in to the atmosphere of a plant also burdens a facilities air conditioning system. Lastly, the process controls required to eliminate bioburden issues add significantly to the complexity and costs of the cleaning process. The energy required to operate a vapor degreasing system is far lower than that required for an aqueous system, which protects the planet and saves money.

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Today's cleaning fluids are much improved over the products used in the 1990s. Today's cleaning fluids must meet strict environmental standards and regulations. Those containing environmentally unfriendly chemicals including HCFC-225, nPB and TCE have been or are being phased-out. Cleaning methods are migrating to newer, better and safer alternatives. These innovative new cleaning fluids available on the market are not only gentle on the planet but also deliver consistent and reliable cleaning with the lowest overall costs.

The Choice is Clean

Manufacturers looking for an effective, low-cost operation should consider migrating to a vapor degreasing process. As medical devices are evolving into more compact and complex components, cleaning becomes more difficult. Perfecting and validating a cleaning method that works effectively on these intricate parts is vital to ensure patient safety.

Vapor degreasers offer a simple, proven, reliable answer. New advances in solvent technology mean that the vapor degreasing processes are an environmentally sound option. They are often more effective than aqueous systems, they are smaller but have equivalent throughput. Plus, they are simpler to use and cheaper to run. It's a win-win, many times over.

About the Author:

Mike Jones, retired Vice President of International Sales for MicroCare, has over 30 years of experience in the critical cleaning industry. He is a prolific writer and educator focusing on critical cleaning in general and vapor degreasing and benchtop cleaning in particular. For more information, visit www.microcare.com.

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