

Why the Swab Matters in Cleanroom Validation

What Is Cleaning Validation?

Since the US Food and Drug Administration (USDA) released its *Guide to Inspections – Validation of Cleaning Process* in 1993, cleaning validation procedures in critical environments have been placed under careful scrutiny. At the heart of this concern is the possibility of cross-contamination.

Particularly in a pharmaceutical manufacturing environment, any sort of cross-contamination can present a safety risk to patients. Extraneous residues can threaten the strength, chemical identity and integrity of a substance formula. Thus it is essential for the production environment to be cleaned consistently, employing validated cleaning protocols to ensure the appropriate level of sterilization.

With a recent emphasis on more robust cleaning protocols, a growth in outsourcing of pharmaceutical manufacturing has heightened the FDA's vigilance over certain cleaning requirements. The most common issues cited include inadequate documentation, training, and validation of cleaning processes.

Why Swabbing?

Cleaning in a pharmaceutical manufacturing environment is generally performed using various chemicals and solvents to remove extraneous residues. To validate cleaning protocol, the sanitized areas must be sampled appropriately.

Two commonly used techniques for sampling include swabbing and rinsing. While swabbing obtains a direct sample, rinsing offers an indirect method of sampling the surface. The choice between the two is typically driven by physical access – for instance, swabbing works well in more restricted areas whereas rinsing is most effective for pipes or tubes. A combination of the two is best to accomplish a comprehensive sampling of surface sterilization; however, FDA guidelines indicate a preference for the direct swabbing method.

The Swabbing Procedure – Considerations

Swabs used in sampling are typically pre-wetted with an appropriate solvent designed to remove surface residues. It is important to remove excess solvent prior to sampling, as the extraneous solvent itself can lead to inaccurate results.

Swab choice is critical to validation, and the swab must be high absorbency with ultra-low particulates and extractables, such as a polyester swab. Considerable operator training is also essential to swabbing, which should serve to minimize subjectivity inherent to the sampling process.

To release collected residues from the swab head, a suitable extractable is also necessary, and the sample may need to be filtered to completely extract residues as well. Anything less than the highest quality polyester swab can contaminate the source during this portion of the sampling process.

Summary

An essential component of the cleaning validation process, proper swabbing methods have a direct and measureable impact on results. It is essential that the swab, filters and other associated materials are of the highest quality possible and do not interfere with the cleaning validation process.

This article is based on an original publication by Texwipe.