

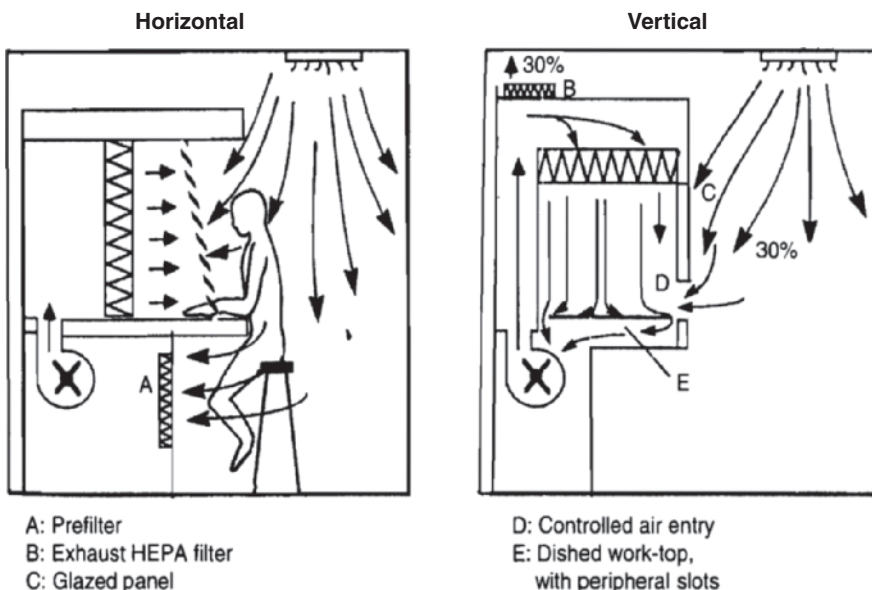
**Laminar-Flow Enclosures**

The required environmental control of aseptic areas has been made possible by the use of LAF, originating through a HEPA filter occupying one entire side of the confined space. Therefore, it bathes the total space with very clean air, sweeping away contaminants. The orientation for the direction of airflow can be horizontal or vertical (Fig. 15-8), and may involve a limited area workbench or an entire room. Figure 15-9 shows a vial-filling line protected with vertical LAF from ceiling-hung HEPA filters, a Class 100/Grade A area. Plastic curtains are installed to maintain the unidirectional airflow to below the filling line and to circumscribe the critical filling portion of the line. The area outside the curtains can be maintained at a slightly lower level of cleanliness than that inside, perhaps Class 1000 or 10,000.

Critical areas of processing, wherein the sterile product and sterile product contact surfaces are exposed to the environment, however briefly, such environments must meet Class 100/Grade A/ISO 5 clean room standards.

It must be borne in mind that any contamination introduced upstream by equipment, arms of the operator, or leaks in the filter will be blown downstream. In the instance of horizontal flow this may be to the critical working site, the face of the operator, or across the room. Should the contaminant be, for example, penicillin powder, a biohazard material, or viable microorganisms, the danger to the operator is apparent.

Further, great care must be exercised to prevent cross-contamination from one operation to another, especially with horizontal LAF. For most large-scale operations a vertical system is much more desirable, with the air flowing through perforations in the countertop or through return louvers at floor level. Laminar-flow environments provide well-controlled work areas only if proper precautions are observed. Any reverse air currents or movements exceeding the velocity of the HEPA-filtered airflow may introduce contamination, as may coughing, reaching, or other manipulations of operators. Therefore, laminar-flow work areas should be protected by being located within controlled environments. Personnel should be attired for aseptic processing, as described below. All movements and processes should be planned carefully to avoid the introduction of contamination upstream of the critical work area. Checks of the air stream should be performed initially and at regular intervals (usually every 6 months) to make sure no leaks have developed through or around the HEPA filters.



**Figure 15-8** Horizontal and vertical laminar airflow. *Source:* From Ref. 2.