Packaging
Compliance Labs

WORST CASE MEDICAL DEVICE CLEANING Q & A

When preparing for cleaning validations, it can be helpful to have a clear starting point. We've compiled a list of routine questions that we frequently ask device engineers to guide the process and ensure cleaning procedures are optimized. To meet with one of PCL's packaging professionals to discuss your project, contact us at info@pkgcompliance.com or request a quote today!

- **Can a coupon be made to cover all materials, worst-case surface areas, and complex geometries to ensure you don't have to re-validate your cleaning process for all different types of products with variable features?**

- **Before being sterile packaged, are the parts coming in clean from the previous supplier?**
  - » If so, this helps with right-sizing!

- **If parts are NOT cleaned before being packaged, what contact materials are used during manufacturing?**
  - » It is helpful to see the process flow from previous suppliers to identify any contact materials. In other words, if parts are molded using CNC coolants or a mold release is applied, that is good information to have during testing. This factors into the Total Organic Carbon/Total Hydrocarbon (TOC/THC) test that looks for lubricants, to help drive a certain value in safety data sheets. It enables us to create protocols that ensure any presence detected is well below the max. By knowing what the product encountered before arrival at the testing lab we have a greater context for optimal recommendations.

- **Did the original supplier use any water in the cleaning process?**
  - If YES, was the water source deionized or otherwise monitored?
    - » Water quality has a big impact on cleanliness because water carries high volumes of bacteria. If the source is unmonitored, it can negatively impact the cleanliness.
  - If YES, the water was monitored, is routine LAL (Limulus Amebocyte Lysate) testing performed regularly?
    - » This bioassay detects endotoxins in water, obviously an advantage for supplier-cleaned parts.

- **Is testing done from the water source or on the finished cleaned product?**
  - If YES and no LAL testing is performed, regular lot release testing for LAL may be required.
  - If YES and LAL testing is performed, you could potentially justify out-of-routine LAL testing.

- **Does the introduction of their contact material present a risk to Packaging Compliance Labs (PCL) cleaning line that is used with other customers?**
  - » Operational Qualification (OQ) tests the low and high limits for temperature, detergent concentrations, and dwell times for a designated load. Performance Qualification (PQ), on the other hand, tests the nominal (middle) range where the process will typically operate and ensures repeatability. For OQ, we provide recommendations based on the equipment and the customer's specific requirements. For most devices made with commonly used materials like stainless steel and titanium—prevalent in medical device manufacturing—we can guide the goals effectively.