5 TECHNIQUES TO MAINTAIN STERILITY: FDA GUIDANCE

STERILE DRUG PRODUCTS PRODUCED BY ASEPTIC PROCESSING — CURRENT GOOD MANUFACTURING PRACTICE

*Content has been adapted from the FDA Guidance Document. Original and full document here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/sterile-drug-products-produced-aseptic-processing-current-good-manufacturing-practice

The FDA guide is intended to help manufacturers meet the requirements in the Agency's current good manufacturing practice (CGMP) regulations (21 CFR parts 210 and 211) when manufacturing sterile drug and biological products using aseptic processing. This infographic **summarizes some of the techniques aimed at maintaining sterility of sterile items and surfaces** :

1 CONTACT STERILE MATERIALS ONLY WITH STERILE INSTRUMENTS

Sterile gloves should be regularly sanitized or changed, as appropriate, to minimize the risk of contamination after initial gowning to minimize contamination risks.

2 MOVE SLOWLY AND DELIBERATELY

Rapid movements can create an unacceptable turbulence in a critical area. Such movements can present challenges to the intended cleanroom design and control parameters that needs to be maintained while housing sterile products. The principle of slow, careful movement should be followed throughout the cleanroom.

3 KEEP THE ENTIRE BODY OUT OF THE PATH OF UNIDIRECTIONAL AIRFLOW

Unidirectional airflow design is used to protect sterile equipment surfaces, container closures, and product. Disruption of the path of unidirectional flow air in the critical area can pose a risk to product sterility.

4 APPROACH A NECESSARY MANIPULATION IN A MANNER THAT DOES NOT COMPROMISE STERILITY OF THE PRODUCT

To maintain sterility of nearby sterile materials, a proper aseptic manipulation should be approached from the side and not above the product (in vertical unidirectional flow operations). Also, operators should refrain from speaking when in direct proximity to the critical area.

5 MAINTAIN PROPER GOWN CONTROL

Prior to and throughout aseptic operations, an operator should not engage in any activity that poses an unreasonable contamination risk to the gown. The gown should provide a barrier between the body and exposed sterilized materials and prevent contamination from particles generated by, and microorganisms shed from, the body.

The Agency recommends gowns that are sterilized and non-shedding, and cover the skin and hair (face-masks, hoods, beard/moustache covers, protective goggles, and elastic gloves are examples of common elements of gowns). Written procedures should detail the methods used to **don each gown component in an aseptic manner.** An adequate barrier should be created by the **overlapping of gown components (e.g., gloves overlapping sleeves).** Gloves should also be sanitized regularly.