Inspections, Compliance, Enforcement, and Criminal Investigations

Evaluation of Production Cleaning Processes for Electronic Medical Devices - Part III, Methods

[Previous Chapter[1]] [Table of Contents[2]] [Next Chapter[3]]

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The development of an appropriate cleaning procedure, that is effective and compatible with work to be cleaned, an the selection of equipment, is as important as selecting the correct solvent. Cleaning equipment and procedures range from cleaning by handbrush using jars of solvent, to automatic production line continuous systems that cost over $50,000. Two of the most popular major cleaning methods used in the manufacture of medical devices are vapo degreasing and ultrasonic cold cleaning.

Vapor Degreasers

Vapor degreasers consist primarily of a boiling sump and clean condensate reservoir with a vapor space over the reservoirs. In principal the vapor degreaser is a continuous recovery system or still. The cleaning solvent is heated ir a reservoir to the boiling point, and pure solvent vapor is boiled out of the solvent creating a vapor above the surface of the solvent. The item to be cleaned (work) is lowered into or moved through the vapor. The hot vapor condenses on the cooler work causing a flushing action over the surface of the work and the condensed solvent and dissolved contaminants drain into the reservoirs. The cooler solvent over-flows into the boiling sump where contaminants are concentrated as the pure vapor is boiled out of the solvent. When the temperature of the work reaches that of the vapor, condensation and cleaning no longer take place. Work should remain in the vapor zone long enough to raise the temperature of the work until all condensation on the work surface ceases. To increase the flushing action, the work is sometimes prechilled in a refrigerated rinse. A handheld spray wand may also be used to periodically flush the work with clean solvent. This provides removal of contaminants in crevices and also lowers the surface temperature of the work allowing additional condensation and cleaning to take place. This hot and cold solvent with vapor and spray is one of the more effective cleaning methods. The vapor provides a clean solvent wash upon condensation, and the spray provides a mechanical cleaning action. Most of the solvent in vapor form is recovered through condensation. Condensing coils are located inside the degreaser tank above the level of hot solvent. The vapor level is normally maintained at about the midpoint of the coils. When work is transferred from one compartment to another, the work should remain in the vapor zone; and it should be moved at a rate that doesn't overly disturb the vapor. If a spray wand is used the nozzle should be held below the vapor level. The solvent level should not be allowed to drop below the uppermost part of the degreaser heating element as overheating can result in solvent decomposition and the formation of a corrosive and toxic solvent.

There are various cleaning cycles used, depending upon the contaminants to be removed and degree of cleanliness strived for. For example, a typical cycle might be vapor, spray, immersion, spray and vapor.

The concentration of contaminants in the vapor degreaser boiling sump should not be allowed to exceed limits that would affect the cleaning performance of the cleaning solution. For example, DuPont recommends that when Freon{{Registered Trademark}} TMS (approx. 94% trichlorotrifluoroethane and 6% methanol) is used in vapor degreasers for flux cleaning, the flux content in the boiling sump should not exceed 9% by volume. Flux contents in excess of this limit reduce the alcohol content of the vapor and rinse which in turn reduce the ionic cleaning capability. Residues must be removed from the boiling sump periodically according to the work load.

Large amounts of water will extract alcohol and stabilizers from solvent mixtures and affect solvent cleaning performance. Water may enter a degreaser from various sources including condensation of atmospheric moisture on the degreaser condensation coils, moisture on the work and steam or cooling system leaks. Degreasers should have a water separator of some kind which separates water from the solvent. Separators normally used separate water by specific gravity and the insolubility characteristic of water. The separator is made up of a cooling chamber and various drains and valves. This area should be explored regarding proper operation and maintenance. Some cleaning solvent manufacturers recommend that desiccate dryers, rather than conventional water separators, be used in the condensate return line. Before using a solvent in a vapor degreaser, the device manufacturer should determine the effect of water on the solvent performance and the extent to which water is generated by the process.

One of the things that can be checked is whether or not the device manufacturer has the cleaning solution specifications for use and knows the manufacturer's recommendations in this area.

Ultrasonic Cleaning

Ultrasonic aided cleaning is widely used in the electronics industry and with a proper cleaning solution is considered effective for removing contaminants. Ultrasonic cleaning is achieved by vigorously agitating the solution with Ultrasonic energy. Energy is transmitted through the use of an ultrasonic frequency generator and a transducer physically fixed to the cleaning solution container or reservoir. When ultrasonic energy is transmitted to a solution, it produces cavitation - a rapid buildup and collapse of numerous tiny bubbles. Cavitation causes a scrubbing action on the surface of the work being cleaned. This scrubbing action, combined with the chemical- action of the solvent, results in cleaning. To remove gross contaminants precleaning cycles often precede ultrasonic cleaning. An effective cleaning cycle employing ultrasonics would be (1) vapor cleaning (2) immersion in an ultrasonic activated liquid chamber (3) spraying and (4) vapor rinse.

Generally ultrasonic cleaning is a cold process and chlorinated solvents are used, although ultrasonic cleaning is used with fluorinated solvents. The optimum frequency range for solvent cavitation is 20-25 KHz, and optimum temperature is 55-60 C. Ultrasonic agitation is also sometimes used in vapor degreasers. Sonic vibration should take place in the clean solvent immersion chamber and not in the boiling chamber. Before using ultrasonic energy in the cleaning process, the manufacturer should evaluate the effect of ultrasonic vibration and energy upon the work cleaned, and performance of the cleaning solution selected. The bath should also be evaluated for inactive cleaning zones or non-uniform ultrasonic activity.

It can be seen through the preceding discussion that a cleaning process can be complex and complicated, especially when degreasers are involved. Because of this, detailed written procedures must be developed so that employees have proper directions for use and maximum cleaning performance can be achieved from the system. Maintenance procedures must also be developed, strictly adhered to and records maintained.

Cleaning load maximums and solvent life should be prescribed to prevent redeposition of contaminants on work during cleaning. Rinsing in clean solvent or vapor is a necessary step to prevent redeposition of contaminants. Processing work too rapidly also results in reduced cleaning. Maximum and minimum times should be specified. Work should be placed into the cleaning solutions in baskets, or on racks or hangers so that the maximum surface area is contacted during cleaning.

References:

1. Modern Vapor Degreasing, Booklet, 1972, Dow Chemical Co., Midland, Michigan 48640
2. Production Cleaning Equipment, Bulletin FS-27, 1976, DuPont Company, Wilmington, DE 19898
3. "FREON" TMS SOLVENT, Bulletin No. FST 5-J, 1976, DuPont Company, Wilmington, DE 19898

[Previous Chapter[4]] [Table of Contents[5]] [Next Chapter[6]]

Page Last Updated: 02/17/2009
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