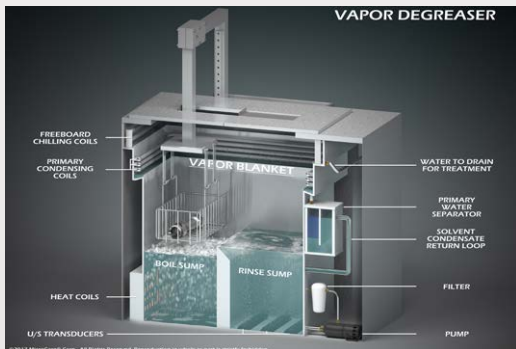


## How Vapor Degreaser Cleaning Supports Your Process Validation

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- Industry: Medical Device Manufacturing
- Published: *Medical Design and Outsourcing*



*Vapor degreaser cleaning is a well-engineered process that is simple, predictable and repeatable*



Process validation is important in the introduction and manufacture of new medical devices and PCBs (printed circuit boards). Critical activities, such as parts cleaning with cleanroom compatibility, must be performed under controlled conditions that are tested and validated. Validation helps ensure that new and often advanced medical devices and their parts consistently meet set quality standards regardless of when made, or size of production run, while still remaining profitable to produce. Validated cleaning ensures the medical devices are free from particulate, oils, and bioburden, making them both effective and reliable. It also helps them comply with FDA (Food and Drug Administration), ISO (International Standards Organization) or other applicable regulatory requirements for device market introduction. To meet validation criteria, the chosen cleaning process must be consistent, easy-to-use and compatible with established cleanroom procedures and validations. Vapor degreaser cleaning is a well-engineered process that is simple, predictable and repeatable, making it easy to qualify and validate for medical device manufacturing.

### Vapor Degreasing: A Process that Works

Vapor degreasers are a closed-loop system that require two elements: a specially designed cleaning machine, and a specific low-boiling, non-flammable cleaning fluid. Vapor degreasers contain two chambers: the boil sump and the rinse sump. In the boil sump, the cleaning fluid is heated to its boiling point to generate a vapor cloud. The soiled parts are lowered through the vapor cloud and immersed and cleaned in the fluid. Once cleaned, the parts are mechanically transferred to the rinse sump for final rinse in pure, uncontaminated fluid. The parts come out clean, dry, spot-free and immediately ready for the next step in the process - whether it be additional assembly operations, or coating/marking, or packaging and ultimately sterilizing prior to shipment.

The cleaning fluids used within the system are engineered to have multiple chemical properties that are advantageous to medical device cleaning. For example, they typically have a low surface tension and a very low viscosity, allowing them to easily penetrate and clean complex assemblies, intricate shapes and delicate parts and then dry quickly and residue free after cleaning. Most vapor degreasing fluids also are very heavy and dense, typically 20-40% heavier than water, which aids in dislodging particulate from the parts. They often will be azeotropes to ensure the chemical formula remains consistent when subjected to repeated cycling from liquid, to vapor, to liquid in the vapor degreaser.

New advances in cleaning fluid technology means that modern vapor degreasing is an environmentally sound option meeting local and national air quality regulations and operator safety requirements. In addition, vapor degreasers are efficient, requiring very little energy to operate, and are compact with a small footprint in the cleanroom. Plus, they do not use water, which removes a potential source of bioburden from the cleaning process and the cleanroom. Here are some other ways vapor degreasing makes cleaning process validation easier.

### Consistent Cleaning with Little Monitoring

The vapor degreasing process, once established and tested, remains constant with little variation. The solvent-based cleaning fluid remains consistent and stable inside the vapor degreaser for thousands of uses. It does not require daily monitoring or acid acceptance testing. This means cleaning outcomes remain consistent, complying with product and process validation specifications.



Vapor degreasing helps manufacturers meet FDA and ISO requirements



Parts come out of the vapor degreaser clean, dry and residue free

## Scalable and Repeatable for Simplicity

Vapor degreasers come in many sizes and shapes from small table-top versions to ultra large versions that hold thousands of gallons of cleaning fluid. But they all work the same way and deliver very similar results. This means vapor degreasers are highly scalable. Large or small batches are cleaned using the exact same repeatable process, so there is rarely a need for added equipment when new products are introduced, nor are alternate methods required depending on changes in batch size or variations in part geometry.

## Easily Documented for Streamlined Record-Keeping

The vapor degreasing methods are clearly defined, dependably repeatable, and are easily documented. The step-by-step nature of the process makes it easy to engineer, easy to audit and simplifies detailed record-keeping. A complete cleaning history of the batch can be kept to demonstrate that all the cleaning steps defined by the procedures and instructions were taken and the outcome was as expected. All supporting the validation process.

## Easy to Use for Qualified, Trained Personnel

To meet process validation specifications, the cleaning process should be engineered by qualified and well-trained personnel. However, the daily operation of a vapor degreaser is simple and can be trusted to even entry-level workers. In many instances, vapor degreasing can be automated at relatively low cost, giving medical device makers a cleaning process that is remarkably consistent. Easy automation also simplifies worker training and ensures there are always qualified personnel on-hand to carry out the parts cleaning procedures correctly.

## Low Maintenance for Easier Use

An essential criterion for process validation is to select and use equipment with minimal or zero maintenance requirements. Vapor degreasers, when used with modern cleaning fluids, have few moving parts and need very little maintenance. The cleaning fluids are very stable with long service life, and do not demand constant monitoring or daily treatments. Nor do they typically require the air quality reporting associated with older chlorinated solvents.

## A More Controlled Work Environment

In addition to the simplicity of operation, a major advantage of using a vapor degreaser is the small footprint relative to the amount of production output. A small footprint means the vapor degreaser takes up little space while sustaining high output, allowing for lower overall operating costs in the expensive cleanroom environment.

Vapor degreasing also helps maintain required cleanroom environmental conditions including temperature and humidity. They do not generate dust, fumes, heat, or moisture, so they do not require special blowers and fans or any special climate controls to maintain cleanroom air quality or ambient temperature and humidity.

Most significantly, solvent-based cleaning fluids do not harbor pyrogens. They help maintain an environment free of bacteria, viruses, or other pathogens and provide a convenient way to validate a cleanroom compatible, bioburden-free cleaning process.

## MicroCare is Your Validation Partner

When introducing a new product, or changing a process for regulatory compliance, it is important to work with a cleaning fluid supplier who has experience in the special requirements associated with medical device manufacturing. MicroCare can provide expert advice to simplify the selection process of a vapor degreaser and fluids. This includes individualized consulting, access to lab testing, and compliant cleaning fluid options such as off-the-shelf and customized formulations to ensure the right cleaning fluids and methods for your specific needs.

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### About the author:

*Jay Tourigny is Senior Vice President at MicroCare which offers precision cleaning, lubricating and debinding solutions. He has been in the industry more than 30 years and holds a BS from The Massachusetts College of Liberal Arts. Tourigny holds numerous U.S. patents for cleaning-related products that are used on a daily basis in medical, fiber optic and precision cleaning applications. For more information, visit [microcare.com](http://microcare.com)*