control strategy. In most cases, for example, protein adsorption onto filter surfaces, the potential problems can be avoided or minimized once understood through experimentation by alternative choices of filter material or predicting the amount of solution to be passed through the filter to saturate the binding sites.

The surge of potential heat-labile products from biotechnology and the inability to terminally sterilize these molecules has accelerated the development of barrier/isolator technology (chap. 23). This technology, when perfected, will enable the processing of protein and peptide solutions to occur under a much higher degree of sterility assurance than what is now achievable with conventional aseptic processing. The main features of barrier/isolator technology are the ability to sterilize, not just sanitize, the environment under which sterile solution is exposed during filling and stoppering, and the removal of humans from direct contact with the exposed sterile solution.

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