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A Technical Approach to Cleaning Fluid and Process Testing in Medical Device Development

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Precision cleaning is an essential part of medical device manufacturing, especially as devices become smaller, more complex, and increasingly reliant on sensitive electronic components

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In medical device manufacturing, cleaning is one of those things that can get overlooked, right up until it starts causing problems. Residues from machining, molding, assembly, or PCBA fabrication don't just sit there harmlessly. They can affect device performance, reliability, and in some cases, patient safety.

As devices get more complex with smaller features, tighter tolerances, mixed materials like metals, plastics, and electronics, the cleaning challenge gets harder. What worked a few years ago doesn't always hold up. Because of that, more manufacturers are starting to rethink how they approach cleaning. Instead of treating it as a last step, they're building it into the process much earlier and relying on actual test data to guide decisions.

At this stage, cleaning validation is best approached as a risk based engineering and testing exercise. Residual contamination, whether it's particulate, organic, ionic, or even biological, must be identified, measured, and consistently removed. That's the only way to meet regulatory requirements and ensure the device performs the way it's supposed to. And with today's designs with complex geometries, mixed materials, and miniaturized PCBAs, you can't leave that to guesswork. Early integration of cleaning considerations reduces downstream validation risk, particularly for high reliability electronic assemblies.

This paper looks at cleaning from a practical, test-focused perspective. It breaks things down into three stages including pre-production, in-production, and post-production, and walks through how cleanliness is evaluated at each step. It also touches on the role of working with specialized labs, like the MicroCare Critical Cleaning Lab, to help reduce risk and get to a validated process faster.

Cleaning as a Test-Driven Process

In regulated environments, you can't assume a cleaning process is effective. You must prove it with evidence. At a minimum, every process must address a few fundamental questions:

- What contaminants are present?
- Are they being removed effectively?
- And can that level of performance be maintained consistently over time and at production scale?

No single test can fully answer these questions. Effective cleaning validation relies on multiple complementary analytical methods, selected based on the expected contaminants and associated risks. In many cases, validation also requires a series of tests performed throughout the product lifecycle to confirm ongoing process control and reproducibility.

1. Pre-Production Testing: Defining the Cleaning Process

This is where most of the heavy lifting happens. Pre-production testing is about understanding the problem and figuring out what's going to work before you commit to a process.

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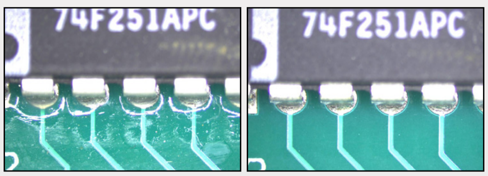
Cleaning validation depends on analytical testing to identify contaminants, verify removal effectiveness, and confirm long-term process consistency



BEFORE **AFTER**

Contamination can include particulates, machining oils, flux residues, and ionic residues depending on the manufacturing process and materials involved

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Contamination Characterization

First step is figuring out what you're dealing with. Contamination varies quite a bit depending on the materials and processes involved:

- Machined metals (stainless, titanium): oils, coolants, fine particulates
- Plastics and polymers: mold release agents, additives, static-attracted debris
- PCBAs: flux residues, solder paste, ionic contamination
- Assembly: adhesives, fingerprints, environmental particles

Tools like FTIR, SEM/EDS, and ion chromatography are commonly used here. You need that data up front, otherwise you're just guessing at cleaning chemistry. Each technique has distinct detection strengths and limitations, making method choice highly dependent on contamination type and anticipated failure modes.

Cleaning Fluid Screening and Compatibility Testing

A cleaning fluid might remove contamination well, but that doesn't mean it's safe for the part. Compatibility testing is just as important.
Typical checks include:

- Immersion testing on plastics to look for swelling, cracking, or discoloration
- Metal surface analysis for corrosion or changes in passivation
- Verifying coatings, adhesives, and bonded areas aren't affected

This becomes more important with mixed-material devices, where one process must work across metals, polymers, and electronics. Compatibility issues are often subtle or cumulative and may only appear after repeated exposure or aging.

Lab-Scale Cleaning Effectiveness Testing

At this stage, testing should be done on real parts whenever possible, not just coupons.

Coupons are useful for screening, but they often do not represent real world geometry, trapped volumes, and surface accessibility that strongly influence cleaning and drying outcomes.

Common methods include:

- Gravimetric analysis for total contamination
- NVR for organic residues
- Particle counts and sizing for critical areas
- Ion chromatography for ionic contamination (especially PCBAs)
- TOC for aqueous systems

Lab-scale testing using real components helps identify cleaning challenges associated with complex geometries, trapped volumes, and mixed materials

Small-batch validation allows manufacturers to optimize cleaning parameters and identify contamination risks before full-scale production begins

For PCBAs, you'll often layer in IPC-based testing to make sure flux removal meets reliability requirements.

Small-Batch Validation

One thing that consistently works well is starting small. Run a limited batch of parts or assemblies through the cleaning process and see what happens. This helps you:

- Set realistic cleanliness targets
- Understand how fluxes, pastes, and cleaners interact
- Spot design features that trap contamination
- Dial in process parameters early

It's a relatively low-cost way to catch issues before scaling up.

2. In-Production Testing: Process Control and Monitoring

Once the process is in place, the focus shifts to keeping it stable.

Process Parameter Verification

Key variables including fluid concentration, temperature, cycle time, and mechanical action need to stay within defined limits. Regular checks confirm nothing is drifting.

Routine Cleanliness Monitoring

Most operations will monitor:

- NVR levels for organic residues
- Particle levels to catch contamination trends
- Ionic contamination for sensitive components
- Surface energy/contact angle for consistency

In PCBA work, ROSE testing is often used for quick checks, with more detailed analysis done as needed. In practice, most cleaning failures result from process drift rather than deficiencies in the originally validated process.

Statistical Process Control (SPC)

Cleanliness data gets tracked over time using SPC. If particle counts or residue levels start trending in the wrong direction, you can catch it early, before it becomes a yield issue.

Equipment and Fluid Monitoring

For solvent or vapor degreasing systems, you also need to keep an eye on the system itself:

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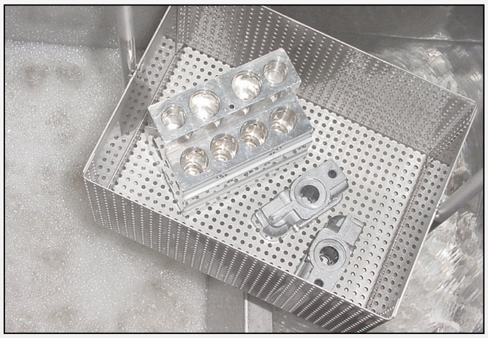

Monitoring fluid condition, rinse quality, and equipment performance is essential for maintaining stable cleaning results over time

- Fluid contamination (oil loading, breakdown)
- Distillation performance
- Residue buildup in the equipment

For aqueous cleaning systems, key aspects include maintaining process chemistry concentration, rinse water quality, and effective drying. Drying should be treated as a separate critical process step for fine pitch PCBAs and implantable devices with complex geometries.

Equipment condition and fluid health often serve as leading indicators of cleaning performance degradation.

3. Post-Production Testing: Final Verification

At the end of the process, you need to confirm the product meets requirements. Final Cleanliness Testing Depending on the device, this might include:

- Gravimetric and particle analysis
- Ion chromatography for ionic limits
- NVR or TOC for organics
- Bioburden or endotoxin testing (where applicable)

Acceptance limits are usually tied to risk and device classification.

Linking Cleanliness to Performance

Cleanliness only matters if it affects performance. And in most cases, it does:

- PCB contamination → electrical reliability issues
- Metal contamination → corrosion or coating failures
- Polymer contamination → bonding or sealing problems

Testing should confirm that cleanliness levels support actual device function. Wherever possible, cleanliness data should be correlated with electrical, corrosion, adhesion, or reliability testing to close the validation loop.

Documentation and Compliance

Everything needs to be documented:

- Test methods and standards
- Acceptance criteria
- Repeatability and reproducibility
- Lot traceability

This is what supports compliance with FDA and ISO requirements.

Partnering with a Specialized Cleaning Testing Laboratory

Because of the complexity, many manufacturers bring in outside expertise.

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Successful cleaning validation combines engineering, analytical testing, and process control to ensure medical devices perform safely and reliably

Labs like the MicroCare Critical Cleaning Lab can run controlled studies using real parts and real contaminants.

They typically offer:

- Detailed contamination analysis
- Side-by-side fluid comparisons
- Material compatibility testing
- Process simulation and optimization

The advantage is accelerated risk reduction through application specific testing that reflects real world manufacturing conditions.

Conclusion

Cleaning in medical device manufacturing isn't a simple step anymore. It's a controlled, data-driven process. The only way to get it right is through structured testing at each stage: pre-production, in-production, and post-production. Starting early, testing with real parts, and collaborating with experienced partners makes a big difference. It helps avoid surprises later, keeps validation on track, and ultimately ensures the device performs the way it's intended to. The most robust cleaning processes are those designed with testing, monitoring, and potential failure modes in mind from the outset.

About the Author:
Elizabeth Norwood is a Senior Chemist at MicroCare, LLC, which offers precision cleaning solutions. She has been in the industry for more than 25 years and holds a BS in Chemistry from the University of St. Joseph. Norwood researches, develops and tests cleaning-related products. She currently has one patent issued and two pending for her work. For more information, visit www. microcare.com.