Table 14-5 Requirements of Critical Areas Versus Controlled Areas for Aseptic Processing Operations

Requirement	Critical work area	Controlled work area
Airborne particle content	Class 100 Grades A and B	Class 10,000–100,000 Grades C and D
Velocity of air	100 ft/min $\pm$ 20%	100 ft/min $\pm$ 20%
Changes of air	60–80 times per hour	Not less than 20 times per hour
Airborne microbes	Not more than 1 CFU per 10 cubic ft	Not more than 5 CFU per 10 cubic ft
Surface microbes	$<$1 CFU per contact plate (24–30 cm^2)	5 CFU per contact plate (24–30 cm^2)
Personnel microbes	Gloves: $<$ 1CFU	Gloves: 5 CFU

Personnel entering the aseptic area should enter only through an airlock. They should be attired in sterile coveralls with sterile hats, masks, goggles, and foot covers. Movement within the room should be minimal and in-and-out movement rigidly be restricted during a filling procedure. The requirements for room preparation and the personnel may be relaxed somewhat if the product is to be sterilized terminally in a sealed container. Some are convinced, however, that it is better to have one standard procedure meeting the most rigid requirements.

MODULAR CONSTRUCTION

Modular construction has become a design standard for a number of sterile product companies worldwide. Standardized rooms are constructed to meet strict engineering guidelines while incorporating flexibility in size, classification, and utilization. Figure 14-5 shows an example of a single modular unit being getting ready to be reassembled at the finished product manufacturing site, while Figure 14-6 shows the exterior view of a fill/finish building comprised of modular units.

Figure 14-5 Example of a modular unit for a sterile manufacturing facility. *Source*: Courtesy of Pharmadule, Inc.