

Enverify™ Viable Surface Sampling Competency Kit

Microbial-coated test surfaces for evaluating surface sampling competency

Help evaluate the competency of your sampling personnel

Qualification of personnel who collect surface samples is a regulatory requirement and a crucial activity for an effective environmental monitoring program. Sampling method performance, including recovery efficiency, consistency, and aseptic technique, drives the quality of data that is generated and significantly impacts the integrity of an environmental monitoring program.

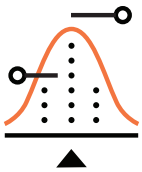


Enverify™, the First Standardized Tool for Evaluating Surface Sampling Competency

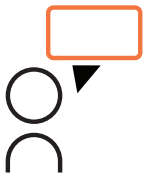
- The Enverify™ Viable Surface Sampling Competency Kit is the first standardized tool that enables you to evaluate and document surface sampling competency with quantitative data.
- Each Enverify™ test surface contains a precise quantity of microorganisms, providing a benchmark for you to evaluate, verify, and compare performance.



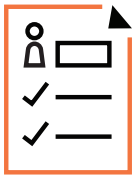
Determine Percent Recovery



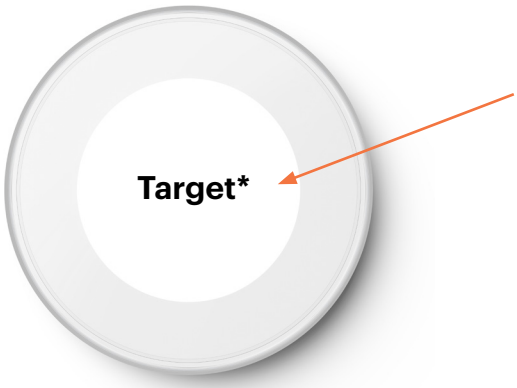
Determine Sampling Consistency



Confirm Aseptic Technique



Document Personnel Competency



Microorganisms are coated and preserved onto the target area for sampling.

Blinded blanks are included to evaluate the competency of reporting negative results.

*The target area is located on the underside of the lid.

Help achieve compliance with pharmaceutical and compound pharmacy industry standards, guidelines and regulations

USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*

- Section 2.0 – *"All personnel who compound or have direct oversight of compounding personnel must be initially trained and qualified by demonstrating knowledge and competency... initially and at least every 12 months in appropriate sterile compounding principles and practices..."*
- Section 6.1 – *"It is important that personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling."*
- Section 20 – *"All facilities where CSPs are prepared must have and maintain written or electronic documentation to demonstrate compliance with the requirements in this chapter. This documentation must include, but is not limited to, the following: Personnel training, competency assessments, and qualification records including corrective actions for any failures..."*

USP General Chapter <1116> *Microbiological Control and Monitoring of Aseptic Processing Environments*

- *"Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained."*

EudraLex Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Annex 1: Manufacture of Sterile Medicinal Products

- Section 7.3 – *"All personnel including those performing cleaning, maintenance, monitoring and those that access cleanrooms should receive regular training, gowning qualification and assessment in disciplines relevant to the correct manufacture of sterile products. This training should include the basic elements of microbiology and hygiene, with a specific focus on cleanroom practices, contamination control, aseptic techniques and the protection of sterile products."*
- Section 9.29 – *"Sampling methods and equipment used should be fully understood and procedures should be in place for the correct operation and interpretation of results obtained. Supporting data for the recovery efficiency of the sampling methods chosen should be available."*

FDA cGMP 21 CFR

- Section 211.25(a) – *"Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions."*

FDA Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice (2004)

- Section X.B – *"The goal of microbiological monitoring is to reproducibly detect microorganisms for purposes of monitoring the state of environmental control."*
- Section V.B – *"The basic principles of training, aseptic technique, and personnel qualification in aseptic manufacturing also are applicable to those performing aseptic sampling and microbiological laboratory analyses. Processes and systems cannot be considered to be in control and reproducible if the validity of data produced by the laboratory is in question."*

Additional Standards and Guidelines

Additional industry standards and guidelines describe the need for and importance of qualification of personnel who collect samples, including:

- The Pharmaceutical Inspection Co-operation Scheme (PIC/S), Guide to Good Manufacturing Practice for Medicinal Products, Part I; Basic Requirements for Medicinal Products.
- FDA Pharmaceutical Microbiology Manual, ORA.007, 2020.
- PDA Technical Report No. 13: Fundamentals of an Environmental Monitoring Program.