Figure 15-9 Filling line under vertical laminar airflow. *Source*: Courtesy of Baxter Healthcare Corporation.

Air Classification in Clean Rooms

The air classification of sterile product work areas generally abides by the following schematic:

> Warehouse (Unclassified) → Preparation of Equipment/Components (Class 100,000) → Compounding of the Product (Class 100,000) → Filling (Class 100) → Capping (Class 100,000) → Sterilization (Unclassified) → Sampling (Unclassified) → Finishing (Unclassified)

Clean room design traditionally has Class 100 rooms adjacent to Class 100,000 rooms. Regulatory authorities have raised serious concerns about this significant change in air quality from critical to controlled areas. It is now preferable to have an area classified from Class 1000 to Class 10,000 in a buffer area between a Class 100 and Class 100,000 area.

Potential Problems

People and equipment, if not positioned properly, will interfere with LAF. When LAF is interrupted, it usually can only be reestablished downstream within a distance equal to three times the diameter of the interfering object. If the interference location is above an open vial, there is usually not sufficient space to reestablish laminarity and turbulent air occurs at the vial opening (Fig. 15-10).

Laminar air filters are fragile and can be easily damaged. Filter material can be punctured easily and chemical splashes can cause filter rupture. This is why filters are usually protected with a screen and good aseptic practices taught so that those working within the confines of these filters realize how easily they are damaged.

An interesting type of problem that is introduced when people work within the confines of LAF is a false sense of security that poor or careless techniques will be compensated by the